



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

Selection Criteria:

Product Name: .;ZECURITY
Product Active Ingredient: .
Active Ingredient: .
Active Moiety: .
FDA Received Date: From: 17-AUG-2011 To: 17-AUG-2016
MedDRA® Version * : 19.0
Total Cases***: 2,685
Number of Pages: 786

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

*. "MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

**."Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.



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The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported; therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting Direct: submitted "directly" to FDA by healthcare professionals, patients and other consumers
Health Professional	Indicates whether the initial source who provided information about the event is a health professional (HP). Possible values are: Y - Yes, N - No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OTI), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Manufacturer Control #	The Manufacturer Control Number is the manufacturer's unique identifier associated with the case. Also referred to as the Company Report Number.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).
Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.



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Field Heading	Definition
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to "code" adverse events, medication errors and other information associated with the use of medical products
Product	Name of a drug or therapeutic biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Manufacturer	The manufacturer of the product, as indicated in the report.



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08-Oct-2015	11614909	DIRECT			S Transdermal			61 YR	Female	USA
Preferred Term										
Application site reaction										
Product adhesion issue										
Product										
ZECUITY										
Manufacturer										
TEVA										
Duration										
1 MTH										
Age										
61 YR										
Sex										
Female										
Country										
USA										
Manufacturer Control #										
US-TEVA-593329USA										
Dosage Text										
Role Route										
S Transdermal										
Outcomes										
Health Professional										
Case Type										
NON-EXPEDITED										
Case #										
11628243										
FDA Received Date										
14-Oct-2015										
Preferred Term										
Choking sensation										
Product										
ZECUITY										
Manufacturer										
TEVA										
Duration										
Age										
Sex										
Female										
Country										
USA										
Manufacturer Control #										
US-TEVA-594450USA										
Dosage Text										
Role Route										
S Unknown										
Outcomes										
Health Professional										
Case Type										
NON-EXPEDITED										
Case #										
11628246										
FDA Received Date										
14-Oct-2015										
Preferred Term										
Drug ineffective										
Product										
ZECUITY										
Manufacturer										
TEVA										
Duration										
Age										
Sex										
Female										
Country										
USA										
Manufacturer Control #										
US-TEVA-596838USA										
Dosage Text										
6.5 mg / 4 hours										
Role Route										
S Transdermal										
Outcomes										
Health Professional										
Case Type										
NON-EXPEDITED										
Case #										
11628247										
FDA Received Date										
14-Oct-2015										
Preferred Term										
Application site paraesthesia										
Product										
ZECUITY										
Manufacturer										
TEVA										
Duration										
Age										
30 YR										
Sex										
Male										
Country										
USA										
Manufacturer Control #										
US-TEVA-597346USA										
Dosage Text										
Role Route										
S Transdermal										
Outcomes										
Health Professional										



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11628248	NON-EXPEDITED			US-TEVA-598397USA		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Application site erythema	ZECURITY	S	Topical			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11628251	NON-EXPEDITED			US-TEVA-593251USA	31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema	ZECURITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11628252	NON-EXPEDITED			US-TEVA-598124USA		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site irritation	ZECURITY	S	Unknown			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11628254	NON-EXPEDITED			US-TEVA-597347USA	46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECURITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11628257	NON-EXPEDITED			US-TEVA-598049USA	35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Application site erythema	ZECURITY	S	Transdermal			TEVA		



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14-Oct-2015	11628258	NON-EXPEDITED			US-TEVA-597720USA	43 YR	Female	USA
Preferred Term								
Application site paraesthesia			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pain			ZECUITY	S				TEVA
Application site pain			TOPAMAX	C				
Application site erythema			SUMATRIPTAN	C				
Application site pain			AMERGE	C				
Sensory disturbance			BOTOX	C				
Oropharyngeal discomfort			HYDROCODONE	C				
Speech disorder								
<hr/>								
14-Oct-2015	11631190	EXPEDITED (15-DAY)			US-TEVA-599663USA	39 YR	Female	USA
Preferred Term								
Application site burn			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal			TEVA
Application site pain								
Device adhesion issue								
Device leakage								
Pruritus								
<hr/>								
16-Oct-2015	11636321	EXPEDITED (15-DAY)			US-TEVA-600351USA	49 YR	Female	USA
Preferred Term								
Application site pain			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site paraesthesia			ZECUITY	S	Transdermal			TEVA
Device issue			ZECUITY	S	Transdermal			TEVA



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16-Oct-2015	11638085	EXPEDITED (15-DAY)		OT	S		6.5 mg/4 hours		TEVA	30 YR	Female	USA
Preferred Term Application site pain Application site erythema Application site urticaria Drug ineffective												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2015	11656297	EXPEDITED (15-DAY)		OT	S	Transdermal			TEVA		Unknown	USA
Preferred Term Application site burn												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2015	11636367	EXPEDITED (15-DAY)		OT	S	Transdermal	6.5 mg/4 hours		TEVA	53 YR	Female	USA
Preferred Term Application site vesicles Application site erythema Application site pain												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2015	11676981	EXPEDITED (15-DAY)		OT	S	Transdermal			TEVA	47 YR	Male	USA
Preferred Term Application site burn Application site erythema Drug ineffective												



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30-Oct-2015	11686465	EXPEDITED (15-DAY)		OT	US-TEVA-603791USA		Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Hypersensitivity								
Underdose								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Nov-2015	11713700	DIRECT	Y			44 YR	Female	USA
Preferred Term								
Application site swelling								
Application site erythema								
Application site pruritus								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Nov-2015	11628439	EXPEDITED (15-DAY)		OT	US-TEVA-598995USA	25 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site irritation								
Application site pain								
Application site vesicles								
Device leakage								
Paraesthesia								
Underdose								



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18-Nov-2015	11751221	EXPEDITED (15-DAY)		OT	US-TEVA-609635USA	26 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical Injury				S Transdermal			TEVA	
Application site burn								
Application site erythema								
Application site exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11753036	EXPEDITED (15-DAY)		OT	US-TEVA-609879USA	33 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site erythema								
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11748267	EXPEDITED (15-DAY)		OT	US-TEVA-608957USA	49 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical Injury				S Transdermal	6.5 mg / 4 hours		TEVA	
Application site burn								
Product adhesion issue								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	11778625	EXPEDITED (15-DAY)		OT	US-TEVA-611048USA	40 YR	Male	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal	1 patch		TEVA	
Hypersensitivity								



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30-Nov-2015	11778987	EXPEDITED (15-DAY)		OT	US-TEVA-612485USA	28 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.25 mg/4 hours		TEVA	
Application site irritation		ZECUITY	S	Transdermal	6.25 mg/4 hours		TEVA	
Application site erythema								
Application site scab								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2015	11779872	EXPEDITED (15-DAY)		OT	US-TEVA-612045USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Thermal burn		ZECUITY	S	Transdermal			TEVA	
Device battery issue								
Device leakage								
Device use error								
Pain								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2015	11802905	EXPEDITED (15-DAY)		OT	US-TEVA-614446USA	32 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pruritus								
Paraesthesia								



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15-Dec-2015	11724326	EXPEDITED (15-DAY)		OT	US-TEVA-607673USA	34 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2015	11837725	EXPEDITED (15-DAY)		OT	US-TEVA-617120USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2015	11837730	EXPEDITED (15-DAY)		OT	US-TEVA-616697USA	62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site bruise				C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2015	11840501	DIRECT	Y			31 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECUITY 6.5 MG TRANSDERMAL PATCH TEVA	S	Transdermal	1 patch 1/24hr		TEVA	



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16-Dec-2015	11628244	EXPEDITED (15-DAY)		OT	US-TEVA-596584USA	39 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site burn	ZECURITY	S	Transdermal			TEVA		
Application site pruritus								
Application site rash								
Application site urticaria								
Device battery issue								
Headache								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2015	11844778	DIRECT		OT		48 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECURITY 6.5 MG TEVA	S	Topical	6.5 mg bid prn topical patch		TEVA		

- SERZONE C
- CLONAZEPAM C
- LAMICTAL C
- 1-METHYLFOLATE C
- PROMETHAZINE C
- OXYCODONE C
- CYCLOBENZAPRINE C
- FIORICET C
- TORADOL C
- DEXAMETHASONE C
- BENADRYL C

Application site burn



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2015	11855173	DIRECT	Y	OT		30 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical Injury		ZECUITY 6.5 MG TEVA		S Topical	6.5 mg, bid pm, topically		TEVA	
Pain		TOPAMAX		C				
Scab		SAXENDA		C				
Blister								
Drug effect decreased								
Swelling								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11630786	EXPEDITED (15-DAY)		OT	US-TEVA-600343USA	24 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal	6.5 mg / 4 hours		TEVA	
Application site erythema		ZECUITY		S Transdermal			TEVA	
Device leakage								
Drug effect incomplete								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11851996	EXPEDITED (15-DAY)		OT	US-TEVA-619496USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Thermal burn		ZECUITY		S Transdermal			TEVA	
Device malfunction								



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22-Dec-2015	11860025	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-620356USA	43 YR	Female	USA
<u>Preferred Term</u>											
Application site burn					S	Transdermal					TEVA
Application site erythema											
Application site irritation											
Application site pain											
Pain in extremity											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2015	11865141	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-619751USA	30 YR	Female	USA
<u>Preferred Term</u>											
Application site scar					S	Transdermal					TEVA
Application site erythema											
Application site pain											
Drug ineffective											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2015	11865479	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-621141USA	36 YR	Female	USA
<u>Preferred Term</u>											
Application site burn					S	Transdermal	6.5 mg / 4 hours				TEVA
Device battery issue											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2015	11876564	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-620976USA	56 YR	Female	USA
<u>Preferred Term</u>											
Application site burn					S	Transdermal	As needed for migraine				TEVA
Application site erythema											



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04-Jan-2016	11885044	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-622502USA			Unknown	USA
<u>Preferred Term</u>			<u>Product</u>						<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY		S					TEVA	
Application site irritation											
Product physical issue											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2016	11887048	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-621835USA			Female	USA
<u>Preferred Term</u>			<u>Product</u>						<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY		S					TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2016	11907800	EXPEDITED (15-DAY)		OT			US-TEVA-623448USA		36 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>						<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY		S					TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11637325	NON-EXPEDITED					US-TEVA-601877USA			Female	USA
<u>Preferred Term</u>			<u>Product</u>						<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY		S	Transdermal	6.5 mg / 4 hours				
Application site paraesthesia											
Chest pain											
Device battery issue											
Drug ineffective											



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12-Jan-2016	11676352	NON-EXPEDITED			US-TEVA-603652USA	53 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
			ZECURITY	S Transdermal	6.5 mg/4 hours			TEVA
Application site paraesthesia								
Device adhesion issue								
Device leakage								
Device malfunction								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11907835	NON-EXPEDITED			US-TEVA-602845USA	27 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Paraesthesia			ZECURITY	S Transdermal	6.5 mg /4 hours			TEVA
Application site pruritus								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909265	NON-EXPEDITED			US-TEVA-601328USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Drug ineffective			ZECURITY	S Transdermal				TEVA
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909266	NON-EXPEDITED			US-TEVA-598986USA		Unknown	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Adverse event			ZECURITY	S Unknown	dose and frequency not provided			TEVA
Drug ineffective								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909268	NON-EXPEDITED			US-TEVA-598961USA		Unknown	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain		ZECURITY	S	Unknown	dose and frequency not provided		TEVA	
Adverse event								
Nausea								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909269	NON-EXPEDITED			US-TEVA-598662USA	52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device battery issue		ZECURITY	S	Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909270	NON-EXPEDITED			US-TEVA-599014USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECURITY	S	Transdermal			TEVA	
Application site paraesthesia								
Device malfunction								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909271	NON-EXPEDITED			US-TEVA-600518USA	61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site reaction		ZECURITY	S	Transdermal			TEVA	



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12-Jan-2016	11909272	NON-EXPEDITED			S	Transdermal		US-TEVA-601542USA		Female	USA
Preferred Term											
Application site erythema											
Application site pruritus											
Application site swelling											
Drug effect incomplete											
Drug ineffective											
<hr/>											
12-Jan-2016	11909273	NON-EXPEDITED						US-TEVA-600521USA		Female	USA
Preferred Term											
Laceration											
Device issue											
Device leakage											
<hr/>											
12-Jan-2016	11909274	NON-EXPEDITED						US-TEVA-599659USA	56 YR	Female	USA
Preferred Term											
Application site erythema											
<hr/>											
12-Jan-2016	11909275	NON-EXPEDITED			S	Transdermal		US-TEVA-601465USA	42 YR	Male	USA
Preferred Term											
Application site urticaria											
Application site erythema											
Application site pruritus											
Product adhesion issue											



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12-Jan-2016	11909276	NON-EXPEDITED			S	Transdermal	6.25 mg/4 hours		TEVA			
<u>Preferred Term</u>												
Drug ineffective												
Application site dryness												
Application site erythema												
Application site rash												
Application site swelling												
Device battery issue												
Dizziness												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
12-Jan-2016	11909277	NON-EXPEDITED			S	Transdermal	US-TEVA-600062USA	56 YR	Female	USA		
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>			
Application site discolouration									TEVA			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
12-Jan-2016	11909278	NON-EXPEDITED			S	Transdermal	US-TEVA-601514USA	34 YR	Female	USA		
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>			
Application site pain									TEVA			
Device battery issue												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
12-Jan-2016	11909279	NON-EXPEDITED			S	Transdermal	US-TEVA-602031USA		Female	USA		
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>			
Hypertidrosis									TEVA			
Device leakage												



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12-Jan-2016	11909280	NON-EXPEDITED			S	Transdermal	US-TEVA-603286USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY						TEVA	
Application site paraesthesia										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909281	NON-EXPEDITED			S	Transdermal	US-TEVA-602192USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache			ZECUITY						TEVA	
Device battery issue										
Drug ineffective										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909282	NON-EXPEDITED			S	Transdermal	US-TEVA-602937USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY						TEVA	
			SUMATRIPTAN							
			ZOMIG							
			SUMAVEL							
			DIVALPROEX							
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909283	NON-EXPEDITED			S	Transdermal	US-TEVA-603097USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY						TEVA	



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12-Jan-2016	11909284	NON-EXPEDITED			US-TEVA-601175USA	52 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site vesicles Application site erythema	ZECUITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909285	NON-EXPEDITED			US-TEVA-600865USA	42 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Chest discomfort Adverse event	ZECUITY ZECUITY	S S		6.5 mg/4 hours 6.4 mg/4 hours		TEVA TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909286	NON-EXPEDITED			US-TEVA-601327USA		Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective Pain	ZECUITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909287	NON-EXPEDITED			US-TEVA-601167USA	52 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Device leakage Migraine	ZECUITY	S	Transdermal			TEVA		



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12-Jan-2016	11909288	NON-EXPEDITED			US-TEVA-602842USA		Female	USA
Preferred Term								
Application site erythema								
Device battery issue								
Device leakage								
Drug ineffective								
Underdose								
<hr/>								
12-Jan-2016	11909289	NON-EXPEDITED			US-TEVA-600339USA	57 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Device battery issue								
Drug ineffective								
<hr/>								
12-Jan-2016	11909290	NON-EXPEDITED			US-TEVA-601845USA		Female	USA
Preferred Term								
Paraesthesia								
Migraine								
<hr/>								
12-Jan-2016	11909291	NON-EXPEDITED			US-TEVA-603304USA	57 YR	Female	USA
Preferred Term								
Application site bruise								
Application site erythema								



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12-Jan-2016	11909292	NON-EXPEDITED			US-TEVA-602184USA	32 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache			ZECURITY	S Transdermal			TEVA	
Device malfunction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909293	NON-EXPEDITED			US-TEVA-602180USA	61 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Migraine			ZECURITY	S Transdermal			TEVA	
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909294	NON-EXPEDITED			US-TEVA-603306USA	29 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Device battery issue								
Drug effect decreased								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909295	NON-EXPEDITED			US-TEVA-603316USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Skin discolouration			ZECURITY	S Transdermal			TEVA	
Device battery issue								
Drug effect decreased								



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12-Jan-2016	11909296	NON-EXPEDITED			US-TEVA-601536USA	20 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909297	NON-EXPEDITED			US-TEVA-602847USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash			ZECUITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909298	NON-EXPEDITED			US-TEVA-602178USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Device leakage								
Incorrect drug administration duration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909299	NON-EXPEDITED			US-TEVA-603360USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site paraesthesia								
Device battery issue								
Headache								



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12-Jan-2016	11909300	NON-EXPEDITED			US-TEVA-602848USA	38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Device battery issue								
Drug ineffective								
Feeling abnormal								
Headache								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909301	NON-EXPEDITED			US-TEVA-603917USA	36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Device battery issue								
Drug ineffective								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909302	NON-EXPEDITED			US-TEVA-604002USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA		
Device battery issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909303	NON-EXPEDITED			US-TEVA-603640USA	43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Drug effect incomplete								



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12-Jan-2016	11909304	NON-EXPEDITED			US-TEVA-603313USA	47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash Application site erythema Application site paraesthesia	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909305	NON-EXPEDITED			US-TEVA-601847USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site dermatitis	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909306	NON-EXPEDITED			US-TEVA-603284USA	37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site pain	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909307	NON-EXPEDITED			US-TEVA-6033918USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site irritation Device battery issue Device leakage Fatigue	ZECUITY	S	Transdermal			TEVA		



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12-Jan-2016	11909313	NON-EXPEDITED			S	Transdermal	US-TEVA-605229USA		Female	USA
Preferred Term Headache Application site laceration Application site rash										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909314	NON-EXPEDITED			S	Transdermal	US-TEVA-605235USA		Female	USA
Preferred Term Application site rash Application site pain Application site vesicles										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909315	NON-EXPEDITED			S	Transdermal	US-TEVA-607281USA	24 YR	Female	USA
Preferred Term Application site erythema Application site rash										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909316	NON-EXPEDITED			S	Transdermal	US-TEVA-605085USA		Female	USA
Preferred Term Drug ineffective Device battery issue										



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12-Jan-2016	11909317	NON-EXPEDITED			S	Transdermal		US-TEVA-606950USA	44 YR	Female	USA
Preferred Term											
Application site erythema											
Application site pruritus											
Application site dryness											
Application site swelling											
<hr/>											
12-Jan-2016	11909318	NON-EXPEDITED			S	Transdermal		US-TEVA-606610USA		Female	USA
Preferred Term											
Drug ineffective											
<hr/>											
12-Jan-2016	11909319	NON-EXPEDITED			S	Transdermal	6.5 mg/4 hours	US-TEVA-607078USA		Female	USA
Preferred Term											
Application site pain											
Application site paraesthesia											
Application site urticaria											
<hr/>											
12-Jan-2016	11909320	NON-EXPEDITED			S	Transdermal		US-TEVA-606406USA	48 YR	Female	USA
Preferred Term											
Application site mass											
Application site erythema											
Application site warmth											
Wrong technique in product usage process											



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12-Jan-2016	11909321	NON-EXPEDITED					US-TEVA-607613USA			Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>				<u>Manufacturer</u>
Device battery issue			ZECURITY		S	Transdermal	6.5 mg/4 hours				TEVA
Drug ineffective											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>		<u>Country</u>
12-Jan-2016	11909322	NON-EXPEDITED					US-TEVA-606937USA	49 YR	Female		USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>			<u>Manufacturer</u>
Application site erythema			ZECURITY		S	Transdermal					TEVA
Application site pruritus			ZECURITY		S	Transdermal					TEVA
Application site pain											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>		<u>Country</u>
12-Jan-2016	11909323	NON-EXPEDITED					US-TEVA-608201USA	40 YR	Female		USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>			<u>Manufacturer</u>
Drug ineffective			ZECURITY		S	Transdermal					TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>		<u>Country</u>
12-Jan-2016	11909324	NON-EXPEDITED					US-TEVA-607679USA	14 YR	Female		USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>			<u>Manufacturer</u>
Application site erythema			ZECURITY		S	Transdermal	6.5mg/4hours				TEVA
Application site swelling											
Device leakage											
Drug administered to patient of inappropriate age											



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12-Jan-2016	11909325	NON-EXPEDITED			S	Transdermal	US-TEVA-607018USA	48 YR	Female	USA
Preferred Term										
Application site pruritus										
Application site erythema										
Drug ineffective										
Rash erythematous										
Rash pruritic										
Underdose										
<hr/>										
12-Jan-2016	11909326	NON-EXPEDITED					US-TEVA-606941USA	53 YR	Female	USA
Preferred Term										
Application site erythema										
Application site exfoliation										
Device battery issue										
<hr/>										
12-Jan-2016	11909327	NON-EXPEDITED			S	Transdermal	US-TEVA-607677USA	21 YR	Male	USA
Preferred Term										
Motion sickness										
<hr/>										
12-Jan-2016	11909328	NON-EXPEDITED			S	Transdermal	US-TEVA-608597USA	58 YR	Male	USA
Preferred Term										
Application site erythema										
Application site rash										
Application site urticaria										
Wrong technique in product usage process										



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12-Jan-2016	11909330	NON-EXPEDITED			US-TEVA-607616USA		Female	USA
<u>Preferred Term</u> Application site erythema								
<u>Product</u> ZECUITY								
<u>Role Route</u> S Transdermal								
<u>Dosage Text</u> TEVA								
<u>Duration</u> TEVA								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909331	NON-EXPEDITED			US-TEVA-608929USA		Female	USA
<u>Preferred Term</u> Application site paraesthesia								
<u>Product</u> ZECUITY								
<u>Role Route</u> S Transdermal								
<u>Dosage Text</u> 6.5mg/4hours								
<u>Duration</u> TEVA								
Application site pain								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909332	NON-EXPEDITED			US-TEVA-607297USA	48 YR	Female	USA
<u>Preferred Term</u> Application site swelling								
<u>Product</u> ZECUITY								
<u>Role Route</u> S Transdermal								
<u>Dosage Text</u> TEVA								
<u>Duration</u> TEVA								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909333	NON-EXPEDITED			US-TEVA-608905USA	45 YR	Female	USA
<u>Preferred Term</u> Application site erythema								
<u>Product</u> ZECUITY								
<u>Role Route</u> S Transdermal								
<u>Dosage Text</u> TEVA								
<u>Duration</u> TEVA								
Application site discoloration								
Application site erythema								
Application site pruritus								
Drug effect incomplete								
Feeling abnormal								
Product physical issue								



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12-Jan-2016	11909334	NON-EXPEDITED			US-TEVA-607318USA	50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective Application site erythema Application site irritation Application site pruritus Device leakage	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909335	NON-EXPEDITED			US-TEVA-608210USA	37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site hypersensitivity Application site pain Skin disorder	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909336	NON-EXPEDITED			US-TEVA-607299USA	27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Application site erythema Application site irritation Drug ineffective	ZECUITY ZECUITY	S S	Transdermal Transdermal			TEVA TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909337	NON-EXPEDITED			US-TEVA-608918USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		



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12-Jan-2016	11909338	NON-EXPEDITED			US-TEVA-608595USA	19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site erythema Application site warmth	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909339	NON-EXPEDITED			US-TEVA-607676USA	58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pruritus Application site rash	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909340	NON-EXPEDITED			US-TEVA-620881USA	42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909341	NON-EXPEDITED			US-TEVA-619980USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909342	NON-EXPEDITED			US-TEVA-620548USA	59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site irritation	ZECURITY	S	Transdermal	As directed		TEVA		



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12-Jan-2016	11909343	NON-EXPEDITED			S	Transdermal	6.5 mg / 4 hours		TEVA	27 YR	Female	USA
<u>Preferred Term</u> Application site erythema Device leakage Nausea Product adhesion issue												
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
12-Jan-2016	11909345	NON-EXPEDITED			S	Transdermal	US-TEVA-608587USA		Female	USA		
<u>Preferred Term</u> Application site pain ZECURITY												
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
12-Jan-2016	11909346	NON-EXPEDITED			S	Transdermal	US-TEVA-607300USA	45 YR	Female	USA		
<u>Preferred Term</u> Application site erythema ZECURITY												
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909347	NON-EXPEDITED			S	Transdermal	US-TEVA-608924USA	37 YR	Male	USA		
<u>Preferred Term</u> Application site erythema Application site discoloration Application site pruritus Application site urticaria												
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909348	NON-EXPEDITED			S	Transdermal	US-TEVA-608876USA	43 YR	Male	USA		
<u>Preferred Term</u> Drug ineffective ZECURITY												



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12-Jan-2016	11909351	NON-EXPEDITED					US-TEVA-619908USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site pain			ZECUITY		S	Transdermal				TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909352	NON-EXPEDITED					US-TEVA-619978USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY		S	Transdermal				TEVA
Application site pain			ZECUITY		S	Transdermal				TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909353	NON-EXPEDITED					US-TEVA-619772USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY		S	Transdermal				TEVA
Device battery issue										
Drug effect incomplete										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909354	NON-EXPEDITED					US-TEVA-622180USA	32 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY		S	Transdermal				TEVA
Application site pain										
Application site paraesthesia										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909355	NON-EXPEDITED					US-TEVA-621713USA	27 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY		S	Transdermal				TEVA
Application site pain										
Application site paraesthesia										



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12-Jan-2016	11909356	NON-EXPEDITED			US-TEVA-621602USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		ZECURITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909357	NON-EXPEDITED			US-TEVA-622185USA	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909358	NON-EXPEDITED			US-TEVA-621704USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Migraine		ZECURITY	S	Transdermal			TEVA	
			C					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909359	NON-EXPEDITED			US-TEVA-621716USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909360	NON-EXPEDITED			US-TEVA-620867USA	28 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECURITY	S	Transdermal			TEVA	



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12-Jan-2016	11909361	NON-EXPEDITED			S	Transdermal		US-TEVA-620839USA	49 YR	Female	USA
Preferred Term											
Application site erythema											
Application site pruritus											
Hyperaesthesia											
<hr/>											
12-Jan-2016	11909362	NON-EXPEDITED						US-TEVA-621722USA	32 YR	Female	USA
Preferred Term											
Application site erythema											
Device battery issue											
<hr/>											
12-Jan-2016	11909364	NON-EXPEDITED						US-TEVA-621711USA	44 YR	Female	USA
Preferred Term											
Incorrect drug administration duration											
Application site erythema											
Application site pruritus											
Application site rash											
<hr/>											
12-Jan-2016	11909365	NON-EXPEDITED						US-TEVA-620811USA	35 YR	Female	USA
Preferred Term											
Application site erythema											
Application site rash											



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12-Jan-2016	11909366	NON-EXPEDITED			S	Transdermal	US-TEVA-620348USA	37 YR	Female	USA
Preferred Term										
Application site bruise										
Application site discoloration										
Application site pain										
Application site swelling										
12-Jan-2016	11909367	NON-EXPEDITED			S	Transdermal	US-TEVA-622605USA	39 YR	Female	USA
Preferred Term										
Drug ineffective										
Application site erythema										
12-Jan-2016	11909370	NON-EXPEDITED			S	Transdermal	US-TEVA-622195USA	50 YR	Female	USA
Preferred Term										
Application site erythema										
12-Jan-2016	11909372	NON-EXPEDITED			S	Transdermal	US-TEVA-604398USA	40 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site urticaria										
Device leakage										
Dyspnoea										
Feeling abnormal										
Incorrect drug administration duration										
Pain in jaw										



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12-Jan-2016	11909376	NON-EXPEDITED			US-TEVA-604823USA	45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Intentional product misuse Application site erythema Application site pruritus	ZECUITY	S	Unknown			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909379	NON-EXPEDITED			US-TEVA-605081USA	61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site urticaria	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909380	NON-EXPEDITED			US-TEVA-604813USA	60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site paraesthesia	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909381	NON-EXPEDITED			US-TEVA-605764USA	65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Device battery issue	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909382	NON-EXPEDITED			US-TEVA-606744USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Device leakage	ZECUITY	S	Transdermal			TEVA		



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12-Jan-2016	11909383	NON-EXPEDITED			S	Transdermal	US-TEVA-606058USA	42 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUITY				6.5MG/4HR			TEVA
Application site erythema										
Application site exfoliation										
Burning sensation										
Device leakage										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909385	NON-EXPEDITED			S	Transdermal	US-TEVA-606828USA	46 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site irritation			ZECUITY				one patch			TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909386	NON-EXPEDITED			S	Transdermal	US-TEVA-606830USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site urticaria			ZECUITY							TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909387	NON-EXPEDITED			S	Transdermal	US-TEVA-609980USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Pain			ZECUITY							TEVA
Drug ineffective										
Incorrect drug administration duration										
Multiple use of single-use product										
Underdose										



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12-Jan-2016	11909388	NON-EXPEDITED			US-TEVA-604814USA	54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site pruritus								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909390	NON-EXPEDITED			US-TEVA-606551USA	37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site urticaria	ZECUITY	S	Transdermal			TEVA		
Device leakage								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909391	NON-EXPEDITED			US-TEVA-605766USA	33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Device battery issue								
Product packaging issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909392	NON-EXPEDITED			US-TEVA-604816USA	48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909393	NON-EXPEDITED			US-TEVA-606366USA	46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		



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12-Jan-2016	11909394	NON-EXPEDITED			S	Transdermal	US-TEVA-606360USA	33 YR	Female	USA
Preferred Term										
Application site erythema										
Device battery issue										
Device leakage										
12-Jan-2016	11909396	NON-EXPEDITED					US-TEVA-623183USA		Female	USA
Preferred Term										
Application site erythema										
Application site pruritus										
12-Jan-2016	11909397	NON-EXPEDITED					US-TEVA-622664USA	59 YR	Female	USA
Preferred Term										
Application site bruise										
12-Jan-2016	11909398	NON-EXPEDITED					US-TEVA-623154USA		Female	USA
Preferred Term										
Application site pain										
Application site bruise										
Device failure										
12-Jan-2016	11909400	NON-EXPEDITED					US-TEVA-609881USA		Female	USA
Preferred Term										
Drug ineffective										



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12-Jan-2016	11909401	NON-EXPEDITED			S Transdermal	US-TEVA-62267USA	54 YR	Female	USA
Preferred Term									
Application site erythema									
Application site pruritus									
Application site vesicles									
Intentional product use issue									
<hr/>									
12-Jan-2016	11909402	NON-EXPEDITED			S Transdermal	US-TEVA-623136USA		Female	USA
Preferred Term									
Application site rash									
Application site pruritus									
<hr/>									
12-Jan-2016	11909405	NON-EXPEDITED			S Transdermal	US-TEVA-611593USA	44 YR	Female	USA
Preferred Term									
Application site erythema									
Application site discoloration									
Application site exfoliation									
Application site pruritus									
Drug ineffective									
<hr/>									
12-Jan-2016	11909406	NON-EXPEDITED			S Transdermal	US-TEVA-609370USA		Female	USA
Preferred Term									
Application site erythema									



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12-Jan-2016	11909407	NON-EXPEDITED			US-TEVA-611234USA	49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Device leakage Application site pain Application site paraesthesia	ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909408	NON-EXPEDITED			US-TEVA-612903USA	34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Rash erythematous	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909409	NON-EXPEDITED			US-TEVA-614454USA	40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Device battery issue	ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909410	NON-EXPEDITED			US-TEVA-610379USA	60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site swelling Device malfunction	ZECUITY	S	Transdermal			TEVA		



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12-Jan-2016	11909411	NON-EXPEDITED			S	Transdermal	US-TEVA-609632USA	62 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY						TEVA	
Application site erythema										
Application site pruritus										
Drug hypersensitivity										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909413	NON-EXPEDITED			S	Transdermal	US-TEVA-623112USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Skin irritation			ZECURITY				6.5 mg over 4 hours		TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909415	NON-EXPEDITED			S	Transdermal	US-TEVA-609369USA	62 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Injection site erythema			ZECURITY						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909416	NON-EXPEDITED			S	Transdermal	US-TEVA-609703USA	56 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash			ZECURITY						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909419	NON-EXPEDITED			S	Transdermal	US-TEVA-609392USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY						TEVA	
Application site erythema										
Application site vesicles										



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12-Jan-2016	11909420	NON-EXPEDITED			S	Unknown		US-TEVA-610402USA		Female	USA
Preferred Term			Product						Duration	Manufacturer	
Headache			ZECURITY							TEVA	
Adverse event											
Decreased appetite											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909421	NON-EXPEDITED			S	Transdermal	6.5 mg/4 hours	US-TEVA-611242USA	14 YR	Female	USA
Preferred Term			Product						Duration	Manufacturer	
Application site pain			ZECURITY							TEVA	
Application site erythema											
Application site pain											
Application site erythema											
Application site urticaria											
Device leakage											
Drug administered to patient of inappropriate age											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909422	NON-EXPEDITED			S	Transdermal	6.5 mg / 4 hours	US-TEVA-616655USA	53 YR	Female	USA
Preferred Term			Product						Duration	Manufacturer	
Application site erythema			ZECURITY							TEVA	
Device leakage											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909424	NON-EXPEDITED			S	Transdermal	39 Milligram Daily, as directed	US-TEVA-612581USA	45 YR	Female	USA
Preferred Term			Product						Duration	Manufacturer	
Application site erythema			ZECURITY							TEVA	
Application site pruritus											



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12-Jan-2016	11909430	NON-EXPEDITED			US-TEVA-611586USA	43 YR	Female	USA
Preferred Term								
Application site pain				Role Route	Dosage Text	Duration	Manufacturer	
Device leakage				S Transdermal	6.5 mg/4 hr		TEVA	
Application site erythema				S Transdermal	6.5 mg/4 hr		TEVA	
Drug ineffective								
Product adhesion issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909434	NON-EXPEDITED			US-TEVA-612506USA	42 YR	Female	USA
Preferred Term								
Application site erythema				Role Route	Dosage Text	Duration	Manufacturer	
				S Transdermal			TEVA	
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909435	NON-EXPEDITED			US-TEVA-614798USA		Female	USA
Preferred Term								
Drug ineffective				Role Route	Dosage Text	Duration	Manufacturer	
				S Transdermal			TEVA	
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909436	NON-EXPEDITED			US-TEVA-610684USA	44 YR	Female	USA
Preferred Term								
Application site pruritus				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema				S Transdermal			TEVA	
Application site urticaria								
Drug administration error								



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12-Jan-2016	11909439	NON-EXPEDITED			US-TEVA-611256USA	46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective Application site paraesthesia Device battery issue	ZECUITY	S	Transdermal	dose not provided		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909441	NON-EXPEDITED			US-TEVA-616639USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash Application site pain	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909442	NON-EXPEDITED			US-TEVA-611590USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Dry skin	ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909443	NON-EXPEDITED			US-TEVA-612940USA	15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema Device leakage	ZECUITY	S	Transdermal			TEVA		



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12-Jan-2016	11909444	NON-EXPEDITED			S	Transdermal	US-TEVA-612513USA	41 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect incomplete			ZECUITY						TEVA	
Device battery issue										
Drug effect delayed										
Product adhesion issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909445	NON-EXPEDITED			S	Transdermal	US-TEVA-618772USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY				6.5 mg / 4 hours		TEVA	
Device adhesion issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909446	NON-EXPEDITED			S	Transdermal	US-TEVA-612913USA	44 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY						TEVA	
Application site rash										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909447	NON-EXPEDITED			S	Transdermal	US-TEVA-615148USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY						TEVA	
Application site dryness										



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12-Jan-2016	11909448	NON-EXPEDITED			US-TEVA-615135USA	59 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain Application site erythema Application site irritation	ZECUITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909449	NON-EXPEDITED			US-TEVA-611585USA	45 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Application site pruritus Intentional product use issue	ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909450	NON-EXPEDITED			US-TEVA-619769USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Burning sensation Device battery issue Hyperhidrosis Pain	ZECUITY	S	Transdermal	6.5 mg /4 hours		TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2016	11909451	NON-EXPEDITED			US-TEVA-614451USA	41 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain Application site pain	ZECUITY	S	Intradermal			TEVA		



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12-Jan-2016	11909453	NON-EXPEDITED			US-TEVA-614529USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device battery issue			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909454	NON-EXPEDITED			US-TEVA-612896USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device battery issue			ZECUITY	S Transdermal			TEVA	
Device leakage								
Dyspnoea								
Product use issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909455	NON-EXPEDITED			US-TEVA-616684USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909456	NON-EXPEDITED			US-TEVA-617998USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site reaction			ZECUITY	S Transdermal			TEVA	



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12-Jan-2016	11909457	NON-EXPEDITED			S	Transdermal	6.5mg/4hr		US-TEVA-618796USA	33 YR	Female	USA
Preferred Term												
Application site pain												
Application site pruritus												
Application site swelling												
Device battery issue												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
12-Jan-2016	11909459	NON-EXPEDITED			S	Transdermal	US-TEVA-616654USA	30 YR	Female	USA		
Preferred Term												
Application site erythema												
Device leakage												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
12-Jan-2016	11909460	NON-EXPEDITED			S	Transdermal	US-TEVA-616705USA	49 YR	Female	USA		
Preferred Term												
Headache												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
12-Jan-2016	11909462	NON-EXPEDITED			S	Transdermal	US-TEVA-616061USA	42 YR	Female	USA		
Preferred Term												
Application site erythema												
Abdominal pain upper												
Diarrhoea												



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12-Jan-2016	11909463	NON-EXPEDITED			US-TEVA-618769USA	29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema Device battery issue	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909464	NON-EXPEDITED			US-TEVA-616397USA	57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Dizziness Device leakage	ZECUITY	S	Transdermal	6.5mg/4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909465	NON-EXPEDITED			US-TEVA-615212USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site laceration Application site pain	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909467	NON-EXPEDITED			US-TEVA-616060USA	39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		



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12-Jan-2016	11909468	NON-EXPEDITED			US-TEVA-614475USA	44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Device battery issue Device leakage Drug ineffective Headache	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909470	NON-EXPEDITED			US-TEVA-615526USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site discolouration Drug ineffective	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909471	NON-EXPEDITED			US-TEVA-614465USA	46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909472	NON-EXPEDITED			US-TEVA-615866USA	40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Device battery issue	ZECURITY	S	Transdermal			TEVA		



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12-Jan-2016	11909473	NON-EXPEDITED			US-TEVA-615508USA	53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Hypersensitivity	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site pain								
Underdose								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909474	NON-EXPEDITED			US-TEVA-617595USA	46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909476	NON-EXPEDITED			US-TEVA-618454USA	34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909477	NON-EXPEDITED			US-TEVA-618030USA	29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site reaction	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909478	NON-EXPEDITED			US-TEVA-618003USA	52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Device battery issue								



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12-Jan-2016	11909479	NON-EXPEDITED			S Transdermal	US-TEVA-619342USA	37 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>			<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY					TEVA	
Application site rash									
Skin lesion									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909480	NON-EXPEDITED			S Transdermal	US-TEVA-616702USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>			<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY					TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909481	NON-EXPEDITED			S Transdermal	US-TEVA-616612USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>			<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea			ZECUITY					TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909482	NON-EXPEDITED			S Transdermal	US-TEVA-617074USA	49 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>			<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECUITY					TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909483	NON-EXPEDITED			S Transdermal	US-TEVA-617450USA	21 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>			<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY					TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909484	NON-EXPEDITED			S Transdermal	US-TEVA-619456USA	35 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>			<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY					TEVA	



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12-Jan-2016	11909485	NON-EXPEDITED			US-TEVA-616064USA	22 YR	Female	USA
Preferred Term								
Application site pain			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site pruritus			ZECURITY	S	Transdermal			TEVA
Application site erythema			ZECURITY	S	Transdermal			TEVA
Application site rash								
Device use error								
Drug ineffective								
<hr/>								
12-Jan-2016	11909486	NON-EXPEDITED			US-TEVA-619476USA	37 YR	Female	USA
Preferred Term								
Application site irritation			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECURITY	S	Transdermal			TEVA
Application site pain								
Mobility decreased								
Nausea								
<hr/>								
12-Jan-2016	11909488	NON-EXPEDITED			US-TEVA-617079USA		Female	USA
Preferred Term								
Application site erythema			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECURITY	S	Transdermal			TEVA
<hr/>								
12-Jan-2016	11909491	NON-EXPEDITED			US-TEVA-615597USA		Female	USA
Preferred Term								
Drug ineffective			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECURITY	S	Transdermal	6.25 mg/4 hours		TEVA
Application site urticaria								



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12-Jan-2016	11909492	NON-EXPEDITED			S	Transdermal	6.5 mg / 4 hours		US-TEVA-617456USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>									
			ZECUITY									TEVA
			Product odour abnormal									
			Device battery issue									
			Device leakage									
			Device use error									
			Drug ineffective									
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909493	NON-EXPEDITED			S		US-TEVA-618771USA		US-TEVA-618771USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>									
			ZECUITY									TEVA
			Paraesthesia									
			Application site erythema									
			Application site pain									
			Application site rash									
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909494	NON-EXPEDITED			S	Transdermal			US-TEVA-618821USA	51 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>									
			ZECUITY									TEVA
			Application site pain									
			Application site erythema									
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909498	NON-EXPEDITED			S	Transdermal	6.5 mg / 4 hours		US-TEVA-618770USA	44 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>									
			ZECUITY									TEVA
			Application site pain									
			Application site erythema									
			Device leakage									



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12-Jan-2016	11909501	NON-EXPEDITED			S Transdermal	US-TEVA-618763USA	38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>					<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema Skin discoloration	ZECUITY							TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909503	NON-EXPEDITED			S Transdermal	US-TEVA-619748USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>					<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema	ZECUITY							TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909504	NON-EXPEDITED			S Transdermal	US-TEVA-618791USA	51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>					<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema	ZECUITY							TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2016	11913173	EXPEDITED (15-DAY)			OT	US-TEVA-624133USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>					<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn	ZECUITY				S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2016	11914003	EXPEDITED (15-DAY)			OT	US-TEVA-624079USA		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>					<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn	ZECUITY				S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2016	11914032	EXPEDITED (15-DAY)			OT	US-TEVA-624896USA		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>					<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn	ZECUITY				S Transdermal			TEVA	



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14-Jan-2016	11915430	NON-EXPEDITED			US-TEVA-624979USA	64 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site urticaria				S Transdermal			TEVA	
Application site erythema				S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2016	11837720	EXPEDITED (15-DAY)		OT	US-TEVA-617101USA	42 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site pain								
Application site rash								
Drug ineffective								
Underdose								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2016	11899194	EXPEDITED (15-DAY)		OT	US-TEVA-623138USA	43 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Malaise				S Transdermal	6.5 m over 4 hours		TEVA	
Dizziness				S Transdermal	6.5 m over 4 hours		TEVA	
Ashtenia								
Dehydration								
Device battery issue								
Drug ineffective								
Nausea								
Vomiting								



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20-Jan-2016	11931870	EXPEDITED (15-DAY)		OT	US-TEVA-626377USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site scar								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2016	11909489	EXPEDITED (15-DAY)		OT	US-TEVA-617598USA	29 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site exfoliation								
Application site pain								
Blisters								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2016	11939862	EXPEDITED (15-DAY)		OT	US-TEVA-626859USA	43 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA	



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22-Jan-2016	11964095	DIRECT				53 YR	Female	USA
Preferred Term			Product	Role	Dosage Text	Duration	Manufacturer	
Application site pain			ZECUITY TEVA PHARMACEUTICALS	S	1 patch, as needed, applied as medicated patch to skin	30 MIN	TEVA	
Application site erythema			DRISDOL	C				
			WELLBUTRIN	C				
			PHEENTERMINE	C				
			LORITAB	C				
			GABAPENTIN	C				
			MICROZIDE	C				
			LIPITOR	C				
			LUNESTA	C				
			MULTI VITAMIN	C				
Application site pain								
Application site rash								
Discomfort								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2016	11966676	EXPEDITED (15-DAY)		OT	US-TEVA-629078USA	40 YR	Female	USA
Preferred Term			Product	Role	Dosage Text	Duration	Manufacturer	
Application site burn			ZECUITY	S				
Application site pain								
Application site paraesthesia								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2016	11980805	EXPEDITED (15-DAY)		OT			US-TEVA-628676USA		29 YR	Female	USA
Preferred Term					Role	Route					Manufacturer
Application site burn					S	Transdermal					TEVA
Application site exfoliation											
Application site pain											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
01-Feb-2016	11983501	EXPEDITED (15-DAY)		OT			US-TEVA-630115USA			Male	USA
Preferred Term					Role	Route	Dosage Text	Dosage Text	Duration	Manufacturer	
Application site burn					S	Transdermal				TEVA	
Drug effect incomplete					C	Oral					
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
02-Feb-2016	11987901	EXPEDITED (15-DAY)		OT			US-TEVA-630770USA			Female	USA
Preferred Term					Role	Route	Dosage Text	Duration	Manufacturer		
Application site burn					S	Transdermal				TEVA	
Application site erythema											
Application site vesicles											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
03-Feb-2016	11876525	EXPEDITED (15-DAY)		OT			US-TEVA-617119USA			Female	USA
Preferred Term					Role	Route	Dosage Text	Duration	Manufacturer		
Application site burn					S	Transdermal				TEVA	
Rash erythematous					S	Transdermal				TEVA	
Application site discoloration											
Application site pain											
Application site rash											



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03-Feb-2016	11999763	DIRECT	Y	OT		31 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECUITY TRANSDERMAL PATCH	S	Topical			TEVA	
		6.5 MG TEVA						
		PHARMACEUTICALS						
Application site rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2016	12031522	EXPEDITED (15-DAY)		OT	US-TEVA-632146USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2016	11914018	EXPEDITED (15-DAY)		OT	US-TEVA-624377USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2016	12070081	EXPEDITED (15-DAY)		OT	US-TEVA-633660USA	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2016	12072181	DIRECT		RI		32 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Wrong technique in product usage process		ZECUITY 6.5MG TEVA	S	Transdermal	6.5mg @mset Transdermal		TEVA	



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16-Feb-2016	11909403	EXPEDITED (15-DAY)		OT	US-TEVA-623155USA	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site erythema								
Application site pruritus								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2016	12085033	EXPEDITED (15-DAY)		OT	US-TEVA-634653USA		Unknown	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2016	12092351	DIRECT	Y	OT		27 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache		ZECUITY 6.5 MG TEVA	S	Topical			TEVA	
Product quality issue		AMBIE	C					
		NUVIGIL	C					
		NEURONTIN	C					
		BOTOX	C					
		ZOFRAN ODT	C					
		OXYCODONE	C					
		ZOCOR	C					
		ZANAFLEX	C					
		ULTRAM	C					
		DIAZEPAM	C					
		WELLBUTRIN	C					
		XOPENEX	C					

Drug ineffective



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17-Feb-2016	12092355	DIRECT	Y	OT		27 YR	Female	USA
<u>Preferred Term</u>								
Product quality issue								
Headache								
<u>Product</u>								
ZECUITY 6.5 MG TEVA				S				
AMBIE				C				
NUVAGIL				C				
NEURONTIN				C				
BOTOX				C				
ZOFRAN ODT				C				
OXYCODONE				C				
ZOCOR				C				
ZANAFLEX				C				
ULTRAM				C				
DIAZEPAM				C				
WELLBUTRIN				C				
XOPENEX				C				
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2016	12052786	EXPEDITED (15-DAY)		OT	US-TEVA-632151USA	27 YR	Female	USA
<u>Preferred Term</u>								
Application site burn								
Application site erythema								
Application site rash								
Device leakage								
Drug ineffective								
Injection site paraesthesia								
<u>Product</u>								
ZECUITY				S				
<u>Role Route</u>								
Transdermal								
<u>Dosage Text</u>								
6.5 mg over 4 hours								
<u>Duration</u>								
<u>Manufacturer</u>								
TEVA								



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19-Feb-2016	12092842	EXPEDITED (15-DAY)		OT	US-TEVA-635763USA	36 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site warmth								
Drug ineffective								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2016	12094368	EXPEDITED (15-DAY)		OT	US-TEVA-635693USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY		S Transdermal	6.5 mg over 4 hours		TEVA	
Application site reaction								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2016	12094385	EXPEDITED (15-DAY)		OT	US-TEVA-635767USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
Application site pain								
Application site rash								
Application site scar								



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EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2016	12110383	EXPEDITED (15-DAY)		OT	US-TEVA-636103USA	45 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Application site vesicles	ZECUITY	S	Transdermal			TEVA		
Application site discoloration								
Application site erythema								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2016	12113587	DIRECT		OT		50 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective	ZECUITY 6.5 MG TEVA PHARMACEUTICALS	S	Topical			TEVA		
	TOPIRAMATE	C						
	OPANA	C						
	CYMBALTA	C						
	BENADRYL	C						
	ALPRAZOLAM	C						
	DILAUDID	C						
	COMPAZINE	C						
	MEDICAL MARIJUANA	C						
	PROVENTIL	C						
	DICYCLOMINE	C						
	BABY ASA	C						
	METOPROLOL	C						

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2016	12113606	DIRECT		OT		49 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Skin reaction	ZECUITY	S	Topical			TEVA		



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25-Feb-2016	12052403	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-631854USA	24 YR	Female	USA
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer</u>			
Rash pustular					S	Transdermal		TEVA			
Application site erythema											
Application site pruritus											
Application site rash											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12115443	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-6336916USA	28 YR	Female	USA
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer</u>			
Sunburn					S	Transdermal		TEVA			
Application site erythema											
Application site pain											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2016	12085767	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-635268USA		Female	USA
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer</u>			
Application site burn					S	Transdermal	6.5 mg / 4 hours				
Burns second degree											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2016	12137011	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-637728USA	30 YR	Female	USA
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer</u>			
Sunburn					S	Transdermal		TEVA			
Application site irritation											
Product adhesion issue											



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02-Mar-2016	12137187	EXPEDITED (15-DAY)		OT	US-TEVA-638168USA	34 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site paraesthesia								
Application site pruritus								
Device battery issue								
Device leakage								
EDA Received Date								
02-Mar-2016	12140959	DIRECT		OT		17 YR	Male	
Preferred Term								
Skin discoloration								
Product								
ZECURITY								
Role Route								
S Topical								
Dosage Text								
1 patch, prn/as needed, topical								
Manufacturer Control #								
Age								
17 YR								
Sex								
Male								
Country								
EDA Received Date								
03-Mar-2016	12140685	EXPEDITED (15-DAY)		OT	US-TEVA-639897USA	31 YR	Female	USA
Preferred Term								
Application site burn								
Application site pruritus								
Application site rash								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
Duration								
Manufacturer								
TEVA								



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03-Mar-2016	12140763	EXPEDITED (15-DAY)		OT	US-TEVA-638841USA	34 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Device battery issue								
Device material issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2016	12142931	EXPEDITED (15-DAY)		OT	US-TEVA-639083USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical injury		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2016	12147315	EXPEDITED (15-DAY)		OT	US-TEVA-639951USA	38 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Drug ineffective		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site irritation								
Application site pain								
Device leakage								
Product adhesion issue								



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07-Mar-2016	12155773	EXPEDITED (15-DAY)		OT	US-TEVA-640230USA	39 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
								Application site erythema Application site pain Application site reaction Device battery issue Device leakage
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	12156905	EXPEDITED (15-DAY)		OT	US-TEVA-640930USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Unknown			TEVA	
								Application site burn
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2016	12159815	EXPEDITED (15-DAY)		OT	US-TEVA-640980USA	44 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal	patient is now on box number 3 of patches, subsequent therapy dates not provided		TEVA	
								Application site discoloration Application site erythema Application site pruritus Application site swelling Device leakage



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09-Mar-2016	11837760	EXPEDITED (15-DAY)		OT	US-TEVA-618005USA	45 YR	Female	USA
Preferred Term								
Application site burn								
Application site pain								
Application site vesicles								
Device leakage								
09-Mar-2016	12128048	EXPEDITED (15-DAY)		OT	US-TEVA-638300USA	47 YR	Female	USA
Preferred Term								
Application site burn								
Application site discoloration								
Application site pain								
Device leakage								
Drug ineffective								
09-Mar-2016	12165534	EXPEDITED (15-DAY)		OT	US-TEVA-640969USA	63 YR	Female	USA
Preferred Term								
Application site scar								
Application site pruritus								
Headache								
10-Mar-2016	11979750	EXPEDITED (15-DAY)		OT	US-TEVA-629438USA	39 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site pain								



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10-Mar-2016	12168988	EXPEDITED (15-DAY)		OT	US-TEVA-641650USA		Male	USA
Preferred Term								
Application site burn								
Application site pruritus								
Device battery issue								
Sunburn								
<hr/>								
11-Mar-2016	12171647	EXPEDITED (15-DAY)		OT	US-TEVA-641319USA	49 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site vesicles								
Drug ineffective								
Paraesthesia								
<hr/>								
14-Mar-2016	12171863	EXPEDITED (15-DAY)		OT	US-TEVA-631858USA	33 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site pain								
Application site pruritus								
Application site scar								
Application site urticaria								
Application site warmth								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2016	12005721	EXPEDITED (15-DAY)		OT	US-TEVA-631696USA	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site discoloration								
Application site pain								
Application site urticaria								
Application site vesicles								
Blood blister								
Device leakage								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2016	12155748	EXPEDITED (15-DAY)		OT	US-TEVA-640231USA	36 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Sunburn		ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Application site discoloration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Drug effect incomplete								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2016	12184634	EXPEDITED (15-DAY)		OT	US-TEVA-642436USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Device leakage								
Product adhesion issue								



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16-Mar-2016	12184943	EXPEDITED (15-DAY)		OT	US-TEVA-642477USA	39 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site exfoliation								
Application site pain								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Age								
39 YR								
Sex								
Female								
Country								
USA								
Manufacturer Control #								
US-TEVA-642477USA								
Outcomes								
OT								
Health Professional								
Case Type								
EXPEDITED (15-DAY)								
Case #								
12184943								
FDA Received Date								
16-Mar-2016								
Preferred Term								
Application site burn								
Application site erythema								
Application site pain								
Application site pruritus								
Application site rash								
Incorrect drug administration duration								
Myalgia								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Age								
39 YR								
Sex								
Female								
Country								
USA								
Manufacturer Control #								
US-TEVA-642477USA								
Outcomes								
OT								
Health Professional								
Case Type								
EXPEDITED (15-DAY)								
Case #								
12185445								
FDA Received Date								
16-Mar-2016								
Preferred Term								
Application site haemorrhage								
Application site pain								
Application site pruritus								
Application site rash								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Age								
39 YR								
Sex								
Female								
Country								
USA								
Manufacturer Control #								
US-TEVA-640977USA								
Outcomes								
OT								
Health Professional								
Case Type								
EXPEDITED (15-DAY)								
Case #								
12185445								
FDA Received Date								
16-Mar-2016								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2016	12186551	EXPEDITED (15-DAY)		OT	US-TEVA-643238USA	21 YR	Female	USA
Preferred Term								
Sunburn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site pruritus								
Application site urticaria								
Application site warmth								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2016	12186692	EXPEDITED (15-DAY)		OT	US-TEVA-643262USA	38 YR	Female	USA
Preferred Term								
Application site burn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site swelling								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2016	12187273	EXPEDITED (15-DAY)		OT	US-TEVA-642822USA	51 YR	Female	USA
Preferred Term								
Application site burn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site reaction								
Drug ineffective								
Skin abrasion								



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17-Mar-2016	12188446	EXPEDITED (15-DAY)		OT	US-TEVA-642864USA	41 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site pain								
Application site urticaria								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2016	12188613	EXPEDITED (15-DAY)		OT	US-TEVA-644158USA	41 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal	6.5 mg/4 hr		TEVA	
Chemical burn of skin				C				
Application site erythema								
Rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2016	12013009	EXPEDITED (15-DAY)		OT	US-TEVA-631377USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Device battery issue								
Skin exfoliation								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2016	12165351	EXPEDITED (15-DAY)		OT	US-TEVA-640923USA	16 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site rash								
Application site urticaria								
Application site vesicles								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2016	12170818	EXPEDITED (15-DAY)		OT	US-TEVA-641653USA	47 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2016	12191494	EXPEDITED (15-DAY)		OT	US-TEVA-643645USA	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Device battery issue								



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18-Mar-2016	12191563	EXPEDITED (15-DAY)		OT	US-TEVA-643592USA	50 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site rash		ZECUITY		S Transdermal			TEVA	
Device battery issue		ZECUITY		S Transdermal			TEVA	
Application site discoloration								
Drug effect incomplete								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	12195897	EXPEDITED (15-DAY)		OT	US-TEVA-643905USA	24 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site coldness								
Dyskinesia								
Muscle twitching								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	12196515	EXPEDITED (15-DAY)		OT	US-TEVA-644008USA	47 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Skin texture abnormal								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	12196785	EXPEDITED (15-DAY)		OT	US-TEVA-644002USA	45 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site pain								



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23-Mar-2016	12173024	EXPEDITED (15-DAY)		OT	US-TEVA-641836USA	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site pruritus								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2016	12203686	EXPEDITED (15-DAY)		OT	US-TEVA-644391USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Drug ineffective								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	12177315	EXPEDITED (15-DAY)		OT	US-TEVA-642397USA	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Sunburn		Janumet	C					
Application site pain								
Application site urticaria								
Incorrect drug administration duration								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	12191583	EXPEDITED (15-DAY)		OT	US-TEVA-644940USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site irritation								
Application site pain								
Application site urticaria								



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24-Mar-2016	12208541	EXPEDITED (15-DAY)		OT	US-TEVA-645048USA	36 YR	Female	USA
Preferred Term								
Sunburn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site pain								
<hr/>								
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
25-Mar-2016	12211733	EXPEDITED (15-DAY)		OT	US-TEVA-646872USA	30 YR	Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECUITY	S Transdermal			TEVA	
<hr/>								
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
28-Mar-2016	12214815	EXPEDITED (15-DAY)		OT	US-TEVA-645663USA	48 YR	Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site dryness			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site reaction								
Application site scar								
Sunburn								



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28-Mar-2016	12215458	EXPEDITED (15-DAY)		OT	US-TEVA-645846USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site pain								
Application site paraesthesia								
Application site scar								
Sunburn								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2016	11913163	EXPEDITED (15-DAY)		OT	US-TEVA-624128USA	29 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site swelling								
Chemical injury								
Dermatitis contact								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2016	12200457	EXPEDITED (15-DAY)		OT	US-TEVA-645399USA	79 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5mg/4 hours		TEVA	
Application site pain								



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30-Mar-2016	12067686	EXPEDITED (15-DAY)		OT	US-TEVA-633631USA	30 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site pain		VITAMIN B12	C					
Application site discoloration		Ziposor	C					
Application site swelling		ZOFRAN	C					
		TOPAMAX	C					
		PHENERGAN	C					
		BOTOX	C					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2016	12192355	EXPEDITED (15-DAY)		OT	US-TEVA-643545USA	30 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY	S	Transdermal			TEVA	
Application site burn								
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site vesicles								
Application site warmth								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2016	12225244	EXPEDITED (15-DAY)		OT	US-TEVA-648089USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECURITY	S	Transdermal			TEVA	
Application site erythema		Imitrex	C					
Application site vesicles								
Skin disorder								



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31-Mar-2016	12226959	EXPEDITED (15-DAY)		OT	US-TEVA-647178USA	30 YR	Female	USA
Preferred Term								
Application site scar				S			Transdermal	TEVA
Application site pain				S			Transdermal	TEVA
Product adhesion issue								
FDA Received Date								
04-Apr-2016	11908939	EXPEDITED (15-DAY)		OT	US-TEVA-621723USA	42 YR	Female	USA
Preferred Term								
Application site burn				S			Transdermal	TEVA
Application site erythema								
Application site pain								
Application site warmth								
Product adhesion issue								
Skin exfoliation								
Skin warm								



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05-Apr-2016	11983483	EXPEDITED (15-DAY)		OT	US-TEVA-630070USA	52 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site pruritus								
Application site irritation								
Application site inflammation								
B12								
BIOTIN								
CALCIUM								
FOLIC ACID								
METABOTIC								
PROBIOTICA								
VITAMIN E								
Levothyroxine								
Metformin								
Lisinopril								
Omeprazole								
Eftexor								
C								
EDA Received Date								
05-Apr-2016	12110704	EXPEDITED (15-DAY)		OT	US-TEVA-638321USA	43 YR	Female	USA
Preferred Term								
Application site scar								
Application site burn								
Application site erythema								
Application site pruritus								
Application site vesicles								
Skin texture abnormal								
ZECUITY								
ZECUITY								
S								
Transdermal								
Product								
Role Route								
Dosage Text								
Duration								
Manufacturer								
Manufacturer Control #								
Age								
Sex								
Country								



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05-Apr-2016	12110710	EXPEDITED (15-DAY)		OT	US-TEVA-638313USA	43 YR	Female	USA
Preferred Term								
Application site scar								
Application site burn								
Application site erythema								
Application site pruritus								
Application site vesicles								
<hr/>								
05-Apr-2016	12215456	EXPEDITED (15-DAY)		OT	US-TEVA-645866USA	49 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site oedema								
Application site pain								
Application site urticaria								
Dry skin								
Fatigue								
<hr/>								
05-Apr-2016	12239170	EXPEDITED (15-DAY)		OT	US-TEVA-648168USA	41 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site pain								
Application site urticaria								
Device battery issue								



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05-Apr-2016	12239265	EXPEDITED (15-DAY)		OT	US-TEVA-648239USA	62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Fatigue								
Somnolence								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2016	12240192	EXPEDITED (15-DAY)		OT	US-TEVA-635055USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site irritation								
Application site pain								
Application site pruritus								
Application site vesicles								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2016	12240201	EXPEDITED (15-DAY)		OT	US-TEVA-648214USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S			TEVA	
Application site erythema								
Device leakage								
Drug ineffective								



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05-Apr-2016	12241679	DIRECT		DS		48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Abdominal pain upper		ZECUITY, 6.5 MG TEVA		S	2 Patch (es) / As needed Applied as medicated patch to skin		TEVA	
Nausea		ZOLOFT		C				
Application site vesicles		OMEPRAZOLE DR		C				
Application site pain		INDRAL LA		C				
		VIT D2		C				
		B-12 SHOTS		C				
		WARFARIN		C				
		TOPOMAX		C				
		MYRBETRIQ		C				
		AMBIEN		C				
		VALIUM		C				
		NARATRIP TAN HCL (AMERGE)		C				
		EPIPEN		C				
		FISH OIL		C				
Application site erythema								
Application site exfoliation								
Diarrhoea								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2016	12142932	EXPEDITED (15-DAY)		OT	US-TEVA-639072USA	43 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S			TEVA	
Device battery issue								
Incorrect drug administration duration								



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06-Apr-2016	12191481	EXPEDITED (15-DAY)		OT	US-TEVA-643635USA	51 YR	Male	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site pain								
Application site swelling								
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	11909363	NON-EXPEDITED			US-TEVA-620358USA	67 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain				S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site urticaria								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	11909417	NON-EXPEDITED			US-TEVA-611241USA	21 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective				S Transdermal	dose not provided		TEVA	
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	11909423	NON-EXPEDITED			US-TEVA-623445USA	20 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain				S Transdermal	6.5 mg / 4 hours		TEVA	



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07-Apr-2016	11909431	NON-EXPEDITED			US-TEVA-617121USA	39 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
			Application site discoloration					
			Device leakage					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	11909433	NON-EXPEDITED			US-TEVA-611235USA	26 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal	6.5 mg/4 hours		TEVA	
			Application site pain					
			Application site erythema					
			Application site pain					
			Device leakage					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	11909466	NON-EXPEDITED			US-TEVA-615462USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
			Application site rash					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12069505	NON-EXPEDITED			US-TEVA-626865USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
			Application site pain					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12110698	EXPEDITED (15-DAY)			US-TEVA-636377USA	43 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
			Application site burn					
			Application site scar					



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07-Apr-2016	12245033	NON-EXPEDITED			US-TEVA-625060USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Aglitation			ZECUITY	S Transdermal			TEVA	
Application site pain			Topiramate	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245035	NON-EXPEDITED			US-TEVA-623590USA	49 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site irritation								
Application site pruritus								
Application site rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245036	NON-EXPEDITED			US-TEVA-623567USA	49 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dysgeusia			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245037	NON-EXPEDITED			US-TEVA-624052USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site reaction								



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07-Apr-2016	12245039	NON-EXPEDITED			US-TEVA-624045USA	33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Device adhesion issue								
Device battery issue								
Device issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245040	NON-EXPEDITED			US-TEVA-623564USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Application site paraesthesia								
Device battery issue								
Device difficult to use								
Device leakage								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245041	NON-EXPEDITED			US-TEVA-625063USA	40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245043	NON-EXPEDITED			US-TEVA-623585USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Device leakage	ZECUITY	S	Transdermal			TEVA		
Application site pain								
Incorrect drug administration duration								



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07-Apr-2016	12245044	NON-EXPEDITED		OT			US-TEVA-623370USA			Female	USA
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>					<u>Manufacturer</u>
Dermatitis contact					S	Transdermal	per 4 hours				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-Apr-2016	12245047	NON-EXPEDITED					US-TEVA-623180USA	41 YR	Female	USA	
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>	
Drug ineffective					S	Transdermal				TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-Apr-2016	12245048	NON-EXPEDITED					US-TEVA-623912USA	56 YR	Female	USA	
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>	
Application site discoloration					S	Transdermal				TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-Apr-2016	12245049	NON-EXPEDITED					US-TEVA-624597USA	58 YR	Female	USA	
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>	
Application site paraesthesia					S	Transdermal				TEVA	
Device battery issue					S	Transdermal				TEVA	
Device use error											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-Apr-2016	12245053	NON-EXPEDITED					US-TEVA-624577USA	36 YR	Female	USA	
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>	
Application site rash					S	Transdermal				TEVA	
Application site erythema											
Application site pain											



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07-Apr-2016	12245054	NON-EXPEDITED			S	Transdermal	US-TEVA-623451USA	62 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
			ZECURITY							TEVA
<u>Application site erythema</u>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245055	NON-EXPEDITED			S	Transdermal	US-TEVA-625573USA	52 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
			ZECURITY							TEVA
<u>Application site erythema</u>										
<u>Application site dryness</u>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245056	NON-EXPEDITED			S	Transdermal	US-TEVA-625020USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
			ZECURITY							TEVA
<u>Application site pain</u>										
<u>Application site discoloration</u>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245057	NON-EXPEDITED			S	Transdermal	US-TEVA-625569USA	55 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
			ZECURITY							TEVA
<u>Nausea</u>										
<u>Drug effect decreased</u>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245058	NON-EXPEDITED			S	Transdermal	US-TEVA-624980USA	73 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
			ZECURITY							TEVA
<u>Drug ineffective</u>										
<u>Application site erythema</u>										
<u>Application site pruritus</u>										



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07-Apr-2016	12245059	NON-EXPEDITED			US-TEVA-623128USA	51 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site paraesthesia								
Application site pruritus								
Dry skin								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245061	NON-EXPEDITED			US-TEVA-623910USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site pain								
Application site erythema								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245062	NON-EXPEDITED			US-TEVA-624054USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site reaction								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245064	NON-EXPEDITED			US-TEVA-625722USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Application site pain								
Device leakage								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245065	NON-EXPEDITED			US-TEVA-624053USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site reaction								
Application site erythema								



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07-Apr-2016	12245066	NON-EXPEDITED			US-TEVA-623915USA	34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECUITY	S	Transdermal			TEVA		
Application site irritation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245067	NON-EXPEDITED			US-TEVA-623568USA	32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site swelling	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Application site erythema								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245069	NON-EXPEDITED			US-TEVA-623211USA	26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site pruritus								
Skin exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245071	NON-EXPEDITED			US-TEVA-625476USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug effect decreased	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245072	NON-EXPEDITED			US-TEVA-625715USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Rash	ZECUITY	S	Transdermal			TEVA		



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07-Apr-2016	12245073	NON-EXPEDITED			S	Transdermal	6.5 mg / 4 hours		US-TEVA-624904USA	34 YR	Female	USA
Preferred Term	Product											
Application site erythema	ZECURITY											
Device adhesion issue												
Device issue												
Device leakage												
Drug ineffective												
Skin fissures												
Skin reaction												
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Duration	Manufacturer	Age	Sex	Country
07-Apr-2016	12245074	NON-EXPEDITED			S	Transdermal	US-TEVA-623586USA				Female	USA
Preferred Term	Product											
Application site pain	ZECURITY											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Duration	Manufacturer	Age	Sex	Country
07-Apr-2016	12245076	NON-EXPEDITED			S	Transdermal	US-TEVA-625022USA	30 YR		Female		USA
Preferred Term	Product											
Application site paraesthesia	ZECURITY											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Duration	Manufacturer	Age	Sex	Country
07-Apr-2016	12245077	NON-EXPEDITED			S	Transdermal	US-TEVA-624505USA	38 YR		Female		USA
Preferred Term	Product											
Application site erythema	ZECURITY											
Device issue												
Device leakage												



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07-Apr-2016	12245078	NON-EXPEDITED			US-TEVA-625563USA	34 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>Application site erythema</u>								
<u>Application site irritation</u>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245079	NON-EXPEDITED			US-TEVA-624613USA	61 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>Paraesthesia</u>								
<u>Application site erythema</u>								
<u>Application site rash</u>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245080	NON-EXPEDITED			US-TEVA-625574USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>Drug ineffective</u>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245081	NON-EXPEDITED			US-TEVA-625892USA	37 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>Application site urticaria</u>								
<u>Application site erythema</u>								



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07-Apr-2016	12245083	NON-EXPEDITED			US-TEVA-625748USA	68 YR	Female	USA
Preferred Term								
Application site reaction			Product	Role Route	Dosage Text	Duration	Manufacturer	
Skin reaction			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Application site pruritus			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Application site rash								
Application site urticaria								
Application site warmth								
Device battery issue								
Drug effect Incomplete								
<hr/>								
07-Apr-2016	12245084	NON-EXPEDITED			US-TEVA-626072USA	54 YR	Female	USA
Preferred Term								
Application site pruritus			Product	Role Route	Dosage Text	Duration	Manufacturer	
Device leakage			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
<hr/>								
07-Apr-2016	12245089	NON-EXPEDITED			US-TEVA-625035USA	61 YR	Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discomfort			ZECUITY	S Transdermal			TEVA	
Application site pruritus								
<hr/>								
07-Apr-2016	12245093	NON-EXPEDITED			US-TEVA-626936USA	48 YR	Male	USA
Preferred Term								
Application site rash			Product	Role Route	Dosage Text	Duration	Manufacturer	
			ZECUITY	S Transdermal			TEVA	



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07-Apr-2016	12245106	NON-EXPEDITED			US-TEVA-626205USA	48 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal			TEVA
Application site discoloration			ZECUITY	S	Transdermal			TEVA
07-Apr-2016	12245107	NON-EXPEDITED			US-TEVA-626073USA		Female	USA
Preferred Term								
Application site pain			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pain			ZECUITY	S	Transdermal			TEVA
Dermatitis contact			ZECUITY	S				TEVA
Application site erythema								
07-Apr-2016	12245108	NON-EXPEDITED			US-TEVA-626208USA	40 YR	Female	USA
Preferred Term								
Application site pruritus			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pruritus			ZECUITY	S	Transdermal			TEVA
Application site erythema								
07-Apr-2016	12245109	NON-EXPEDITED			US-TEVA-626935USA	45 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA
Application site pruritus								
Application site rash								
Device battery issue								



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07-Apr-2016	12245111	NON-EXPEDITED			US-TEVA-626913USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Migraine			ZECUITY	S Transdermal			TEVA	
Drug ineffective								
Nausea								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245112	NON-EXPEDITED			US-TEVA-626202USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245113	NON-EXPEDITED			US-TEVA-627875USA	55 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal	6.5mg/4 hours		TEVA	
Device malfunction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245116	NON-EXPEDITED			US-TEVA-626194USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245118	NON-EXPEDITED			US-TEVA-626191USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Surgery			ZECUITY	S Transdermal			TEVA	



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07-Apr-2016	12245119	NON-EXPEDITED			US-TEVA-626848USA	20 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site pain			ZECURITY	S Transdermal			TEVA	
Application site papules								
<hr/>								
07-Apr-2016	12245121	NON-EXPEDITED			US-TEVA-626871USA		Female	USA
Preferred Term								
Hypersensitivity			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site pain								
Application site rash								
Application site vesicles								
<hr/>								
07-Apr-2016	12245122	NON-EXPEDITED			US-TEVA-6268378USA	31 YR	Female	USA
Preferred Term								
Application site irritation			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECURITY	S Transdermal			TEVA	
Application site dryness								
Application site exfoliation								
<hr/>								
07-Apr-2016	12245123	NON-EXPEDITED			US-TEVA-627592USA	42 YR	Female	USA
Preferred Term								
Paraesthesia			Product	Role Route	Dosage Text	Duration	Manufacturer	
Skin irritation			ZECURITY	S Transdermal			TEVA	



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07-Apr-2016	12245124	NON-EXPEDITED			US-TEVA-626196USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site dryness	ZECUITY	S	Transdermal			TEVA		
Application site fissure								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245125	NON-EXPEDITED			US-TEVA-626855USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site reaction	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Application site pruritus								
Application site warmth								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245127	NON-EXPEDITED			US-TEVA-626869USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245128	NON-EXPEDITED			US-TEVA-626861USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Application site rash								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12246351	EXPEDITED (15-DAY)		OT	US-TEVA-648496USA	42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Application site pain								
Application site pruritus								



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07-Apr-2016	12246355	EXPEDITED (15-DAY)		OT	US-TEVA-648495USA	48 YR	Female	USA
Preferred Term								
Application site burn								
Application site dryness								
Application site erythema								
Application site pain								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12246222	EXPEDITED (15-DAY)		OT	US-TEVA-648809USA	36 YR	Female	USA
Preferred Term								
Sunburn								
Application site coldness								
Application site discoloration								
Application site erythema								
Application site pain								
Incorrect drug administration duration								
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12246730	EXPEDITED (15-DAY)		OT	US-TEVA-648536USA	35 YR	Female	USA
Preferred Term								
Application site burn								
Application site dryness								
Application site discoloration								
Application site pruritus								
Device battery issue								



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08-Apr-2016	12054386	EXPEDITED (15-DAY)		OT	US-TEVA-632781USA	53 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site rash								
Sunburn								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12119668	EXPEDITED (15-DAY)		OT	US-TEVA-637312USA	30 YR	Male	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal	6.5 mg / 4 hours		TEVA	
Device leakage								
Headache								
Intentional device misuse								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12245034	NON-EXPEDITED			US-TEVA-624046USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective				S Transdermal	6.5 mg / 4 hours		TEVA	
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12245052	NON-EXPEDITED			US-TEVA-625889USA	60 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain				S Transdermal			TEVA	
Application site pain								
Myalgia								



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08-Apr-2016	12247920	NON-EXPEDITED			S	Transdermal		US-TEVA-627678USA		Female	USA
<u>Preferred Term</u> Application site paraesthesia											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247921	NON-EXPEDITED			S	Transdermal		US-TEVA-629432USA	45 YR	Female	USA
<u>Preferred Term</u> Application site pain Application site urticaria Application site erythema Application site pruritus Device adhesion issue Device issue											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247923	NON-EXPEDITED			S	Transdermal		US-TEVA-629324USA		Female	USA
<u>Preferred Term</u> Device battery issue Drug effect decreased											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247924	NON-EXPEDITED			S	Transdermal	6.5 mg over 4 hours	US-TEVA-628436USA		Male	USA
<u>Preferred Term</u> Application site rash Application site pain Application site urticaria											



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08-Apr-2016	12247925	NON-EXPEDITED			S	Transdermal	US-TEVA-628431USA		Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash									TEVA	
Application site irritation										
Application site irritation										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247926	NON-EXPEDITED			S	Transdermal	US-TEVA-628270USA	51 YR	Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema							6.5 mg / 4 hours		TEVA	
Application site pruritus										
Application site urticaria										
Device battery issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247928	NON-EXPEDITED			S	Transdermal	US-TEVA-627634USA		Male	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash									TEVA	
Application site discoloration										
Application site erythema										
Application site pruritus										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247929	NON-EXPEDITED			S	Transdermal	US-TEVA-628691USA		Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Feeling abnormal							6.5 mg over 4 hours		TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247930	NON-EXPEDITED			S	Transdermal	US-TEVA-628425USA	60 YR	Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pruritus									TEVA	



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08-Apr-2016	12247936	NON-EXPEDITED			US-TEVA-628687USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache			ZECUITY	S Transdermal			TEVA	
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247937	NON-EXPEDITED			US-TEVA-629323USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site exfoliation								
Device battery issue								
Dry skin								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247938	NON-EXPEDITED			US-TEVA-627878USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect incomplete			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Device battery issue								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247940	NON-EXPEDITED			US-TEVA-628651USA	51 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	



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08-Apr-2016	12247941	NON-EXPEDITED			S	Transdermal	6.5 mg over 4 hours		TEVA			
Preferred Term Drug ineffective Application site pruritus Application site rash												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247942	NON-EXPEDITED			S	Transdermal			TEVA			
Preferred Term Application site pruritus Application site erythema												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247943	NON-EXPEDITED			S	Transdermal			TEVA			
Preferred Term Application site inflammation Application site erythema Application site pruritus Application site urticaria Dermatitis contact												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247945	NON-EXPEDITED			S	Transdermal			TEVA			
Preferred Term Application site pain Application site erythema Product adhesion issue Product physical issue												



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08-Apr-2016	12247946	NON-EXPEDITED			US-TEVA-628678USA	50 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECURITY	S Transdermal			TEVA	
Migraine								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247947	NON-EXPEDITED			US-TEVA-627880USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Application site pain								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247949	NON-EXPEDITED			US-TEVA-628437USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Formication			ZECURITY	S Transdermal			TEVA	
Application site pain								
Application site paraesthesia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247950	NON-EXPEDITED			US-TEVA-628269USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site irritation			ZECURITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247951	NON-EXPEDITED			US-TEVA-628650USA	37 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY	S Transdermal			TEVA	



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08-Apr-2016	12247952	NON-EXPEDITED			S	Transdermal	US-TEVA-629493USA	46 YR	Female	USA
Preferred Term										
Application site urticaria										
Application site erythema										
Application site erosion										
Application site pain										
<hr/>										
08-Apr-2016	12247954	NON-EXPEDITED			S	Transdermal	US-TEVA-627756USA	30 YR	Female	USA
Preferred Term										
Product physical issue										
Application site irritation										
Drug effect incomplete										
<hr/>										
08-Apr-2016	12247955	NON-EXPEDITED			S	Transdermal	US-TEVA-628688USA		Female	USA
Preferred Term										
Application site rash										
<hr/>										
08-Apr-2016	12247956	NON-EXPEDITED			S	Transdermal	US-TEVA-629125USA	57 YR	Female	USA
Preferred Term										
Application site rash										
Skin exfoliation										
<hr/>										
08-Apr-2016	12247957	NON-EXPEDITED			S	Transdermal	US-TEVA-627757USA		Female	USA
Preferred Term										
Application site irritation										



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08-Apr-2016	12247959	NON-EXPEDITED			US-TEVA-629133USA	38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247961	NON-EXPEDITED			US-TEVA-629508USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247962	NON-EXPEDITED			US-TEVA-628675USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247963	NON-EXPEDITED			US-TEVA-628677USA	61 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	



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08-Apr-2016	12247964	NON-EXPEDITED			US-TEVA-627879USA	57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site irritation Application site pruritus Device battery issue	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247965	NON-EXPEDITED			US-TEVA-629318USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247966	NON-EXPEDITED			US-TEVA-629450USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247969	NON-EXPEDITED			US-TEVA-629123USA	42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247970	NON-EXPEDITED			US-TEVA-629490USA	27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site swelling	ZECUITY	S	Transdermal			TEVA		



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08-Apr-2016	12247971	NON-EXPEDITED			S	Transdermal	US-TEVA-629131USA	38 YR	Female	USA
<u>Preferred Term</u> Application site pain Application site erythema										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247972	NON-EXPEDITED			S	Transdermal	US-TEVA-629486USA		Female	USA
<u>Preferred Term</u> Application site pain Application site erythema Application site pruritus Application site paraesthesia										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247973	NON-EXPEDITED			S	Transdermal	US-TEVA-629101USA	44 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site pruritus										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247974	NON-EXPEDITED			S	Transdermal	US-TEVA-629319USA		Female	USA
<u>Preferred Term</u> Application site pain Application site erythema										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247975	NON-EXPEDITED			S	Transdermal	US-TEVA-629132USA	39 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site pruritus Application site vesicles										



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08-Apr-2016	12247976	NON-EXPEDITED			US-TEVA-629510USA	39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site vesicles Drug ineffective	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247979	NON-EXPEDITED			US-TEVA-629966USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site pruritus Device battery issue Incorrect drug administration duration	ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247984	NON-EXPEDITED			US-TEVA-630434USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash Application site vesicles	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247985	NON-EXPEDITED			US-TEVA-630499USA	51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247986	NON-EXPEDITED			US-TEVA-631225USA	47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Device leakage	ZECURITY	S	Transdermal			TEVA		



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08-Apr-2016	12247987	NON-EXPEDITED			US-TEVA-630790USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site erythema	S Transdermal			TEVA	
			Application site swelling					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247990	NON-EXPEDITED			US-TEVA-630791USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site rash	S Transdermal	6.5mg/4 hours		TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247991	NON-EXPEDITED			US-TEVA-630503USA	25 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Paraesthesia	S Transdermal			TEVA	
			Application site rash					
			Burning sensation					
			Incorrect drug administration duration					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247992	NON-EXPEDITED			US-TEVA-630767USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Drug effect decreased	S Transdermal			TEVA	
			Device battery issue					
			Drug ineffective					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247993	NON-EXPEDITED			US-TEVA-630065USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site erythema	S Transdermal			TEVA	



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08-Apr-2016	12247994	NON-EXPEDITED			S	Transdermal	US-TEVA-630046USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Migraine			ZECURITY							TEVA
			Imitrex		C					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247995	NON-EXPEDITED					US-TEVA-630044USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECURITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12247998	NON-EXPEDITED					US-TEVA-630113USA	15 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site pain			ZECURITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248000	NON-EXPEDITED					US-TEVA-630098USA	48 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug effect incomplete			ZECURITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248001	NON-EXPEDITED					US-TEVA-630118USA	49 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site pain			ZECURITY		S	Transdermal				TEVA



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08-Apr-2016	12248002	NON-EXPEDITED			US-TEVA-630119USA		Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Application site hypersensitivity								
Application site rash								
Drug ineffective								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2016	12248003	NON-EXPEDITED			US-TEVA-630084USA	53 YR	Male	USA
Preferred Term								
Application site rash								
Application site irritation								
Application site pruritus								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Apr-2016	12248004	NON-EXPEDITED			US-TEVA-630398USA	28 YR	Female	USA
Preferred Term								
Hypersensitivity								
Application site erythema								
Application site pruritus								
Application site vesicles								



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08-Apr-2016	12248005	NON-EXPEDITED			S	Transdermal	US-TEVA-630324USA	46 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Device adhesion issue										
Device battery issue										
EDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
08-Apr-2016	12248006	NON-EXPEDITED			S	Transdermal	US-TEVA-631297USA	44 YR	Female	USA
Preferred Term										
Application site discoloration										
Application site erythema										
EDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer Control #										
Age										
Sex										
Country										
08-Apr-2016	12248007	NON-EXPEDITED			S	Transdermal	US-TEVA-630699USA	30 YR	Female	USA
Preferred Term										
Application site bruise										
EDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer Control #										
Age										
Sex										
Country										
08-Apr-2016	12248009	NON-EXPEDITED			S	Transdermal	US-TEVA-630116USA		Female	USA
Preferred Term										
Drug ineffective										
Application site rash										
EDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer Control #										
Age										
Sex										
Country										
08-Apr-2016	12248010	NON-EXPEDITED			S	Transdermal	US-TEVA-630130USA		Female	USA
Preferred Term										
Application site erythema										
Drug ineffective										



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08-Apr-2016	12248011	NON-EXPEDITED			US-TEVA-630123USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUIITY	S Transdermal			TEVA	
<u>Application site erythema</u>								
<u>FDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248012	NON-EXPEDITED			US-TEVA-630507USA	31 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUIITY	S Transdermal			TEVA	
<u>Application site pain</u>								
<u>Application site discolouration</u>								
<u>Application site erythema</u>								
<u>Application site pruritus</u>								
<u>Incorrect drug administration duration</u>								
<u>Underdose</u>								
<u>FDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248013	NON-EXPEDITED			US-TEVA-630323USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUIITY	S Transdermal	6.5 mg over 4 hours		TEVA	
<u>Drug ineffective</u>								
<u>Application site pruritus</u>								
<u>FDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248014	NON-EXPEDITED			US-TEVA-630325USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUIITY	S Transdermal			TEVA	
<u>Application site erythema</u>								
<u>Application site pain</u>								
<u>Application site discomfort</u>								
<u>Application site irritation</u>								
<u>Application site reaction</u>								
<u>Device leakage</u>								



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08-Apr-2016	12248015	NON-EXPEDITED			US-TEVA-630326USA	25 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY	S Transdermal			TEVA	
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248016	NON-EXPEDITED			US-TEVA-630512USA	34 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Pruritus								
Skin exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248017	NON-EXPEDITED			US-TEVA-630650USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Drug effect incomplete								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248018	NON-EXPEDITED			US-TEVA-630128USA	57 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site urticaria			ZECUITY	S Transdermal			TEVA	
Application site papules								
Application site pruritus								
Application site rash								



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08-Apr-2016	12248022	NON-EXPEDITED			US-TEVA-631273USA	44 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site vesicles			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Drug ineffective								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248024	NON-EXPEDITED			US-TEVA-630722USA	36 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Skin swelling								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248025	NON-EXPEDITED			US-TEVA-632306USA	43 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECURITY	S Transdermal			TEVA	
Device leakage								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248026	NON-EXPEDITED			US-TEVA-631263USA	28 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pruritus			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site dryness								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12248033	NON-EXPEDITED			US-TEVA-630712USA	72 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site laceration			ZECURITY	S Transdermal			TEVA	
Application site erythema			Imitrex	C				



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08-Apr-2016	12248034	NON-EXPEDITED			S	Transdermal		US-TEVA-632140USA		Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Application site pruritus											
Device leakage											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
08-Apr-2016	12248035	NON-EXPEDITED			S	Transdermal		US-TEVA-631248USA		Female	USA
Preferred Term											
Application site vesicles											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
08-Apr-2016	12248925	NON-EXPEDITED			S	Transdermal		US-TEVA-628686USA		Female	USA
Preferred Term											
Application site irritation											
Application site erythema											
Application site exfoliation											
Application site pain											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
08-Apr-2016	12249838	EXPEDITED (15-DAY)			OT			US-TEVA-648500USA	47 YR	Female	USA
Preferred Term											
Application site burn											
Application site erythema											
Application site pain											
Application site papules											
Application site pruritus											



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11-Apr-2016	12242793	EXPEDITED (15-DAY)		OT	US-TEVA-648551USA	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
		ZECUITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12253637	EXPEDITED (15-DAY)		OT	US-TEVA-649854USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Breast cancer		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site erythema								
Device battery issue								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12254542	EXPEDITED (15-DAY)		OT	US-TEVA-649752USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical injury		ZECUITY	S	Transdermal			TEVA	
Application site burn								
Application site pain								
Application site urticaria								
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12254730	EXPEDITED (15-DAY)		OT	US-TEVA-649708USA	30 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								



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12-Apr-2016	12255697	EXPEDITED (15-DAY)		OT	US-TEVA-649821USA	46 YR	Female	USA
Preferred Term								
Application site burn								
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site pruritus								
<hr/>								
12-Apr-2016	12258272	EXPEDITED (15-DAY)		OT	US-TEVA-649822USA	54 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Device battery issue								
Device leakage								
Drug ineffective								
Intentional product use issue								
Product adhesion issue								
<hr/>								
12-Apr-2016	12261210	DIRECT		HO			Female	USA
Preferred Term								
Dyspnoea								
Product ZECURITY, 6.5 MG TEVA PHARMACEUTICAL								
Role Route S								
Dosage Text								
Duration								
Manufacturer TEVA								



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13-Apr-2016	12245798	EXPEDITED (15-DAY)		OT	US-TEVA-648868USA	64 YR	Female	USA
Preferred Term								
Sunburn				<u>Role Route</u> S Transdermal	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u> TEVA	
Application site erythema								
Application site pain								
Application site paraesthesia								
Drug effect incomplete								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2016	12245828	EXPEDITED (15-DAY)		OT	US-TEVA-648869USA	60 YR	Female	USA
Preferred Term								
Application site burn				<u>Role Route</u> S Transdermal	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u> TEVA	
Application site discoloration								
Application site erythema								
Application site hyperaesthesia								
Application site pain								
Application site pruritus								
Application site swelling								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2016	12265696	EXPEDITED (15-DAY)		OT	US-TEVA-651019USA		Female	USA
Preferred Term								
Sunburn				<u>Role Route</u> S Transdermal	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u> TEVA	
Application site erythema								
Application site exfoliation								
Application site hypoaesthesia								
Application site irritation								
Application site pain								



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EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Apr-2016	12245819	EXPEDITED (15-DAY)		OT	US-TEVA-648874USA	35 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Sunburn	ZECUITY	S	Transdermal			TEVA		
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Application site swelling								
Application site urticaria								
Drug ineffective								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Apr-2016	12253651	EXPEDITED (15-DAY)		OT	US-TEVA-649823USA	54 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Application site exfoliation								
Application site irritation								
Application site vesicles								
Device battery issue								
Device leakage								
Sunburn								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Apr-2016	12267804	EXPEDITED (15-DAY)		OT	US-TEVA-651039USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Application site discolouration								



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14-Apr-2016	12269172	EXPEDITED (15-DAY)		OT	US-TEVA-651072USA		Unknown	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S				TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2016	12269222	EXPEDITED (15-DAY)		OT	US-TEVA-651073USA	31 YR	Unknown	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S				TEVA	
Application site irritation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2016	12269308	EXPEDITED (15-DAY)		OT	US-TEVA-651097USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S				TEVA	
Application site bruise								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2016	12269673	EXPEDITED (15-DAY)		OT	US-TEVA-651067USA		Unknown	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Device issue								



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15-Apr-2016	11909412	NON-EXPEDITED			US-TEVA-622648USA	40 YR	Female	USA
Preferred Term								
Application site dyiness								
Application site erythema								
Application site irritation								
Application site pain								
Application site pruritus								
Skin reaction								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Age								
69 YR								
Sex								
Female								
Country								
USA								
Manufacturer Control #								
US-TEVA-609276USA								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Role Route								
S Transdermal								
Outcomes								
C								
Product								
ZECURITY								
Prolia								
Application site rash								
Application site pruritus								
Application site erythema								
EDA Received Date								
15-Apr-2016								
Case #								
11909458								
Case Type								
NON-EXPEDITED								
Health Professional								
Outcomes								
Manufacturer Control #								
US-TEVA-616653USA								
Age								
51 YR								
Sex								
Female								
Country								
USA								
Manufacturer Control #								
US-TEVA-616653USA								
Dosage Text								
6.5 mg / 4 hours								
Duration								
TEVA								
Manufacturer								
TEVA								
Role Route								
S Transdermal								
Outcomes								
C								
Product								
ZECURITY								
CYMBALTA								
GABAPENTIN								
DILAUDID								
PRILOSEC								
PHENERGAN								
SUMATRIPTAN								
TRAZODONE								
AMBIEN								
Product								
ZECURITY								
Application site paraesthesia								
Device leakage								
Product adhesion issue								
Application site irritation								



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15-Apr-2016	11909502	NON-EXPEDITED			US-TEVA-618768USA	36 YR	Female	USA
Preferred Term								
Application site paraesthesia			Product	Role Route	Dosage Text	Duration	Manufacturer	
Device battery issue			ZECURITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Device leakage			ZECURITY	S Transdermal			TEVA	
<hr/>								
15-Apr-2016	12245115	NON-EXPEDITED			US-TEVA-627877USA	47 YR	Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Device adhesion issue								
Device leakage								
Migraine								
<hr/>								
15-Apr-2016	12245120	NON-EXPEDITED			US-TEVA-626181USA	47 YR	Male	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site bruise			ZECURITY	S Transdermal			TEVA	
Application site pruritus								
Application site swelling								



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15-Apr-2016	12247977	NON-EXPEDITED			US-TEVA-629447USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECUITY	S	Transdermal			TEVA	
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12247981	NON-EXPEDITED		OT	US-TEVA-630755USA	61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Blood pressure increased		ZECUITY	S	Transdermal			TEVA	
Anxiety		ZECUITY	S	Transdermal			TEVA	
Device adhesion issue								
Device leakage								
Drug effect decreased								
Drug ineffective								
Migraine								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12247983	NON-EXPEDITED			US-TEVA-630497USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pruritus		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Drug ineffective								
Skin exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12247997	NON-EXPEDITED			US-TEVA-630074USA	34 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECUITY	S	Transdermal			TEVA	



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15-Apr-2016	12247999	NON-EXPEDITED			US-TEVA-63014USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scab		ZECURITY	S	Transdermal			TEVA	
Inappropriate schedule of drug administration								
15-Apr-2016	12248008	NON-EXPEDITED			US-TEVA-630706USA	48 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site hypersensitivity								
Application site pruritus								
15-Apr-2016	12248021	NON-EXPEDITED			US-TEVA-631230USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device leakage		ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Drug ineffective								



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15-Apr-2016	12248023	NON-EXPEDITED			US-TEVA-631229USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device battery issue				S Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
Application site papules								
Application site rash								
Device issue								
Device use error								
Drug ineffective								
Incorrect product storage								
Parasthesia								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12248027	NON-EXPEDITED			US-TEVA-631266USA	49 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective				S Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
Application site pruritus								
Drug effect decreased								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12248028	NON-EXPEDITED			US-TEVA-631267USA	44 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective				S Transdermal	6.5 mg over 4 hours		TEVA	
Headache								
Product adhesion issue								



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15-Apr-2016	12270778	NON-EXPEDITED			S	Transdermal	US-TEVA-631842USA	24 YR	Female	USA
Preferred Term										
Application site erythema										
Application site paraesthesia										
Application site pruritus										
Device leakage										
Product adhesion issue										
<hr/>										
15-Apr-2016	12270779	NON-EXPEDITED			S	Transdermal	US-TEVA-631856USA	53 YR	Female	USA
Preferred Term										
Application site erythema										
Application site discoloration										
<hr/>										
15-Apr-2016	12270780	NON-EXPEDITED			S	Transdermal	US-TEVA-631844USA		Female	USA
Preferred Term										
Drug effect delayed										
<hr/>										
15-Apr-2016	12270783	NON-EXPEDITED			S	Transdermal	US-TEVA-631989USA	55 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site urticaria										
<hr/>										
15-Apr-2016	12270784	NON-EXPEDITED			S	Transdermal	US-TEVA-633026USA		Female	USA
Preferred Term										
Drug effect incomplete										



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15-Apr-2016	12270785	NON-EXPEDITED			S	Transdermal		US-TEVA-632786USA	55 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site swelling											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270786	NON-EXPEDITED			S	Transdermal		US-TEVA-632540USA	49 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site pain Device leakage											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270787	NON-EXPEDITED			S	Transdermal		US-TEVA-632782USA		Female	USA
<u>Preferred Term</u> Application site laceration Application site erythema Application site irritation											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270788	NON-EXPEDITED			S	Transdermal		US-TEVA-633031USA	43 YR	Female	USA
<u>Preferred Term</u> Application site pain Application site erythema Application site exfoliation Application site pain Application site swelling Device leakage Drug effect Incomplete											



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15-Apr-2016	12270789	NON-EXPEDITED			US-TEVA-632778USA	44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site swelling Application site urticaria	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270792	NON-EXPEDITED			US-TEVA-632975USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Drug ineffective	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270793	NON-EXPEDITED			US-TEVA-632981USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site exfoliation Application site pruritus Application site rash	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270794	NON-EXPEDITED			US-TEVA-632916USA	39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site paraesthesia	ZECURITY	S	Transdermal			TEVA		



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15-Apr-2016	12270795	NON-EXPEDITED			US-TEVA-632539USA		Female	USA
Preferred Term								
Application site erythema								
Device battery issue								
Device leakage								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
Manufacturer								
TEVA								
Age								
Sex								
Female								
Country								
USA								
Manufacturer Control #								
US-TEVA-632923USA								
Age								
33 YR								
Sex								
Female								
Country								
USA								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 6 hours								
Duration								
Manufacturer								
TEVA								
Outcomes								
S Transdermal								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 6 hours								
Duration								
Manufacturer								
TEVA								
Health Professional								
Outcomes								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 6 hours								
Duration								
Manufacturer								
TEVA								
Case #								
12270797								
Case Type								
NON-EXPEDITED								
Health Professional								
Outcomes								
Manufacturer Control #								
US-TEVA-633034USA								
Age								
30 YR								
Sex								
Female								
Country								
USA								
Dosage Text								
6.5 mg over 6 hours								
Duration								
Manufacturer								
TEVA								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 6 hours								
Duration								
Manufacturer								
TEVA								
Health Professional								
Outcomes								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 6 hours								
Duration								
Manufacturer								
TEVA								
Case #								
12270798								
Case Type								
NON-EXPEDITED								
Health Professional								
Outcomes								
Manufacturer Control #								
US-TEVA-632152USA								
Age								
43 YR								
Sex								
Female								
Country								
USA								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Health Professional								
Outcomes								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Case #								
12270796								
Case Type								
NON-EXPEDITED								
Health Professional								
Outcomes								
Manufacturer Control #								
US-TEVA-632923USA								
Age								
33 YR								
Sex								
Female								
Country								
USA								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Health Professional								
Outcomes								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Health Professional								
Outcomes								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Case #								
12270797								
Case Type								
NON-EXPEDITED								
Health Professional								
Outcomes								
Manufacturer Control #								
US-TEVA-633034USA								
Age								
30 YR								
Sex								
Female								
Country								
USA								
Dosage Text								
6.5 mg over 6 hours								
Duration								
Manufacturer								
TEVA								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 6 hours								
Duration								
Manufacturer								
TEVA								
Health Professional								
Outcomes								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 6 hours								
Duration								
Manufacturer								
TEVA								
Case #								
12270795								
Case Type								
NON-EXPEDITED								
Health Professional								
Outcomes								
Manufacturer Control #								
US-TEVA-632539USA								
Age								
Sex								
Female								
Country								
USA								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								
Health Professional								
Outcomes								
Role Route								
S Transdermal								
Dosage Text								
6.5 mg over 4 hours								
Duration								
Manufacturer								
TEVA								



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15-Apr-2016	12270799	NON-EXPEDITED			US-TEVA-632147USA	59 YR	Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Application site pain								
Device leakage								
<hr/>								
15-Apr-2016	12270801	NON-EXPEDITED			US-TEVA-632792USA	39 YR	Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Application site pain								
Application site papules								
Application site pruritus								
Application site warmth								
Device leakage								
<hr/>								
15-Apr-2016	12270802	NON-EXPEDITED			US-TEVA-633045USA	33 YR	Female	USA
Preferred Term								
Headache								
Product ZECURITY								
Role Route S Transdermal								
Manufacturer Control #								
Dosage Text								
Age								
Sex								
Country								
Duration								
Manufacturer								



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15-Apr-2016	12270803	NON-EXPEDITED			US-TEVA-632149USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal	6.5 mg / 4 hours		TEVA	
			Application site pain					
			Application site discoloration					
			Application site erythema					
			Device leakage					
			Drug ineffective					
			Skin reaction					
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270804	NON-EXPEDITED			US-TEVA-633037USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
			Application site urticaria					
			Application site pruritus					
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270805	NON-EXPEDITED			US-TEVA-632141USA	53 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal	6.5 mg / 4 hours		TEVA	
			Application site erythema					
			Application site erythema					
			Device battery issue					
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270806	NON-EXPEDITED			US-TEVA-632783USA	57 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
			Dizziness					
			Application site erythema					
			Bradyphrenia					
			Feeling abnormal					



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15-Apr-2016	12270807	NON-EXPEDITED			US-TEVA-633999USA	56 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Drug effect incomplete								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270808	NON-EXPEDITED			US-TEVA-633874USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270809	NON-EXPEDITED			US-TEVA-633895USA	36 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Device battery issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270810	NON-EXPEDITED			US-TEVA-634024USA	38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site pain								
Application site swelling								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270811	NON-EXPEDITED			US-TEVA-633639USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY	S Transdermal			TEVA	



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15-Apr-2016	12270813	NON-EXPEDITED			S	Transdermal		US-TEVA-633593USA	49 YR	Male	USA
Preferred Term											
Application site dryness											
Application site exfoliation											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
15-Apr-2016	12270814	NON-EXPEDITED			S	Transdermal		US-TEVA-633643USA	35 YR	Female	USA
Preferred Term											
Application site erythema											
Drug ineffective											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
15-Apr-2016	12270815	NON-EXPEDITED			S	Transdermal		US-TEVA-633691USA		Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Application site pain											
Application site swelling											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
15-Apr-2016	12270816	NON-EXPEDITED			S	Transdermal		US-TEVA-633083USA	54 YR	Male	USA
Preferred Term											
Incorrect drug administration duration											
Application site erythema											
Application site pain											
Application site pruritus											
Application site rash											
Rash erythematous											



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15-Apr-2016	12270817	NON-EXPEDITED			S	Transdermal	US-TEVA-633676USA	42 YR	Female	USA
Preferred Term										
Application site pruritus										
Application site hypersensitivity										
Application site rash										
Application site swelling										
Device battery issue										
Drug hypersensitivity										
<hr/>										
15-Apr-2016	12270818	NON-EXPEDITED			S	Transdermal	US-TEVA-633825USA	63 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site swelling										
<hr/>										
15-Apr-2016	12270819	NON-EXPEDITED			S	Transdermal	US-TEVA-633662USA	46 YR	Female	USA
Preferred Term										
Application site erythema										
Device leakage										
<hr/>										
15-Apr-2016	12270820	NON-EXPEDITED			S	Transdermal	US-TEVA-633644USA	22 YR	Female	USA
Preferred Term										
Application site erythema										
Device leakage										
Product adhesion issue										
Product packaging issue										



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15-Apr-2016	12270821	NON-EXPEDITED			S	Transdermal		US-TEVA-633610USA	40 YR	Female	USA
<u>Preferred Term</u>											<u>Manufacturer</u>
Application site bruise											TEVA
Device battery issue											
Drug ineffective											
Paraesthesia											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270822	NON-EXPEDITED			S	Transdermal		US-TEVA-633826USA	44 YR	Female	USA
<u>Preferred Term</u>											<u>Manufacturer</u>
Application site pain											TEVA
Laceration											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270823	NON-EXPEDITED			S	Transdermal		US-TEVA-633458USA	49 YR	Male	USA
<u>Preferred Term</u>											<u>Manufacturer</u>
Application site bruise											TEVA
Application site erythema											
Application site pain											
Drug ineffective											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270824	NON-EXPEDITED			S	Transdermal		US-TEVA-633656USA	54 YR	Female	USA
<u>Preferred Term</u>											<u>Manufacturer</u>
Migraine											TEVA
Application site erythema											
Application site pain											



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15-Apr-2016	12270825	NON-EXPEDITED			US-TEVA-633475USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Device adhesion issue Application site rash Device leakage	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270829	NON-EXPEDITED			US-TEVA-634183USA	38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Device battery issue Application site paraesthesia	ZECUITY	S	Transdermal	6.5 mg/ 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270831	NON-EXPEDITED			US-TEVA-634408USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270832	NON-EXPEDITED			US-TEVA-634833USA	20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site inflammation Application site pain Application site rash	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270833	NON-EXPEDITED			US-TEVA-634383USA	19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site pain	ZECUITY	S	Transdermal			TEVA		



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15-Apr-2016	12270834	NON-EXPEDITED			S	Transdermal	US-TEVA-633671USA	46 YR	Female	USA
<u>Preferred Term</u> Application site urticaria										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270835	NON-EXPEDITED			S	Transdermal	US-TEVA-633652USA	49 YR	Female	USA
<u>Preferred Term</u> Application site pain Application site erythema Application site pain Application site swelling Device leakage										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270836	NON-EXPEDITED			S	Transdermal	US-TEVA-633654USA		Female	USA
<u>Preferred Term</u> Hypersensitivity										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270838	NON-EXPEDITED			S	Transdermal	US-TEVA-633824USA	49 YR	Female	USA
<u>Preferred Term</u> Drug ineffective Application site erythema Application site pain Device adhesion issue Vomiting										



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15-Apr-2016	12270839	NON-EXPEDITED			S	Transdermal	US-TEVA-634788USA		Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea									TEVA	
Headache										
Incorrect drug administration duration										
Nasal septum deviation										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270840	NON-EXPEDITED			S	Transdermal	US-TEVA-635062USA	40 YR	Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain									TEVA	
Application site paraesthesia										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270841	NON-EXPEDITED			S	Transdermal	US-TEVA-634681USA	41 YR	Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site reaction									TEVA	
Muscular weakness										
Oropharyngeal pain										
Application site erythema										
Application site pruritus										
Application site swelling										
Device battery issue										
Dysphagia										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270842	NON-EXPEDITED			S	Transdermal	US-TEVA-635043USA	39 YR	Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema									TEVA	
Application site pain										



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15-Apr-2016	12270843	NON-EXPEDITED			US-TEVA-636464USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Device adhesion issue	ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA		
Device battery issue								
Device leakage								
Drug effect incomplete								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270844	NON-EXPEDITED			US-TEVA-635074USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECUITY	S	Transdermal			TEVA		
Application site pruritus								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270845	NON-EXPEDITED			US-TEVA-634456USA	23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270846	NON-EXPEDITED			US-TEVA-635738USA	42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270847	NON-EXPEDITED			US-TEVA-634947USA	40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Device leakage	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Application site pain								



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15-Apr-2016	12270848	NON-EXPEDITED			US-TEVA-635751USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site erythema	S Transdermal	6.5 mg / 4 hours		TEVA	
			Application site hypersensitivity					
			Device leakage					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270849	NON-EXPEDITED			US-TEVA-634345USA	24 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site pain	S Transdermal			TEVA	
			Application site erythema					
			Application site urticaria					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270850	NON-EXPEDITED			US-TEVA-635088USA	58 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site erythema	S Transdermal			TEVA	
			Application site dryness					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270851	NON-EXPEDITED			US-TEVA-635791USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site erythema	S Transdermal			TEVA	
			Application site dryness					



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15-Apr-2016	12270852	NON-EXPEDITED			US-TEVA-636087USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY	S Transdermal	6.5 mg/ 5 hours		TEVA	
Headache								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270853	NON-EXPEDITED			US-TEVA-634317USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site induration								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270854	NON-EXPEDITED			US-TEVA-635792USA	39 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site discoloration								
Application site vesicles								
Scab								
Wound drainage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270855	NON-EXPEDITED			US-TEVA-635788USA	49 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site rash								



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15-Apr-2016	12270856	NON-EXPEDITED			S	Transdermal	US-TEVA-634654USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY						TEVA	
			Adverse event							
			Application site erythema							
			Application site pruritus							
			Application site rash							
			Application site reaction							
			Device leakage							
			Hypersensitivity							
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270857	NON-EXPEDITED			S	Transdermal	US-TEVA-638317USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY						TEVA	
			Rash							
			Application site discolouration							
			Application site erythema							
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270858	NON-EXPEDITED			S	Transdermal	US-TEVA-638725USA	54 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY						TEVA	
			Application site erythema							
			Application site irritation							
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270859	NON-EXPEDITED			S	Transdermal	US-TEVA-638319USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY						TEVA	
			Rash							
			Application site discolouration							
			Application site erythema							



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15-Apr-2016	12270860	NON-EXPEDITED			US-TEVA-634949USA	55 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270861	NON-EXPEDITED			US-TEVA-634832USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash			ZECUITY	S Transdermal			TEVA	
Application site pain								
Application site urticaria								
Headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270862	NON-EXPEDITED			US-TEVA-636165USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash			ZECUITY	S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270864	NON-EXPEDITED			US-TEVA-634831USA	22 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12270865	NON-EXPEDITED			US-TEVA-635736USA	54 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	



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15-Apr-2016	12270868	NON-EXPEDITED			US-TEVA-638316USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash			ZECURITY	S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12271546	EXPEDITED (15-DAY)		OT	US-TEVA-651430USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECURITY	S Transdermal			TEVA	
Application site vesicles								
Drug effect incomplete								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12272138	EXPEDITED (15-DAY)		OT	US-TEVA-651106USA	43 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECURITY	S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site pain								
Application site scab								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12272244	EXPEDITED (15-DAY)		OT	US-TEVA-651438USA	56 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn			ZECURITY	S Transdermal			TEVA	
Application site pain								



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15-Apr-2016	12272248	EXPEDITED (15-DAY)		OT	US-TEVA-651456USA	37 YR	Female	USA
Preferred Term								
Sunburn				Role Route S Transdermal	Dosage Text	Duration	Manufacturer	TEVA
Application site erythema								
Application site pain								
Device battery issue								
Drug ineffective								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Apr-2016	12272682	EXPEDITED (15-DAY)		OT	US-TEVA-650660USA		Female	USA
Preferred Term								
Application site burn				Role Route S Transdermal	Dosage Text 6.5 mg over 4 hours	Duration	Manufacturer	TEVA
Application site erythema								
Chemical injury								
Drug effect incomplete								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Apr-2016	12273064	EXPEDITED (15-DAY)		OT	US-TEVA-651547USA	34 YR	Female	USA
Preferred Term								
Chemical burn of skin				Role Route S Transdermal	Dosage Text 6.5 mg over 4 hours	Duration	Manufacturer	TEVA
Application site burn								
Application site discoloration								
Application site discomfort								
Application site irritation								
Device battery issue								



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15-Apr-2016	12274684	EXPEDITED (15-DAY)		OT			US-TEVA-651783USA				Female	USA
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>			<u>Manufacturer</u>			
Sunburn					S	Transdermal			TEVA			
Application site pain												
Application site vesicles												
Intentional product use issue												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
18-Apr-2016	11909399	NON-EXPEDITED					US-TEVA-622613USA	66 YR	Male	USA		
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>			
Application site erythema					S	Transdermal			TEVA			
Application site paraesthesia												
Application site pruritus												
Application site urticaria												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
18-Apr-2016	11909418	NON-EXPEDITED					US-TEVA-623190USA	40 YR	Female	USA		
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>			
Application site bruise					S	Transdermal			TEVA			
Application site erythema												
Application site pruritus												
Application site urticaria												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
18-Apr-2016	11909499	NON-EXPEDITED					US-TEVA-618773USA	59 YR	Male	USA		
<u>Preferred Term</u>					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>			
Application site erythema					S	Transdermal	6.5 mg / 4 hours		TEVA			
Application site pain												
Application site paraesthesia												
Application site rash												



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18-Apr-2016	12215139	NON-EXPEDITED			S	Transdermal		US-TEVA-640286USA		Female	USA
Preferred Term											
Application site irritation											
Application site erythema											
Application site paraesthesia											
Drug effect incomplete											
<hr/>											
18-Apr-2016	12245038	NON-EXPEDITED						US-TEVA-624126USA	32 YR	Female	USA
Preferred Term											
Application site erythema											
Application site pain											
Application site erythema											
Skin discoloration											
<hr/>											
18-Apr-2016	12245050	NON-EXPEDITED						US-TEVA-625905USA		Female	USA
Preferred Term											
Application site rash											
<hr/>											
18-Apr-2016	12245051	NON-EXPEDITED						US-TEVA-625552USA		Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Application site rash											



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18-Apr-2016	12245068	NON-EXPEDITED			US-TEVA-625031USA	57 YR	Female	USA
Preferred Term								
Device battery issue				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain				S Transdermal	6.5 mg / 4 hours		TEVA	
Application site discoloration				S Transdermal	6.5 mg / 4 hours		TEVA	
Application site pruritus								
Device use error								
<hr/>								
18-Apr-2016	12245070	NON-EXPEDITED			US-TEVA-624132USA	58 YR	Female	USA
Preferred Term								
Application site urticaria				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema				S Transdermal			TEVA	
Application site rash								
Application site swelling								
Drug ineffective								
<hr/>								
18-Apr-2016	12245075	NON-EXPEDITED			US-TEVA-625900USA		Female	USA
Preferred Term								
Application site erythema				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain				S Transdermal			TEVA	
Device leakage								
Drug effect incomplete								
Product adhesion issue								



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18-Apr-2016	12245082	NON-EXPEDITED			S	Transdermal			TEVA			
Preferred Term												
Application site erythema												
Device battery issue												
Device leakage												
Device use error												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
18-Apr-2016	12245105	NON-EXPEDITED			S	Transdermal	US-TEVA-627561USA	48 YR	Female	USA		
Preferred Term												
Application site erythema												
Application site pain												
Application site rash												
Device leakage												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12245126	NON-EXPEDITED			S	Transdermal			TEVA			
Preferred Term												
Application site erythema												
Application site urticaria												
Application site rash												
Application site pain												
Drug ineffective												
Application site erosion												
Application site swelling												
Drug effect incomplete												



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18-Apr-2016	12247948	NON-EXPEDITED			US-TEVA-629453USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Dry skin			sumatriptan	C				
Skin discoloration			floricet	C				
			ibuprofen	C				
			nexplanon	C				
			PERCOCET	C				
			zofran	C				
			paroxetine	C				
			sucralfate	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12247960	NON-EXPEDITED			US-TEVA-627883USA	35 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Application site pain								
Device adhesion issue								
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12248029	NON-EXPEDITED			US-TEVA-631302USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site discoloration			ZECUITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12248037	NON-EXPEDITED			US-TEVA-631286USA	39 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash			ZECUITY	S Transdermal			TEVA	



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18-Apr-2016	12254565	EXPEDITED (15-DAY)		OT			US-TEVA-649760USA	44 YR	Female USA
Preferred Term									
Application site burn									
Application site pruritus									
Application site rash									
FDA Received Date									
Case #									
Case Type									
Health Professional									
Outcomes									
Role									
Route									
Dosage Text									
Duration									
Manufacturer									
18-Apr-2016	12277160	NON-EXPEDITED			S	Transdermal	US-TEVA-636153USA		Female USA
Preferred Term									
Application site erythema									
Application site pain									
Application site pruritus									
Application site scab									
Application site swelling									
Drug effect decreased									
FDA Received Date									
Case #									
Case Type									
Health Professional									
Outcomes									
Role									
Route									
Dosage Text									
Duration									
Manufacturer									
18-Apr-2016	12277166	NON-EXPEDITED			S	Transdermal	US-TEVA-631849USA	53 YR	Female USA
Preferred Term									
Application site erythema									
Application site irritation									
FDA Received Date									
Case #									
Case Type									
Health Professional									
Outcomes									
Role									
Route									
Dosage Text									
Duration									
Manufacturer									
18-Apr-2016	12277167	NON-EXPEDITED			S	Transdermal	US-TEVA-633039USA	47 YR	Female USA
Preferred Term									
Application site erythema									
Application site discoloration									
Application site scab									



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18-Apr-2016	12277169	NON-EXPEDITED			US-TEVA-631978USA	50 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site dryness			ZECURITY	S	Transdermal			TEVA
EDA Received Date								
18-Apr-2016	12277180	NON-EXPEDITED			US-TEVA-633686USA	45 YR	Female	USA
Preferred Term								
Drug ineffective			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA
Application site discoloration			ZECURITY	S				TEVA
Application site irritation								
Application site pruritus								
Application site rash								
EDA Received Date								
18-Apr-2016	12277181	NON-EXPEDITED			US-TEVA-633024USA	46 YR	Female	USA
Preferred Term								
Drug ineffective			Product	Role	Route	Dosage Text	Duration	Manufacturer
Product adhesion issue			ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Application site erythema			ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Application site pain								
Application site swelling								
Application site urticaria								
Device battery issue								
Device leakage								



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18-Apr-2016	12277192	NON-EXPEDITED			US-TEVA-633693USA	35 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site bruise								
Application site erythema								
Application site irritation								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277194	NON-EXPEDITED			US-TEVA-633816USA	35 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Drug ineffective								
Application site discolouration								
Application site erythema								
Application site hypersensitivity								
Application site laceration								
Application site swelling								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277196	NON-EXPEDITED			US-TEVA-636126USA	54 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site swelling								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277198	NON-EXPEDITED			US-TEVA-636145USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Drug effect incomplete								
Product adhesion issue								



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18-Apr-2016	12277201	NON-EXPEDITED			S	Transdermal	US-TEVA-631982USA		Female	USA
<u>Preferred Term</u>										
Application site rash										
Application site erythema										
Application site pain										
Incorrect drug administration duration										
18-Apr-2016	12277205	NON-EXPEDITED					US-TEVA-636151USA	49 YR	Female	USA
<u>Preferred Term</u>										
Application site erythema										
Application site swelling										
18-Apr-2016	12277206	NON-EXPEDITED			S	Transdermal	US-TEVA-636143USA	63 YR	Female	USA
<u>Preferred Term</u>										
Application site erythema										
Application site swelling										
Application site papules										
Application site pruritus										
SYNTHROID										
18-Apr-2016	12277207	NON-EXPEDITED					US-TEVA-636123USA	40 YR	Female	USA
<u>Preferred Term</u>										
Application site discoloration										
Application site erythema										
Application site pain										



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18-Apr-2016	12277212	NON-EXPEDITED			US-TEVA-633921USA	62 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device battery issue			ZECUITY	S Transdermal	6/5 mg over 4 hours		TEVA	
Abdominal discomfort								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277213	NON-EXPEDITED			US-TEVA-636003USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site vesicles			ZECUITY	S Transdermal			TEVA	
Application site bruise								
Application site erythema								
Application site pain								
Application site papules								
Device stimulation issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277215	NON-EXPEDITED			US-TEVA-638287USA	38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277216	NON-EXPEDITED			US-TEVA-638238USA	72 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site pruritus								
Application site urticaria								



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18-Apr-2016	12277218	NON-EXPEDITED			US-TEVA-638191USA	17 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect Incomplete			ZECUITY	S Transdermal			TEVA	
Application site urticaria								
Migraine								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277219	NON-EXPEDITED			US-TEVA-637746USA	51 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect delayed			ZECUITY	S Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277220	NON-EXPEDITED			US-TEVA-638174USA	30 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal	6.5 mg/ 4h		TEVA	
Application site pain								
Device battery issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277221	NON-EXPEDITED			US-TEVA-637726USA	61 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Palpitations			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Anxiety								
Feeling jittery								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277222	NON-EXPEDITED			US-TEVA-637792USA	37 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal	6.5mg/ 4 hours		TEVA	
Device battery issue								



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18-Apr-2016	12277223	NON-EXPEDITED			US-TEVA-637734USA		Female	USA
Preferred Term								
Application site bruise								
Application site dryness								
Application site dybness								
Device battery issue								
Device leakage								
Product adhesion issue								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277224	NON-EXPEDITED			US-TEVA-637731USA	34 YR	Female	USA
Preferred Term								
Application site pruritus								
Application site urticaria								
Drug effect incomplete								
Drug hypersensitivity								
Dry skin								
Incorrect drug administration duration								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277225	NON-EXPEDITED			US-TEVA-638173USA	47 YR	Female	USA
Preferred Term								
Application site erythema								
Application site irritation								
Application site pain								
Application site vesicles								



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18-Apr-2016	12277226	NON-EXPEDITED			S	Transdermal	US-TEVA-639895USA	44 YR	Male	USA
Preferred Term										
Application site discomfort										
Application site erythema										
Application site pruritus										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
Product										
ZECUITY										
Preferred Term										
Application site paraesthesia										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer Control #										
Age										
Sex										
Country										
Product										
ZECUITY										
Preferred Term										
Application site erythema										
Application site pruritus										
Application site swelling										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer Control #										
Age										
Sex										
Country										
Product										
ZECUITY										
Preferred Term										
Application site pain										
Application site erythema										
Application site paraesthesia										



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18-Apr-2016	12277230	NON-EXPEDITED			S	Transdermal	US-TEVA-638350USA		Female	USA
Preferred Term										
Application site erythema										
Application site irritation										
Application site pain										
Application site pruritus										
<hr/>										
18-Apr-2016	12277232	NON-EXPEDITED					US-TEVA-638294USA		Female	USA
Preferred Term										
Drug ineffective										
Application site irritation										
Application site pain										
Application site pruritus										
<hr/>										
18-Apr-2016	12277233	NON-EXPEDITED					US-TEVA-638848USA	44 YR	Female	USA
Preferred Term										
Application site paraesthesia										
Application site erythema										
<hr/>										
18-Apr-2016	12277235	NON-EXPEDITED					US-TEVA-638825USA	47 YR	Female	USA
Preferred Term										
Application site reaction										
Device battery issue										
Drug effect incomplete										
Product adhesion issue										
Skin tightness										



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18-Apr-2016	12277236	NON-EXPEDITED			US-TEVA-638305USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY	S Transdermal			TEVA	
Application site rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277237	NON-EXPEDITED			US-TEVA-638835USA	43 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY	S Transdermal	worn a total of 10 patches between Dec-2015 - Feb-2016		TEVA	
Application site discoloration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277238	NON-EXPEDITED			US-TEVA-638838USA	56 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Application site reaction								
Application site swelling								



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18-Apr-2016	12277240	NON-EXPEDITED			US-TEVA-639062USA	44 YR	Female	USA
<u>Preferred Term</u>								
Application site erythema			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site inflammation			ZECUITY	S	Transdermal	6.5 mg/ 4 hours		TEVA
Application site pruritus			ZECUITY	S	Transdermal	6.5 mg/ 4 hours		TEVA
Application site discoloration			BOTOX	C				
Application site pain								
Application site rash								
Application site reaction								
Application site swelling								
Application site vesicles								
Device battery issue								
Skin reaction								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277241	NON-EXPEDITED			US-TEVA-639905USA	44 YR	Female	USA
<u>Preferred Term</u>								
Application site erythema			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site inflammation			ZECUITY	S	Transdermal			TEVA
Device leakage			ZECUITY	S	Transdermal			TEVA
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277242	NON-EXPEDITED			US-TEVA-639901USA	54 YR	Female	USA
<u>Preferred Term</u>								
Drug ineffective			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
			ZECUITY	S	Transdermal			TEVA



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18-Apr-2016	12277243	NON-EXPEDITED			S	Transdermal	US-TEVA-639950USA	45 YR	Female	USA
Preferred Term										
Application site erythema										
Application site pain										
Application site paraesthesia										
FDA Received Date										
18-Apr-2016	12277245	NON-EXPEDITED					US-TEVA-639973USA	24 YR	Female	USA
Preferred Term										
Application site erythema										
Application site swelling										
FDA Received Date										
18-Apr-2016	12277246	NON-EXPEDITED					US-TEVA-639943USA	53 YR	Female	USA
Preferred Term										
Application site pain										
Application site discoloration										
Application site erythema										
Application site irritation										
Drug ineffective										
FDA Received Date										
18-Apr-2016	12277247	NON-EXPEDITED					US-TEVA-639915USA	60 YR	Female	USA
Preferred Term										
Application site discoloration										



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18-Apr-2016	12277249	NON-EXPEDITED			US-TEVA-639075USA	53 YR	Female	USA
Preferred Term								
Application site erythema								
Application site vesicles								
Device leakage								
Product adhesion issue								
Underdose								
<hr/>								
18-Apr-2016	12277250	NON-EXPEDITED			US-TEVA-639069USA	59 YR	Female	USA
Preferred Term								
Drug ineffective								
Application site pain								
Application site paraesthesia								
Application site erythema								
Application site swelling								
Device issue								
<hr/>								
18-Apr-2016	12277251	NON-EXPEDITED			US-TEVA-639082USA	54 YR	Female	USA
Preferred Term								
Drug ineffective								
Application site paraesthesia								
Headache								



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18-Apr-2016	12277252	NON-EXPEDITED			US-TEVA-639932USA	30 YR	Female	USA
Preferred Term								
Paraesthesia				<u>Role Route</u> S Transdermal	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u> TEVA	
Application site erythema								
Application site irritation								
Application site pain								
Application site papules								
Application site vesicles								
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
18-Apr-2016	12277255	NON-EXPEDITED			US-TEVA-639908USA	25 YR	Female	USA
Preferred Term								
Application site rash				<u>Role Route</u> S Transdermal	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u> TEVA	
Application site erythema								
Application site irritation								
Application site pain								
Application site swelling								
Diarrhoea								
Headache								
Vomiting								
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
18-Apr-2016	12277256	NON-EXPEDITED			US-TEVA-640172USA		Female	USA
Preferred Term								
Application site erythema				<u>Role Route</u> S Transdermal	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u> TEVA	



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18-Apr-2016	12277259	NON-EXPEDITED			S	Transdermal			US-TEVA-636502USA	23 YR	Female	USA
Preferred Term												
Application site erythema												
Application site exfoliation												
Application site swelling												
Application site urticaria												
<hr/>												
18-Apr-2016	12277260	NON-EXPEDITED							US-TEVA-640226USA		Female	USA
Preferred Term												
Application site pain												
Application site erythema												
<hr/>												
18-Apr-2016	12277261	NON-EXPEDITED							US-TEVA-639912USA	52 YR	Female	USA
Preferred Term												
Application site erythema												
Application site pain												
Application site pruritus												
<hr/>												
18-Apr-2016	12277264	NON-EXPEDITED							US-TEVA-639953USA	56 YR	Female	USA
Preferred Term												
Application site erythema												
Application site pain												
Migraine												



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18-Apr-2016	12277265	NON-EXPEDITED			S	Transdermal						
<u>Preferred Term</u>												
Skin reaction											TEVA	
Rash												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
18-Apr-2016	12277266	NON-EXPEDITED					US-TEVA-640121USA	63 YR	Female	USA		
<u>Preferred Term</u>												
Application site vesicles					S	Transdermal	6.5 mg / 4 hours				TEVA	
Device battery issue					S	Transdermal	6.5 mg / 4 hours				TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
18-Apr-2016	12277267	NON-EXPEDITED					US-TEVA-639974USA	45 YR	Female	USA		
<u>Preferred Term</u>												
Application site pruritus					S	Transdermal					TEVA	
Application site pain												
Application site swelling												
Application site warmth												
Insomnia												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
18-Apr-2016	12277268	NON-EXPEDITED					US-TEVA-639972USA	42 YR	Female	USA		
<u>Preferred Term</u>												
Application site paraesthesia					S	Transdermal					TEVA	
Drug ineffective												



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18-Apr-2016	12277269	NON-EXPEDITED			US-TEVA-636416USA	55 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
			Application site erythema					
			Application site pain					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277270	NON-EXPEDITED			US-TEVA-636374USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
			Application site rash					
			Application site erythema					
			Application site pruritus					
			Device leakage					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277271	NON-EXPEDITED			US-TEVA-636846USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
			Application site reaction					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277272	NON-EXPEDITED			US-TEVA-636658USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal	6.5mg/4 hour apply 1 patch at onset of migraine apply 2nd patch after 2 hrs as needed		TEVA	
			Dizziness					



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18-Apr-2016	12277273	NON-EXPEDITED			US-TEVA-640237USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Hypersensitivity	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277276	NON-EXPEDITED			US-TEVA-636156USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug effect incomplete Application site pain	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277277	NON-EXPEDITED			US-TEVA-636927USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277278	NON-EXPEDITED			US-TEVA-640189USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277279	NON-EXPEDITED			US-TEVA-640199USA	43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Dizziness Drug ineffective	ZECUITY	S	Transdermal			TEVA		



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18-Apr-2016	12277280	NON-EXPEDITED			S	Transdermal	US-TEVA-636507USA	53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Paraesthesia Application site pain Application site rash Underdose	ZECUITY								TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277281	NON-EXPEDITED			S	Transdermal	US-TEVA-636496USA	54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site bruise	ZECUITY								TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277282	NON-EXPEDITED		OT			US-TEVA-640170USA	52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Serotonin syndrome Emotional disorder	ZECUITY				S	Transdermal			TEVA	
					S	Unknown				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277284	NON-EXPEDITED					US-TEVA-636853USA	42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device battery issue Paraesthesia	ZECUITY				S	Transdermal	6.5 mg over 4 hours		TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277285	NON-EXPEDITED					US-TEVA-636512USA	30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema	ZECUITY				S	Transdermal			TEVA	



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18-Apr-2016	12277286	NON-EXPEDITED			US-TEVA-637304USA	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECURITY	S	Transdermal			TEVA	
Application site erosion								
Application site erythema								
Application site irritation								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Application site urticaria								
Device use error								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277287	NON-EXPEDITED			US-TEVA-640205USA	52 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dyspnoea		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site swelling								
Application site warmth								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277288	NON-EXPEDITED			US-TEVA-636845USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect incomplete		ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Device battery issue								



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18-Apr-2016	12277289	NON-EXPEDITED			US-TEVA-637317USA	34 YR	Female	USA
Preferred Term								
Application site discolouration				Role Route	Dosage Text	Duration		Manufacturer
Application site pain				S Transdermal				TEVA
Application site pruritus				S Transdermal				TEVA
Application site dybness				S Transdermal				TEVA
Application site erythema								
Application site exfoliation								
Application site vesicles								
Drug effect incomplete								
<hr/>								
18-Apr-2016	12277291	NON-EXPEDITED			US-TEVA-637709USA	48 YR	Female	USA
Preferred Term								
Application site discolouration				Role Route	Dosage Text	Duration		Manufacturer
Application site reaction				S Transdermal				TEVA
<hr/>								
18-Apr-2016	12277292	NON-EXPEDITED			US-TEVA-640221USA		Female	USA
Preferred Term								
Application site pain				Role Route	Dosage Text	Duration		Manufacturer
Application site erythema				S Transdermal				TEVA
Application site injury								
Application site pruritus								
Application site vesicles								
Product physical issue								



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<u>Preferred Term</u> Application site reaction Application site rash	12277293	NON-EXPEDITED			S	Transdermal	6.5 mg over 4 hours	US-TEVA-636849USA		Female	USA
<u>Preferred Term</u> Application site reaction Application site rash	12277295	NON-EXPEDITED			S	Transdermal	6.5 mg over 4 hours	US-TEVA-636515USA	60 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site rash	12277297	NON-EXPEDITED			S	Transdermal	6.5 mg over 4 hours	US-TEVA-636857USA		Female	USA
<u>Preferred Term</u> Drug effect incomplete	12277298	NON-EXPEDITED			S	Transdermal	6.5 mg over 4 hours	US-TEVA-637329USA		Male	USA
<u>Preferred Term</u> Application site rash Device battery issue	12277302	NON-EXPEDITED			S	Transdermal	6.5 mg every 4 hours	US-TEVA-640281USA		Female	USA
<u>Preferred Term</u> Application site erythema Application site rash Device leakage Product adhesion issue					S	Transdermal					



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18-Apr-2016	12277303	NON-EXPEDITED			S	Transdermal	US-TEVA-637376USA	57 YR	Female	USA
<u>Preferred Term</u> Application site pain										
<u>Product</u>	ZECUITY									TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277304	NON-EXPEDITED			S	Transdermal	US-TEVA-637422USA	30 YR	Female	USA
<u>Preferred Term</u> Migraine Dizziness Feeling abnormal Feeling cold Intentional device misuse Nausea Tremor Underdose										
<u>Product</u>	ZECUITY									TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277305	NON-EXPEDITED			S	Transdermal	US-TEVA-641360USA	38 YR	Female	USA
<u>Preferred Term</u> Device battery issue Drug ineffective Incorrect drug administration duration										
<u>Product</u>	ZECUITY									TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12277307	NON-EXPEDITED			S	Transdermal	US-TEVA-640275USA	44 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site paraesthesia Application site pruritus										
<u>Product</u>	ZECUITY									TEVA



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18-Apr-2016	12277319	NON-EXPEDITED			US-TEVA-637701USA	22 YR	Female	USA
Preferred Term								
Application site erythema								
Application site bruise								
Application site pain								
Device battery issue								
Device leakage								
<hr/>								
18-Apr-2016	12277320	NON-EXPEDITED			US-TEVA-640284USA		Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Application site pruritus								
Intentional product use issue								
Migraine								
<hr/>								
18-Apr-2016	12277321	NON-EXPEDITED			US-TEVA-637292USA		Female	USA
Preferred Term								
Application site bruise								
Incorrect drug administration duration								
<hr/>								
18-Apr-2016	12277325	NON-EXPEDITED			US-TEVA-637722USA		Female	USA
Preferred Term								
Drug ineffective								



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18-Apr-2016	12277874	EXPEDITED (15-DAY)		OT	US-TEVA-652198USA		Female	USA
Preferred Term								
Application site burn								
Application site irritation								
Application site swelling								
Drug ineffective								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Manufacturer Control #								
TEVA								
Age								
43 YR								
Sex								
Female								
Country								
USA								
Case #								
12278573								
Case Type								
EXPEDITED (15-DAY)								
Health Professional								
Outcomes								
OT								
Manufacturer Control #								
US-TEVA-651813USA								
Age								
43 YR								
Sex								
Female								
Country								
USA								
Preferred Term								
Sunburn								
Application site erythema								
Application site pain								
Application site rash								
Drug effect incomplete								
Headache								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Manufacturer Control #								
TEVA								
Age								
43 YR								
Sex								
Female								
Country								
USA								
Case #								
12280751								
Case Type								
DIRECT								
Health Professional								
Outcomes								
OT								
Manufacturer Control #								
US-TEVA-651813USA								
Age								
34 YR								
Sex								
Female								
Country								
USA								
Preferred Term								
Application site pain								
Product								
ZECURITY SUMATRIPTAN IONTOPHORET, 6.5 MG								
Role Route								
S Topical								
Dosage Text								
1 Patch(es) As Needed Applied to a surface, usually the skin								
Duration								
NUPATHE								
Manufacturer								
NUPATHE								
Manufacturer Control #								
NUPATHE								
Age								
34 YR								
Sex								
Female								
Country								
USA								
Case #								
12280751								
Case Type								
DIRECT								
Health Professional								
Outcomes								
OT								
Manufacturer Control #								
US-TEVA-651813USA								
Age								
34 YR								
Sex								
Female								
Country								
USA								



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18-Apr-2016	12280920	DIRECT				46 YR	Female	
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Product adhesion issue			ZECUITY NUPATH INC	S		As needed applied as medicated patch to skin		NUPATHE
Application site scar			OTHER MIGRAINE PRESCRIPTIONS	C				
			B2	C				
			COQ10	C				
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	11628256	NON-EXPEDITED			US-TEVA-596873USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Dizziness			ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA
Application site erythema								
Device leakage								
Drug effect incomplete								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	11909344	NON-EXPEDITED			US-TEVA-620947USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site urticaria			ZECUITY	S	Transdermal			TEVA
Application site erythema								
Application site pruritus								
Application site rash								
Application site vesicles								



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19-Apr-2016	11909369	NON-EXPEDITED			US-TEVA-622178USA	47 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burning sensation				S Transdermal			TEVA	
Application site erythema				S Transdermal			TEVA	
Drug ineffective				C				
Application site irritation				C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	11909395	NON-EXPEDITED			US-TEVA-623122USA	30 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Medication overuse headache				S Transdermal	6.5 mg over 4 hours		TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	11909404	NON-EXPEDITED			US-TEVA-623375USA	35 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site vesicles				S Transdermal	6.5 mg / 4 hours		TEVA	
Application site pain				C				
Application site pain				C	30 Milligram Daily; 30mg at hs			
Application site urticaria				C				
Device leakage				C	1.25/3mL neub			
Application site rash				C				
Application site erythema				C	12 Milligram Daily;			
Headache				C				
Insomnia				C	20 GBq Daily;			
				C	2400 Milligram Daily;			
				C	400 Milligram Daily;			
				C				



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Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
	MAG-OX	C	Oral	400 Milligram Daily;				
	mefenamic acid	C						
	SINGULAIR	C						
	BACTROBAN	C						
	ZEGERID	C	Oral	1 capsule by mouth before breakfast/40-1.1 mg-gram				
	NORFLEX	C	Oral	50 Milligram Daily;				
	PHENERGAN	C	Oral	150 Milligram Daily;				
	SEROQUEL	C	Oral	200 Milligram Daily;				
	SEROQUEL	C	Oral	film 8-2 mg				
	SEROQUEL	C		16 Milligram Daily;				
	ZANAFLEX	C	Oral	Patient taking 4 times a day				
	TIZANIDINE	C		150 MG Cp24				
	EFFEXOR-XR	C		150 Milligram Daily;				
	venlafaxine	C	Oral	TR24				
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	11909487	NON-EXPEDITED			US-TEVA-619336USA	32 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site urticaria	HYDROXYZINE	C						
Application site erythema	AMITRIPTYLINE	C						
	LAMOTRIGINE	C						
	PHENERGAN	C						



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19-Apr-2016	12245063	NON-EXPEDITED			US-TEVA-623916USA	54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Nausea	ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Blood pressure increased	MAXAL T	C						
Headache	NORTRIPTYLINE	C						
Drug ineffective	Relpax	C		30 Milligram Daily;				
	Adderall	C						
	Neurontin	C						
	Valium	C						
	Vitamin E	C						
	Promethazine	C		as directed (ud)				
	Hydrochlorothiazide	C		12.5 Milligram Daily;				
	Linzess	C		290 Microgram Daily;				
	Cymbalta	C		60 Milligram Daily;				
	Bystolic	C		2.5 Milligram Daily;				
	Synthroid	C		50 Microgram Daily;				



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19-Apr-2016	12247953	NON-EXPEDITED			US-TEVA-628429USA	43 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site swelling			ZECUITY	S	Transdermal			TEVA
Application site pruritus			ZECUITY	S	Transdermal			TEVA
Application site vesicles			ZECUITY	S	Transdermal			TEVA
Application site exfoliation								
Application site rash								
<hr/>								
19-Apr-2016	12248032	NON-EXPEDITED			US-TEVA-630506USA	42 YR	Female	USA
Preferred Term								
Application site pain			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal			TEVA
Application site pain								
Incorrect drug administration duration								
Underdose								
<hr/>								
19-Apr-2016	12276363	EXPEDITED (15-DAY)			US-TEVA-651774USA			
Preferred Term								
Application site burn			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal			TEVA
Device battery issue								
Product adhesion issue								



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19-Apr-2016	12277186	NON-EXPEDITED			S	Transdermal	US-TEVA-636104USA	31 YR	Female	USA
Preferred Term										
Application site discolouration										
Application site erythema										
Application site pruritus										
Device issue										
<hr/>										
19-Apr-2016	12277187	NON-EXPEDITED					US-TEVA-634828USA	66 YR	Female	USA
Preferred Term										
Application site laceration										
Drug ineffective										
<hr/>										
19-Apr-2016	12277244	NON-EXPEDITED					US-TEVA-639975USA	38 YR	Female	USA
Preferred Term										
Application site erythema										
Application site pain										
Application site swelling										
Incorrect drug administration duration										
<hr/>										
19-Apr-2016	12277254	NON-EXPEDITED					US-TEVA-639948USA	40 YR	Female	USA
Preferred Term										
Drug effect incomplete										
Migraine										



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19-Apr-2016	12277257	NON-EXPEDITED			US-TEVA-640197USA	60 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site pain								
Application site erythema								
Application site irritation								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Device leakage								
<u>FDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12277262	NON-EXPEDITED			US-TEVA-639952USA	52 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site pruritus								
Application site rash								
<u>FDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12277296	NON-EXPEDITED			US-TEVA-637371USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Drug ineffective								
<u>FDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12277299	NON-EXPEDITED			US-TEVA-637700USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site pain								
Application site erythema								
Application site discoloration								



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19-Apr-2016	12281570	NON-EXPEDITED			US-TEVA-631861USA	59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site dryness								
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281576	NON-EXPEDITED			US-TEVA-640559USA	26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281578	NON-EXPEDITED			US-TEVA-635741USA	26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site pruritus								
Application site reaction								
Application site swelling								
Application site warmth								
Skin texture abnormal								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281582	NON-EXPEDITED			US-TEVA-640603USA	45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECUITY	S	Transdermal			TEVA		



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19-Apr-2016	12281583	NON-EXPEDITED			US-TEVA-640824USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Adverse event			ZECUITY	S Transdermal			TEVA	
Application site reaction								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281586	NON-EXPEDITED			US-TEVA-640925USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site pruritus								
Application site rash								
Application site vesicles								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281587	NON-EXPEDITED			US-TEVA-64057USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site reaction			ZECUITY	S Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281588	NON-EXPEDITED			US-TEVA-640615USA	17 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site discolouration								
Application site swelling								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281590	NON-EXPEDITED			US-TEVA-640535USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Feeling abnormal			ZECUITY	S Transdermal			TEVA	



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19-Apr-2016	12281591	NON-EXPEDITED					US-TEVA-640924USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281593	NON-EXPEDITED					US-TEVA-640553USA	17 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Burning sensation			ZECUITY		S	Transdermal				TEVA
Urticaria										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281594	NON-EXPEDITED					US-TEVA-640919USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY		S	Transdermal				TEVA
Application site discoloration										
Application site dryness										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281595	NON-EXPEDITED					US-TEVA-641290USA	38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY		S	Transdermal				TEVA
Device battery issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281604	NON-EXPEDITED					US-TEVA-640937USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUITY		S	Transdermal				TEVA



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19-Apr-2016	12281605	NON-EXPEDITED			US-TEVA-641325USA	43 YR	Female	USA
Preferred Term								
Application site paraesthesia			Product	Role Route	Dosage Text	Duration	Manufacturer	
Device battery issue			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Product odour abnormal								
Product packaging issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281700	NON-EXPEDITED			US-TEVA-641366USA	39 YR	Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Incorrect drug administration duration			ZECUITY	S Transdermal			TEVA	
Multiple use of single-use product								
Product use issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281702	NON-EXPEDITED			US-TEVA-640626USA	34 YR	Male	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site irritation			ZECUITY	S Transdermal			TEVA	
Application site pruritus								
Application site rash								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281703	NON-EXPEDITED			US-TEVA-640935USA	46 YR	Female	USA
Preferred Term								
Drug ineffective			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	



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19-Apr-2016	12281704	NON-EXPEDITED			US-TEVA-641731USA	20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Migraine with aura Drug effect incomplete Tinidus	ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281705	NON-EXPEDITED			US-TEVA-640946USA	16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site exfoliation Application site erythema Application site pain Application site scab	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281706	NON-EXPEDITED			US-TEVA-641358USA	30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site irritation Application site erythema Application site urticaria	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281707	NON-EXPEDITED			US-TEVA-641773USA	46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECURITY	S	Transdermal			TEVA		



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19-Apr-2016	12281708	NON-EXPEDITED			US-TEVA-641763USA	45 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site pruritus			ZECURITY	S Transdermal			TEVA	
Application site rash								
<hr/>								
19-Apr-2016	12281709	NON-EXPEDITED			US-TEVA-641384USA	33 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Device battery issue			ZECURITY	S Transdermal	6.5 mg/4 hours		TEVA	
Device leakage								
<hr/>								
19-Apr-2016	12281710	NON-EXPEDITED			US-TEVA-640933USA		Female	USA
Preferred Term								
Application site pruritus			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site rash			ZECURITY	S Transdermal			TEVA	
<hr/>								
19-Apr-2016	12281711	NON-EXPEDITED			US-TEVA-641835USA		Female	USA
Preferred Term								
Application site pruritus			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Device leakage								
<hr/>								
19-Apr-2016	12281712	NON-EXPEDITED			US-TEVA-641807USA	38 YR	Female	USA
Preferred Term								
Drug ineffective			Product	Role Route	Dosage Text	Duration	Manufacturer	
			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	



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19-Apr-2016	12281714	NON-EXPEDITED			US-TEVA-641729USA	41 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site dryness								
Application site erythema								
Device difficult to use								
Device leakage								
Product adhesion issue								
<hr/>								
19-Apr-2016	12281715	NON-EXPEDITED			US-TEVA-640539USA		Female	USA
Preferred Term								
Drug effect incomplete								
Application site erythema								
Application site pain								
Device adhesion issue								
Device battery issue								
Device leakage								
Device use error								
<hr/>								
19-Apr-2016	12281724	NON-EXPEDITED			US-TEVA-642147USA	46 YR	Female	USA
Preferred Term								
Application site erythema								
Application site urticaria								
Application site pruritus								
Application site swelling								
Application site warmth								



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19-Apr-2016	12281730	NON-EXPEDITED			US-TEVA-641839USA	39 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site paraesthesia	S Transdermal	6.5 mg / 4 hours		TEVA	
			Device battery issue					
			Hypoaesthesia					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281732	NON-EXPEDITED			US-TEVA-641673USA	41 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site paraesthesia	S Transdermal			TEVA	
			Application site discomfort					
			Device battery issue					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281733	NON-EXPEDITED			US-TEVA-642401USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site erythema	S Transdermal			TEVA	
			Application site irritation					
			Application site urticaria					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281736	NON-EXPEDITED			US-TEVA-641767USA	27 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			Application site pain	S Transdermal			TEVA	
			Application site dryness					
			Application site erythema					
			Application site hypoaesthesia					
			Application site pruritus					
			Device leakage					
			Product adhesion issue					



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19-Apr-2016	12281737	NON-EXPEDITED			S	Transdermal	US-TEVA-643993USA	29 YR	Female	USA
<u>Preferred Term</u> Application site erythema										
<u>Product</u> ZECUITY										
<u>Migraine</u>										
19-Apr-2016	12281739	NON-EXPEDITED					US-TEVA-643985USA	41 YR	Female	USA
<u>Preferred Term</u> Musculoskeletal pain										
<u>Product</u> ZECUITY										
<u>Role</u> S										
<u>Route</u> Transdermal										
<u>Dosage Text</u>										
<u>Duration</u>										
<u>Manufacturer</u> TEVA										
<u>Incorrect drug administration duration</u>										
<u>Wrong technique in product usage process</u>										
19-Apr-2016	12281740	NON-EXPEDITED					US-TEVA-642072USA	58 YR	Female	USA
<u>FDA Received Date</u>										
<u>Case #</u>										
<u>Case Type</u>										
<u>Health Professional</u>										
<u>Outcomes</u>										
<u>Role</u>										
<u>Route</u>										
<u>Dosage Text</u>										
<u>Duration</u>										
<u>Manufacturer</u> TEVA										
<u>Preferred Term</u> Application site pain										
<u>Product</u> ZECUITY										
<u>Role</u> S										
<u>Route</u> Transdermal										
<u>Dosage Text</u>										
<u>Duration</u>										
<u>Manufacturer</u> TEVA										
<u>Application site bruise</u>										
<u>Application site erythema</u>										
<u>Application site pain</u>										
<u>Rash</u>										
<u>Urticaria</u>										
19-Apr-2016	12281741	NON-EXPEDITED					US-TEVA-640943USA	30 YR	Male	USA
<u>FDA Received Date</u>										
<u>Case #</u>										
<u>Case Type</u>										
<u>Health Professional</u>										
<u>Outcomes</u>										
<u>Role</u>										
<u>Route</u>										
<u>Dosage Text</u>										
<u>Duration</u>										
<u>Manufacturer</u> TEVA										
<u>Preferred Term</u> Application site vesicles										
<u>Product</u> ZECUITY										
<u>Role</u> S										
<u>Route</u> Transdermal										
<u>Dosage Text</u>										
<u>Duration</u>										
<u>Manufacturer</u> TEVA										



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19-Apr-2016	12281742	NON-EXPEDITED			S	Transdermal	US-TEVA-641843USA	38 YR	Female	USA
Preferred Term										
Application site pain										
Application site paraesthesia										
Device leakage										
Device use error										
<hr/>										
19-Apr-2016	12281745	NON-EXPEDITED			S	Transdermal	US-TEVA-641760USA	54 YR	Female	USA
Preferred Term										
Application site pain										
Incorrect drug administration duration										
<hr/>										
19-Apr-2016	12281746	NON-EXPEDITED			S	Transdermal	US-TEVA-643995USA	42 YR	Female	USA
Preferred Term										
Application site erythema										
Application site discoloration										
Application site pruritus										
Skin sensitisation										
<hr/>										
19-Apr-2016	12281747	NON-EXPEDITED			S	Transdermal	US-TEVA-642071USA	44 YR	Female	USA
Preferred Term										
Application site erythema										
Application site irritation										



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19-Apr-2016	12281748	NON-EXPEDITED			S	Transdermal	US-TEVA-644398USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Constipation			ZECUITY						TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281749	NON-EXPEDITED			S	Transdermal	US-TEVA-644003USA	52 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY						TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281750	NON-EXPEDITED			S	Transdermal	US-TEVA-641776USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECUITY				6.5 mg over 4 hours		TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281751	NON-EXPEDITED			S	Transdermal	US-TEVA-644006USA	50 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY						TEVA	
Application site exfoliation										
Device leakage										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281752	NON-EXPEDITED			S	Transdermal	US-TEVA-644367USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY						TEVA	
Application site discoloration										
Application site pruritus										
Application site rash										
Application site urticaria										



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19-Apr-2016	12281753	NON-EXPEDITED			S	Transdermal	US-TEVA-642144USA	61 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site pain										
Rash macular										
<hr/>										
19-Apr-2016	12281754	NON-EXPEDITED			S	Transdermal	US-TEVA-643216USA	43 YR	Female	USA
Preferred Term										
Application site pain										
ZECURITY										
<hr/>										
19-Apr-2016	12281755	NON-EXPEDITED			S	Transdermal	US-TEVA-641848USA	45 YR	Female	USA
Preferred Term										
Application site erythema										
Application site irritation										
Application site rash										
<hr/>										
19-Apr-2016	12281756	NON-EXPEDITED			S	Transdermal	US-TEVA-644098USA	40 YR	Female	USA
Preferred Term										
Application site pruritus										
Application site erythema										
Application site swelling										
Application site urticaria										



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19-Apr-2016	12281758	NON-EXPEDITED			US-TEVA-643983USA	42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal	6.5mg/4 hours		TEVA		
Application site dyyness	ZECUITY	S	Transdermal	6.5mg/4 hours		TEVA		
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281759	NON-EXPEDITED			US-TEVA-644000USA	63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281760	NON-EXPEDITED			US-TEVA-642088USA	31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECUITY	S				TEVA		
Application site erythema								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281761	NON-EXPEDITED			US-TEVA-644384USA	38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site discolouration								
Device use error								
Drug ineffective								
Migraine								



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19-Apr-2016	12281762	NON-EXPEDITED			US-TEVA-644001USA	57 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Application site pain Application site pruritus Application site warmth Device use error	ZECURITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281765	NON-EXPEDITED			US-TEVA-642903USA	48 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Rash	ZECURITY	S				TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281767	NON-EXPEDITED			US-TEVA-644359USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Application site discoloration Application site urticaria	ZECURITY	S	Transdermal	has used 8 patches/ dates unknown		TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281768	NON-EXPEDITED			US-TEVA-643181USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective	ZECURITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281770	NON-EXPEDITED			US-TEVA-644005USA	61 YR	Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECURITY	S	Transdermal			TEVA		



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19-Apr-2016	12281771	NON-EXPEDITED			US-TEVA-643601USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Application site erythema Application site pain Device battery issue	ZECURITY	S	Transdermal			TEVA		
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281773	NON-EXPEDITED			US-TEVA-644385USA	49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Device battery issue Device leakage Product adhesion issue	ZECURITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281774	NON-EXPEDITED			US-TEVA-643122USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281775	NON-EXPEDITED			US-TEVA-643636USA	17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Feeling abnormal Hangover	ZECURITY	S	Transdermal			TEVA		



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19-Apr-2016	12281778	NON-EXPEDITED			US-TEVA-642429USA		Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site rash	ZECURITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281779	NON-EXPEDITED			US-TEVA-643120USA	34 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Dermatitis atopic Hypersensitivity	ZECURITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281780	NON-EXPEDITED			US-TEVA-643587USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pruritus	ZECURITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281783	NON-EXPEDITED			US-TEVA-643263USA	41 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Paraesthesia Application site erythema Application site pain Application site warmth Device leakage	ZECURITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Apr-2016	12281784	NON-EXPEDITED			US-TEVA-642446USA	34 YR	Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Application site pruritus	ZECURITY	S	Transdermal			TEVA		



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19-Apr-2016	12281785	NON-EXPEDITED			US-TEVA-644383USA	49 YR	Female	USA
Preferred Term								
Application site reaction								
Application site discoloration								
Application site dryness								
Application site erythema								
Skin wrinkling								
<hr/>								
19-Apr-2016	12281789	NON-EXPEDITED			US-TEVA-643228USA	38 YR	Female	USA
Preferred Term								
Application site erythema								
Application site paraesthesia								
Device battery issue								
Device use error								
Incorrect drug administration duration								
<hr/>								
19-Apr-2016	12281790	NON-EXPEDITED			US-TEVA-643915USA	35 YR	Female	USA
Preferred Term								
Application site vesicles								
Application site irritation								



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19-Apr-2016	12281791	NON-EXPEDITED			US-TEVA-642456USA	46 YR	Female	USA
Preferred Term								
Application site erythema								
Application site discoloration								
Application site pruritus								
Application site vesicles								
Dermatitis contact								
Device battery issue								
Drug effect incomplete								
<hr/>								
19-Apr-2016	12281793	NON-EXPEDITED			US-TEVA-644021USA	52 YR	Female	USA
Preferred Term								
Application site erythema								
Application site pain								
Complication of device removal								
Paraesthesia								
<hr/>								
19-Apr-2016	12281794	NON-EXPEDITED			US-TEVA-643224USA	48 YR	Female	USA
Preferred Term								
Application site pain								
Application site erythema								
<hr/>								
19-Apr-2016	12281795	NON-EXPEDITED			US-TEVA-642793USA		Female	USA
Preferred Term								
Application site erythema								
Application site rash								



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19-Apr-2016	12281796	NON-EXPEDITED			US-TEVA-642871USA	49 YR	Female	USA
Preferred Term								
Application site erythema								
Application site dryness								
Application site irritation								
Device leakage								
Product adhesion issue								
<hr/>								
19-Apr-2016	12281798	NON-EXPEDITED			US-TEVA-642781USA	41 YR	Female	USA
Preferred Term								
Application site erythema								
Application site swelling								
Device leakage								
Product adhesion issue								
<hr/>								
19-Apr-2016	12281802	NON-EXPEDITED			US-TEVA-644820USA		Female	USA
Preferred Term								
Drug effect incomplete								
Device leakage								
Product adhesion issue								



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19-Apr-2016	12281803	NON-EXPEDITED			US-TEVA-643227USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect incomplete			ZECURITY	S Transdermal			TEVA	
Device battery issue								
Device issue								
Device leakage								
Headache								
Medication residue present								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281805	NON-EXPEDITED			US-TEVA-643221USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site vesicles			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site pruritus								
Application site warmth								
Dermatitis contact								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281806	NON-EXPEDITED			US-TEVA-643237USA	53 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site oedema								
Application site pain								



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19-Apr-2016	12281807	NON-EXPEDITED			S	Transdermal	US-TEVA-643610USA		Female	USA
Preferred Term										
Application site erythema										
Device battery issue										
Device leakage										
19-Apr-2016	12281808	NON-EXPEDITED					US-TEVA-643123USA		Male	USA
Preferred Term										
Application site pain										
Device battery issue										
Product adhesion issue										
19-Apr-2016	12281809	NON-EXPEDITED					US-TEVA-643589USA	39 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
19-Apr-2016	12281810	NON-EXPEDITED					US-TEVA-643233USA	62 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Nausea										



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19-Apr-2016	12281816	NON-EXPEDITED			US-TEVA-643266USA	47 YR	Female	USA
Preferred Term								
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site pain								
Application site pruritus								
Device battery issue								
<hr/>								
19-Apr-2016	12281817	NON-EXPEDITED			US-TEVA-643379USA	61 YR	Female	USA
Preferred Term								
Application site erythema								
Application site dryness								
Dermatitis contact								
Dry skin								
Skin exfoliation								
Skin tightness								
<hr/>								
19-Apr-2016	12281818	NON-EXPEDITED			US-TEVA-643917USA	43 YR	Female	USA
Preferred Term								
Application site erythema								
Application site pruritus								
Device battery issue								



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19-Apr-2016	12281819	NON-EXPEDITED			US-TEVA-64243USA	50 YR	Female	USA
Preferred Term								
Application site pain								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site pruritus								
Application site rash								
Application site warmth								
Device leakage								
Device use error								
Drug effect incomplete								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281820	NON-EXPEDITED			US-TEVA-64243USA	52 YR	Female	USA
Preferred Term								
Application site erythema								
Application site pain								
Product								
ZECURITY								
ZECURITY								
ZECURITY								
Role Route								
S Transdermal								
S Transdermal								
S Transdermal								
Outcomes								
S								
Dosage Text								
TEVA								
TEVA								
TEVA								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281823	NON-EXPEDITED			US-TEVA-642778USA		Female	USA
Preferred Term								
Nausea								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Manufacturer								
TEVA								



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19-Apr-2016	12281824	NON-EXPEDITED			US-TEVA-642792USA	34 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Pruritus				S Transdermal	6.5 mg/4 hours			TEVA
Application site erythema								
Application site urticaria								
Device adhesion issue								
Device leakage								
Urticaria								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281825	NON-EXPEDITED			US-TEVA-642433USA	37 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Application site irritation				S Transdermal				TEVA
Device battery issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281827	NON-EXPEDITED			US-TEVA-642431USA	45 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Application site erythema				S Transdermal	6.5 mg / 4 hours			TEVA
Device battery issue				S Transdermal	6.5 mg / 4 hours			TEVA
Application site urticaria				S Transdermal	6.5 mg / 4 hours			TEVA
Application site exfoliation								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281828	NON-EXPEDITED			US-TEVA-643953USA	34 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Application site vesicles				S Transdermal				TEVA
Application site erythema								
Application site pruritus								
Application site urticaria								



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19-Apr-2016	12281829	NON-EXPEDITED			US-TEVA-642575USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281830	NON-EXPEDITED			US-TEVA-642869USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281831	NON-EXPEDITED			US-TEVA-642789USA	35 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal	6.5mg/4 hours		TEVA	
Application site dryness								
Application site pruritus								
Device leakage								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281834	NON-EXPEDITED			US-TEVA-642785USA	21 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash			ZECUITY	S Transdermal	6.5mg/4 hours		TEVA	
Application site erythema								
Application site pruritus								
Application site urticaria								
Device leakage								
Drug effect Incomplete								



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20-Apr-2016	11909438	NON-EXPEDITED			US-TEVA-611986USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Migraine			ZECURITY	S Transdermal			TEVA	
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12247982	NON-EXPEDITED			US-TEVA-630493USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash			ZECURITY	S Transdermal			TEVA	
Application site pain								
Application site vesicles								
Dry skin								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12247988	NON-EXPEDITED			US-TEVA-630494USA	37 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12248019	NON-EXPEDITED			US-TEVA-631294USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY	S Transdermal			TEVA	
Application site discomfort								



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20-Apr-2016	12248030	NON-EXPEDITED			US-TEVA-630652USA	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECURITY		S Transdermal	6.5 mg / 4 hours		TEVA	
Application site pain								
Device battery issue								
Device use error								
Skin reaction								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12248031	NON-EXPEDITED			US-TEVA-631226USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECURITY		S Transdermal	6.5 mg over 4 hours		TEVA	
Device battery issue								



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20-Apr-2016	12277170	NON-EXPEDITED			US-TEVA-632768USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site paraesthesia			ZECUITY	S Transdermal			TEVA	
Device leakage			AMANTADINE	C				
Device adhesion issue			AMITIZA	C				
Migraine			APLENSIN	C				
Malaise			ATIVAN	C				
Device use error			CAMBIA	C				
Product adhesion issue			FLONASE	C				
Application site pruritus			GEDON	C				
Application site pain			LITHIUM	C				
Application site urticaria			LYRICA	C				
Application site exfoliation			MS CONTIN	C				
			NEXIUM	C				
			SINGULAIR	C				
			PERCOCET	C				
			VYVANSE	C				
			ZOLOFT	C				
			ZYRTEC	C				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12277199	NON-EXPEDITED			US-TEVA-636140USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug hypersensitivity			ZECUITY	S Transdermal			TEVA	
Application site dryness								
Application site pruritus								
Application site rash								



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20-Apr-2016	12277214	NON-EXPEDITED			US-TEVA-636148USA	50 YR	Female	USA
<u>Preferred Term</u>								
Hypersensitivity				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Drug effect incomplete				S Transdermal				TEVA
Device battery issue								
Application site urticaria								
Application site erythema								
Application site rash								
Application site pruritus								
Application site discoloration								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12277234	NON-EXPEDITED			US-TEVA-638250USA	44 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug effect incomplete				S Transdermal				TEVA
Chest pain								
Contraindicated drug administered								
Device battery issue								
Migraine								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12277253	NON-EXPEDITED			US-TEVA-639893USA	26 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site rash				S Transdermal				TEVA
Application site discoloration								
Application site warmth								
Skin texture abnormal								



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20-Apr-2016	12277274	NON-EXPEDITED			US-TEVA-636922USA	20 YR	Female	USA
Preferred Term								
Application site erythema				<u>Role</u>	<u>Route</u>			<u>Manufacturer</u>
Application site discoloration				S	Transdermal			TEVA
Application site pruritus				S	Transdermal			TEVA
Application site rash								
Application site swelling								
Application site warmth								
Device battery issue								
<hr/>								
20-Apr-2016	12277294	NON-EXPEDITED			US-TEVA-637402USA	24 YR	Female	USA
Preferred Term								
Application site erythema				<u>Role</u>	<u>Route</u>			<u>Manufacturer</u>
Application site discoloration				S	Transdermal			TEVA
Application site dryness				S	Transdermal			TEVA
Application site exfoliation								
<hr/>								
20-Apr-2016	12277306	NON-EXPEDITED			US-TEVA-637719USA		Male	USA
Preferred Term								
Drug ineffective				<u>Role</u>	<u>Route</u>			<u>Manufacturer</u>
				S	Transdermal			TEVA



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20-Apr-2016	12279885	NON-EXPEDITED			S	Transdermal	US-TEVA-644388USA	35 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site pruritus										
Application site rash										
Device leakage										
<hr/>										
20-Apr-2016	12281579	NON-EXPEDITED			S	Transdermal	US-TEVA-631859USA		Female	USA
Preferred Term										
Drug effect incomplete										
<hr/>										
20-Apr-2016	12281766	NON-EXPEDITED			S	Transdermal	US-TEVA-643266USA	34 YR	Female	USA
Preferred Term										
Drug ineffective										
Application site erythema										
Application site pain										
Application site pruritus										
Application site swelling										
Application site warmth										
Dermatitis contact										



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20-Apr-2016	12281804	NON-EXPEDITED			US-TEVA-643631USA	48 YR	Female	USA
Preferred Term								
Application site erythema				Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration				S Transdermal	6.5 mg / 4 hours		TEVA	
Application site pruritus								
Application site swelling								
Device battery issue								
<hr/>								
20-Apr-2016	12284651	NON-EXPEDITED			US-TEVA-634025USA	30 YR	Female	USA
Preferred Term								
Application site pain				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema				S Transdermal			TEVA	
Application site rash				S Transdermal			TEVA	
				C	20 Milligram Daily,			
<hr/>								
20-Apr-2016	12284652	NON-EXPEDITED			US-TEVA-633658USA	31 YR	Female	USA
Preferred Term								
Application site pain				Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration				S Transdermal			TEVA	
Application site erythema								
Application site paraesthesia								
Application site reaction								
Product adhesion issue								
Skin reaction								



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20-Apr-2016	12284653	NON-EXPEDITED			S	Transdermal		US-TEVA-634019USA		Female	USA
Preferred Term											
Headache											
Product											
ZECUITY											
Manufacturer											
TEVA											
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284654	NON-EXPEDITED			S	Transdermal		US-TEVA-634843USA	35 YR	Female	USA
Preferred Term											
Application site bruise											
Product											
ZECUITY											
Manufacturer											
TEVA											
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284656	NON-EXPEDITED			S	Transdermal		US-TEVA-633876USA	55 YR	Female	USA
Preferred Term											
Drug effect incomplete											
Device battery issue											
Product											
ZECUITY											
Manufacturer											
TEVA											
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284657	NON-EXPEDITED			S	Transdermal		US-TEVA-634268USA		Female	USA
Preferred Term											
Drug ineffective											
Application site urticaria											
Application site discoloration											
Product											
ZECUITY											
Manufacturer											
TEVA											
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284658	NON-EXPEDITED			S	Transdermal		US-TEVA-633818USA	37 YR	Female	USA
Preferred Term											
Application site erythema											
Application site discoloration											
Application site pruritus											
Application site swelling											



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20-Apr-2016	12284659	NON-EXPEDITED			US-TEVA-635756USA	42 YR	Female	USA
Preferred Term								
Application site discolouration			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pruritus			ZECUITY	S	Transdermal			TEVA
Application site rash								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Apr-2016	12284660	NON-EXPEDITED			US-TEVA-632150USA	76 YR	Female	USA
Preferred Term								
Device battery issue			Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective			ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Product packaging issue								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Apr-2016	12284661	NON-EXPEDITED			US-TEVA-635082USA	36 YR	Female	USA
Preferred Term								
Application site bruise			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pruritus			ZECUITY	S	Transdermal			TEVA
Application site bruise			ZECUITY	S	Transdermal			TEVA
Application site discoloration								
Application site pruritus								
Application site rash								



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20-Apr-2016	12284662	NON-EXPEDITED			US-TEVA-633670USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Headache			ZECUITY	S Transdermal			TEVA	
Drug effect incomplete			WELLBUTRIN SR	C				
			AMITRIPTYLINE	C				
			NADOLOL	C				
			PROMETHAZINE	C				
			NARATRIP TAN	C				
			KETOROLAC	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284663	NON-EXPEDITED			US-TEVA-635752USA	51 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site pruritus								
Drug ineffective								
Rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284664	NON-EXPEDITED			US-TEVA-634424USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284665	NON-EXPEDITED			US-TEVA-641393USA	51 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site dryness			ZECUITY	S Transdermal			TEVA	
Device battery issue								



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20-Apr-2016	12284671	NON-EXPEDITED			US-TEVA-647171USA	58 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site erythema								
Device battery issue								
Device use error								
Drug effect incomplete								
<hr/>								
20-Apr-2016	12284675	NON-EXPEDITED			US-TEVA-647173USA	44 YR	Female	USA
Preferred Term								
Application site erythema								
Application site pain								
Application site pruritus								
<hr/>								
20-Apr-2016	12284677	NON-EXPEDITED			US-TEVA-647184USA	45 YR	Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Application site swelling								
<hr/>								
20-Apr-2016	12284678	NON-EXPEDITED			US-TEVA-647167USA		Female	USA
Preferred Term								
Application site oedema								
Application site erythema								
Incorrect drug administration duration								



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20-Apr-2016	12284680	NON-EXPEDITED			S	Transdermal	US-TEVA-647183USA	57 YR	Male	USA
Preferred Term Drug ineffective										
<u>Product</u>	ZECUITY									TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284683	NON-EXPEDITED			S	Transdermal	US-TEVA-645560USA	25 YR	Female	USA
Preferred Term Application site pain Device leakage Drug effect incomplete										
<u>Product</u>	ZECUITY									TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284684	NON-EXPEDITED			S	Transdermal	US-TEVA-646263USA		Female	USA
Preferred Term Neck pain										
<u>Product</u>	ZECUITY									TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284688	NON-EXPEDITED			S	Transdermal	US-TEVA-647182USA		Female	USA
Preferred Term Application site discoloration Application site pain										
<u>Product</u>	ZECUITY									TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284689	NON-EXPEDITED			S	Transdermal	US-TEVA-646001USA		Female	USA
Preferred Term Application site erythema										
<u>Product</u>	ZECUITY									TEVA



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20-Apr-2016	12284690	NON-EXPEDITED			S	Transdermal	US-TEVA-645571USA		Female	USA
<u>Preferred Term</u> Application site paraesthesia										
<u>Product</u>	ZECURITY									TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284691	NON-EXPEDITED			S	Transdermal	US-TEVA-646298USA	58 YR	Female	USA
<u>Preferred Term</u> Application site paraesthesia Device issue										
<u>Product</u>	ZECURITY									TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284692	NON-EXPEDITED			S	Transdermal	US-TEVA-645562USA	43 YR	Female	USA
<u>Preferred Term</u> Drug ineffective										
<u>Product</u>	ZECURITY									TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284693	NON-EXPEDITED			S	Transdermal	US-TEVA-646264USA	30 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site exfoliation Application site pain Application site paraesthesia Application site pruritus Incorrect drug administration duration Wrong technique in product usage process										
<u>Product</u>	ZECURITY									TEVA



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20-Apr-2016	12284694	NON-EXPEDITED			S	Transdermal	US-TEVA-646337USA		Female	USA
Preferred Term										
Hypersensitivity										
Application site erythema										
Application site pruritus										
Application site rash										
Application site reaction										
<hr/>										
20-Apr-2016	12284696	NON-EXPEDITED			S	Transdermal	US-TEVA-645845USA		Female	USA
Preferred Term										
Application site erythema										
Device battery issue										
Device issue										
<hr/>										
20-Apr-2016	12284697	NON-EXPEDITED			S	Transdermal	US-TEVA-646308USA	17 YR	Female	USA
Preferred Term										
Application site pain										
Application site discoloration										
Application site erythema										
<hr/>										
20-Apr-2016	12284699	NON-EXPEDITED			S	Transdermal	US-TEVA-645599USA	32 YR	Female	USA
Preferred Term										
Application site bruise										
Application site discoloration										



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20-Apr-2016	12284701	NON-EXPEDITED			S	Transdermal	US-TEVA-647165USA		Female	USA
Preferred Term										
Drug effect Incomplete										
ZECURITY										
Application site pain										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Manufacturer Control #										
Age										
Sex										
Country										
20-Apr-2016	12284702	NON-EXPEDITED			S	Transdermal	US-TEVA-645838USA	59 YR	Female	USA
Preferred Term										
Application site pain										
ZECURITY										
Application site erythema										
Incorrect drug administration duration										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Manufacturer Control #										
Age										
Sex										
Country										
20-Apr-2016	12284703	NON-EXPEDITED			S		US-TEVA-645717USA	32 YR	Female	USA
Preferred Term										
Application site erythema										
ZECURITY										
Application site pain										
ZECURITY										
Application site pain										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Manufacturer Control #										
Age										
Sex										
Country										
20-Apr-2016	12284704	NON-EXPEDITED			S	Transdermal	US-TEVA-646936USA	23 YR	Female	USA
Preferred Term										
Drug effect Incomplete										
ZECURITY										
Device leakage										
Product adhesion issue										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Manufacturer Control #										
Age										
Sex										
Country										
20-Apr-2016	12284705	NON-EXPEDITED			S	Transdermal	US-TEVA-644645USA		Female	USA
Preferred Term										
Application site pain										
ZECURITY										



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20-Apr-2016	12284707	NON-EXPEDITED			US-TEVA-646256USA	44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Application site dryness Application site erythema Application site exfoliation Application site pain	ZECURITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284708	NON-EXPEDITED			US-TEVA-646874USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site dermatitis	ZECURITY	S				TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284710	NON-EXPEDITED			US-TEVA-646689USA	16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284712	NON-EXPEDITED			US-TEVA-646250USA	42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pruritus Application site erythema	ZECURITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284713	NON-EXPEDITED			US-TEVA-645030USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site pruritus	ZECURITY	S	Transdermal			TEVA		



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20-Apr-2016	12284714	NON-EXPEDITED			S	Transdermal	US-TEVA-646719USA	32 YR	Female	USA		
Preferred Term Application site urticaria												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284715	NON-EXPEDITED			S	Transdermal	US-TEVA-646732USA	57 YR	Female	USA		
Preferred Term Application site erythema Application site oedema Application site pain												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284716	NON-EXPEDITED			S	Transdermal	6.5 mg/4 hr patch		TEVA	53 YR	Female	USA
Preferred Term Application site oedema Application site erythema Application site rash Application site urticaria												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284717	NON-EXPEDITED			S	Transdermal	US-TEVA-646506USA	39 YR	Female	USA		
Preferred Term Application site pain Application site erythema												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
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20-Apr-2016	12284722	NON-EXPEDITED			S	Transdermal	US-TEVA-645040USA	35 YR	Female	USA
Preferred Term										
Application site rash										
Application site pruritus										
Incorrect drug administration duration										
20-Apr-2016	12284723	NON-EXPEDITED			S	Transdermal	US-TEVA-646739USA		Female	USA
Preferred Term										
Application site discolouration										
Application site swelling										
20-Apr-2016	12284724	NON-EXPEDITED			S	Transdermal	US-TEVA-645536USA	47 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
20-Apr-2016	12284725	NON-EXPEDITED			S	Transdermal	US-TEVA-644811USA	30 YR	Female	USA
Preferred Term										
Application site erythema										
Application site irritation										
Device leakage										
Product adhesion issue										



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20-Apr-2016	12284726	NON-EXPEDITED			S	Transdermal	US-TEVA-645071USA	63 YR	Female	USA
Preferred Term										
Drug ineffective										
ZECURITY										
Migraine										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284727	NON-EXPEDITED			S	Transdermal	US-TEVA-644599USA		Female	USA
Preferred Term										
Application site erythema										
ZECURITY										
Application site pain										
Device malfunction										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284728	NON-EXPEDITED			S	Transdermal	US-TEVA-644779USA		Female	USA
Preferred Term										
Drug effect incomplete										
ZECURITY										
Application site discoloration										
Application site erythema										
Application site pain										
Application site swelling										
Device battery issue										
Device leakage										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284729	NON-EXPEDITED			S	Transdermal	US-TEVA-644810USA	42 YR	Female	USA
Preferred Term										
Drug effect incomplete										
ZECURITY										
Device battery issue										
Product adhesion issue										



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20-Apr-2016	12284730	NON-EXPEDITED			S	Transdermal				
Preferred Term Application site pain Application site erythema Device use error Dizziness										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284731	NON-EXPEDITED			S	Transdermal	US-TEVA-644789USA	62 YR	Female	USA
Preferred Term Drug ineffective Feeling abnormal Headache Nausea										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284732	NON-EXPEDITED			S	Transdermal	US-TEVA-644763USA	45 YR	Female	USA
Preferred Term Application site erythema										
					S	Transdermal				
					S	Transdermal				
					S	Transdermal				



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20-Apr-2016	12284733	NON-EXPEDITED			US-TEVA-645557USA	47 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site rash								
Application site swelling								
Device leakage								
Product adhesion issue								
Skin reaction								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284735	NON-EXPEDITED			US-TEVA-645037USA	64 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284736	NON-EXPEDITED			US-TEVA-645045USA	35 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Migraine								
Application site erythema								
Application site pain								
Device battery issue								
Drug ineffective								



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20-Apr-2016	12284737	NON-EXPEDITED			S	Transdermal	US-TEVA-647168USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY						TEVA	
Device battery issue										
Device issue										
Device use error										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284742	NON-EXPEDITED			S	Transdermal	US-TEVA-645595USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY						TEVA	
Application site pain										
Device battery issue										
Device issue										
Device use error										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284743	NON-EXPEDITED			S	Transdermal	US-TEVA-645659USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY						TEVA	
Drug ineffective										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284744	NON-EXPEDITED			S	Transdermal	US-TEVA-645653USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY						TEVA	
Drug effect incomplete										



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20-Apr-2016	12284745	NON-EXPEDITED			S	Transdermal	US-TEVA-645840USA	40 YR	Male	USA
Preferred Term										
Drug ineffective										
Device battery issue										
Device leakage										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
20-Apr-2016	12284746	NON-EXPEDITED			S	Transdermal	US-TEVA-645909USA		Female	USA
Preferred Term										
Device battery issue										
Application site erythema										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
20-Apr-2016	12284747	NON-EXPEDITED			S	Transdermal	US-TEVA-646722USA	71 YR	Female	USA
Preferred Term										
Application site rash										
Application site erythema										
Application site pruritus										
Application site vesicles										
Application site warmth										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
20-Apr-2016	12284749	NON-EXPEDITED			S	Transdermal	US-TEVA-645018USA		Female	USA
Preferred Term										
Application site erythema										
Application site discoloration										
Application site pain										
Application site paraesthesia										
Drug effect incomplete										
Herpes zoster										



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20-Apr-2016	12284750	NON-EXPEDITED			US-TEVA-644808USA	44 YR	Female	USA
Preferred Term								
Anxiety								
Product ZECURITY								
Role Route S Transdermal								
Application site paraesthesia								
<hr/>								
20-Apr-2016	12284751	NON-EXPEDITED			US-TEVA-645218USA		Female	USA
Preferred Term								
Migraine								
Product ZECURITY								
Role Route S Transdermal								
Dosage Text 6.5 mg over 4 hours								
Manufacturer TEVA								
<hr/>								
20-Apr-2016	12284812	NON-EXPEDITED			US-TEVA-647825USA	39 YR	Female	USA
Preferred Term								
Application site erythema								
Product ZECURITY								
Role Route S Transdermal								
Application site pain								
Drug effect incomplete								
Pain								
<hr/>								
20-Apr-2016	12284818	NON-EXPEDITED			US-TEVA-647436USA	31 YR	Male	USA
Preferred Term								
Application site erythema								
Product ZECURITY								
Role Route S								
Application site irritation								
Manufacturer TEVA								



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20-Apr-2016	12284823	NON-EXPEDITED			S	Transdermal		US-TEVA-648172USA	53 YR	Female	USA
Preferred Term											
Application site rash											
Application site pain											
Application site pruritus											
Wrong technique in product usage process											
<hr/>											
20-Apr-2016	12284825	NON-EXPEDITED			S	Transdermal		US-TEVA-647819USA	58 YR	Female	USA
Preferred Term											
Headache											
<hr/>											
20-Apr-2016	12284828	NON-EXPEDITED			S	Transdermal		US-TEVA-647733USA		Unknown	USA
Preferred Term											
Application site pain											
Application site rash											
<hr/>											
20-Apr-2016	12284831	NON-EXPEDITED			S	Transdermal		US-TEVA-648063USA		Female	USA
Preferred Term											
Application site erythema											
Application site pain											
Application site inflammation											
Application site paraesthesia											
Application site pruritus											
Application site vesicles											



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20-Apr-2016	12284839	NON-EXPEDITED			S	Transdermal	US-TEVA-647197USA	32 YR	Female	USA
Preferred Term										
Nausea										
Dizziness										
Feeling drunk										
Incorrect drug administration duration										
Underdose										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284840	NON-EXPEDITED			S		US-TEVA-648213USA	57 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Device leakage										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284843	NON-EXPEDITED			S	Transdermal	US-TEVA-647849USA		Female	USA
Preferred Term										
Application site erythema										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284846	NON-EXPEDITED			S		US-TEVA-648066USA		Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site irritation										
Application site pain										
Application site pruritus										



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20-Apr-2016	12284848	NON-EXPEDITED			S	Transdermal	US-TEVA-648507USA	22 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY						TEVA	
<u>Electroencephalogram abnormal</u>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284849	NON-EXPEDITED			S		US-TEVA-648091USA		Unknown	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY						TEVA	
<u>Drug ineffective</u>										
<u>Product physical issue</u>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284850	NON-EXPEDITED			S	Transdermal	US-TEVA-647734USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY				4 hours		TEVA	
<u>Application site hypersensitivity</u>										
<u>Application site irritation</u>										
<u>Device battery issue</u>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284851	NON-EXPEDITED			S	Transdermal	US-TEVA-647199USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY						TEVA	
<u>Application site pain</u>										
<u>Application site dryness</u>										
<u>Application site warmth</u>										
<u>Device battery issue</u>										



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20-Apr-2016	12284852	NON-EXPEDITED			S	Transdermal	US-TEVA-648447USA	35 YR	Female	USA
Preferred Term										
Application site pruritus										
Application site erythema										
Application site swelling										
Arthralgia										
Dyspnoea										
Malaise										
Paraesthesia										
<hr/>										
20-Apr-2016	12284855	NON-EXPEDITED			S	Transdermal	US-TEVA-648245USA	41 YR	Female	USA
Preferred Term										
Device battery issue										
<hr/>										
20-Apr-2016	12284856	NON-EXPEDITED			S	Transdermal	US-TEVA-648520USA		Male	USA
Preferred Term										
Drug effect incomplete										
<hr/>										
20-Apr-2016	12284857	NON-EXPEDITED			S	Transdermal	US-TEVA-647437USA	47 YR	Female	USA
Preferred Term										
Nausea										
Diarrhoea										



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20-Apr-2016	12284858	NON-EXPEDITED			S		US-TEVA-648205USA	43 YR	Female	USA
Preferred Term										
Application site erythema										
Application site induration										
Application site pain										
Application site pruritus										
Drug ineffective										
Incorrect drug administration duration										
<hr/>										
20-Apr-2016	12284859	NON-EXPEDITED			S		US-TEVA-647193USA	55 YR	Female	USA
Preferred Term										
Application site erythema										
<hr/>										
20-Apr-2016	12284860	NON-EXPEDITED			S		US-TEVA-648248USA	26 YR	Female	USA
Preferred Term										
Application site erythema										
<hr/>										
20-Apr-2016	12284862	NON-EXPEDITED			S		US-TEVA-648806USA	33 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site irritation										



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20-Apr-2016	12284863	NON-EXPEDITED			US-TEVA-648741USA		Unknown	USA
<u>Preferred Term</u>								
Drug ineffective				<u>Role Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Application site erythema				S Transdermal	6.5 mg / 4 hours			TEVA
Application site irritation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Device leakage								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284865	NON-EXPEDITED			US-TEVA-648871USA	38 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site paraesthesia				<u>Role Route</u>				TEVA
Application site erythema				S Transdermal				
Application site irritation								
Drug ineffective								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284866	NON-EXPEDITED			US-TEVA-649448USA	53 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site urticaria				<u>Role Route</u>				TEVA
Application site pruritus				S Transdermal				



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20-Apr-2016	12284867	NON-EXPEDITED			S	Transdermal	US-TEVA-647794USA	44 YR	Female	USA
Preferred Term										
Application site rash										
Application site discomfort										
Application site dryness										
Application site erythema										
Application site pain										
Application site pruritus										
Application site swelling										
<hr/>										
20-Apr-2016	12284868	NON-EXPEDITED					US-TEVA-647414USA		Male	USA
Preferred Term										
Drug ineffective										
Device battery issue										
<hr/>										
20-Apr-2016	12284869	NON-EXPEDITED					US-TEVA-648255USA	34 YR	Female	USA
Preferred Term										
Application site erythema										
<hr/>										
20-Apr-2016	12284870	NON-EXPEDITED					US-TEVA-648506USA		Female	USA
Preferred Term										
Application site irritation										



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20-Apr-2016	12284872	NON-EXPEDITED			US-TEVA-647584USA	54 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site reaction	ZECUITY	S	Transdermal	6.5 Milligram Daily; 6.5mg/4hrs		TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Apr-2016	12284873	NON-EXPEDITED			US-TEVA-647818USA	49 YR	Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Dysgeusia	ZECUITY	S	Transdermal			TEVA		
Device leakage								
Drug ineffective								
Product adhesion issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Apr-2016	12284874	NON-EXPEDITED			US-TEVA-648176USA	26 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECUITY	S				TEVA		
Application site discoloration								
Application site exfoliation								
Pain in extremity								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Apr-2016	12284875	NON-EXPEDITED			US-TEVA-648175USA	60 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECUITY	S				TEVA		
Application site dryness								
Application site irritation								
Application site pruritus								



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20-Apr-2016	12284876	NON-EXPEDITED			S	Transdermal	US-TEVA-648240USA	52 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUIITY							TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284877	NON-EXPEDITED					US-TEVA-648093USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUIITY		S					TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284878	NON-EXPEDITED					US-TEVA-648497USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug effect incomplete			ZECUIITY		S	Transdermal				TEVA
Application site erythema										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284879	NON-EXPEDITED					US-TEVA-648494USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Nausea			ZECUIITY		S	Transdermal				TEVA
Drug intolerance										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284880	NON-EXPEDITED					US-TEVA-647413USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site pain			ZECUIITY		S	Transdermal				TEVA
Application site discolouration										
Device leakage										



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284882	NON-EXPEDITED			S	Transdermal	US-TEVA-648464USA	28 YR	Female	USA
Preferred Term										
Hypersensitivity										
Application site erythema										
Application site pruritus										
Application site swelling										
Application site urticaria										
Application site warmth										
<hr/>										
20-Apr-2016	12284883	NON-EXPEDITED					US-TEVA-647878USA	42 YR	Female	USA
Preferred Term										
Application site erythema										
Application site pruritus										
Application site discoloration										
Device battery issue										
<hr/>										
20-Apr-2016	12284884	NON-EXPEDITED					US-TEVA-648867USA	48 YR	Female	USA
Preferred Term										
Device leakage										
Application site erythema										



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284885	NON-EXPEDITED			S	Transdermal	US-TEVA-648469USA	63 YR	Female	USA
Preferred Term										
Application site pain										
Application site discomfort										
Application site erythema										
Application site pain										
Incorrect drug administration duration										
20-Apr-2016	12284890	NON-EXPEDITED			S	Transdermal	US-TEVA-648501USA	52 YR	Female	USA
Preferred Term										
Application site rash										
Application site irritation										
Application site pruritus										
Wrong technique in product usage process										
20-Apr-2016	12284891	NON-EXPEDITED			S	Transdermal	US-TEVA-648438USA	62 YR	Female	USA
Preferred Term										
Application site pain										
20-Apr-2016	12284892	NON-EXPEDITED			S	Transdermal	US-TEVA-648775USA	32 YR	Female	USA
Preferred Term										
Device leakage										
Application site erythema										
Application site pain										
Application site swelling										
Incorrect drug administration duration										



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284894	NON-EXPEDITED			US-TEVA-648504USA	41 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECURITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284895	NON-EXPEDITED			US-TEVA-648873USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECURITY	S	Transdermal			TEVA	
Application site hyperaesthesia								
Application site swelling								
Application site vesicles								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12284896	NON-EXPEDITED			US-TEVA-648855USA	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device leakage		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site swelling								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12285533	EXPEDITED (15-DAY)		OT	US-TEVA-652205USA	30 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site paraesthesia								
Device leakage								
Sunburn								



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20-Apr-2016	12287286	EXPEDITED (15-DAY)		OT	US-TEVA-652955USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Product adhesion issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12287296	EXPEDITED (15-DAY)		OT	US-TEVA-653236USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site urticaria								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12287634	NON-EXPEDITED			US-TEVA-648578USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECUITY	S				TEVA	
Application site erythema								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Device adhesion issue								
Device leakage								
Drug effect decreased								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12289174	DIRECT	Y			33 YR	Female	
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Topical		1 DAY		
Application site rash								



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21-Apr-2016	12289539	EXPEDITED (15-DAY)		OT	US-TEVA-653090USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
<u>EDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	12289580	EXPEDITED (15-DAY)		OT	US-TEVA-653100USA	28 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site scab								
Device battery issue								
<u>EDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	12289597	NON-EXPEDITED			US-TEVA-648182USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECUITY	S				TEVA	
Application site erythema								
Application site pain								
Application site swelling								
<u>EDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12070099	EXPEDITED (15-DAY)		OT	US-TEVA-634017USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12294633	EXPEDITED (15-DAY)		OT	US-TEVA-653055USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site papules								
Application site pruritus								
Application site rash								
Application site swelling								
Drug ineffective								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12295276	EXPEDITED (15-DAY)		OT	US-TEVA-653461USA	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Application site swelling								
Application site vesicles								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12295277	EXPEDITED (15-DAY)		OT	US-TEVA-653065USA	49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Chromaturia								
Dyspnoea								
Ear infection								
Feeling abnormal								
Flank pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12297773	EXPEDITED (15-DAY)		OT	US-TEVA-653993USA	37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site rash								
Application site vesicles								
Skin sensitisation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2016	11909368	NON-EXPEDITED			US-TEVA-621834USA	28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sensory disturbance	ZECUITY	S	Transdermal			TEVA		
Device leakage								
Product adhesion issue								



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25-Apr-2016	12301139	EXPEDITED (15-DAY)		OT	US-TEVA-653944USA	53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
		ZECURITY		S Transdermal			TEVA	
Application site burn								
Application site erythema								
Application site paraesthesia								
Application site pruritus								
Application site warmth								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2016	12302283	EXPEDITED (15-DAY)		OT	US-TEVA-653919USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
		ZECURITY		S Transdermal			TEVA	
Application site burn								
Application site erythema								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2016	12306804	EXPEDITED (15-DAY)		OT	US-TEVA-654291USA	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
		ZECURITY		S Transdermal			TEVA	
Sunburn								
Application site erythema								
Application site irritation								
Drug effect incomplete								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2016	12306815	EXPEDITED (15-DAY)		OT	US-TEVA-654703USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
		ZECURITY		S Transdermal			TEVA	
Application site burn								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site vesicles								



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26-Apr-2016	12308022	EXPEDITED (15-DAY)		OT			US-TEVA-654709USA		Female	USA
Preferred Term										
Sunburn										
Application site bruise										
Application site dryness										
Application site erythema										
Application site paraesthesia										
Application site pruritus										
Product physical issue										
<hr/>										
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
27-Apr-2016	12232919	EXPEDITED (15-DAY)		OT			US-TEVA-647824USA	44 YR	Female	USA
Preferred Term										
Application site burn										
ZECURITY										
S										
Transdermal										
<hr/>										
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Duration	Manufacturer	Country
27-Apr-2016	12301446	EXPEDITED (15-DAY)		OT			US-TEVA-653975USA		Male	USA
Preferred Term										
Application site burn										
Application site discoloration										
Application site pain										
Application site paraesthesia										
Application site pruritus										
Device battery issue										
Drug ineffective										
Wrong technique in product usage process										



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12314623	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-654293USA	55 YR	Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burns second degree					S	Transdermal			TEVA	
Application site pruritus										
Application site rash										
Application site vesicles										
Application site warmth										
Product physical issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12253773	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-649427USA	37 YR	Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar					S	Transdermal			TEVA	
Application site discoloration										
Application site erythema										
Application site pain										
Application site reaction										
Application site swelling										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12319121	EXPEDITED (15-DAY)		OT		Unknown	US-TEVA-655260USA		Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn					S	Unknown			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2016	12295274	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-653481USA	45 YR	Female	USA
<u>Preferred Term</u>							<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn					S	Transdermal			TEVA	
Application site pain										
Application site vesicles										



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12331346	EXPEDITED (15-DAY)		OT	US-TEVA-656408USA	47 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site oedema								
Application site rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12333969	EXPEDITED (15-DAY)		OT	US-TEVA-656383USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12335098	EXPEDITED (15-DAY)		OT	US-TEVA-656565USA	42 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site bruise								
Application site discoloration								
Application site erosion								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site rash								



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05-May-2016	12338914	EXPEDITED (15-DAY)		OT	US-TEVA-656609USA	33 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pruritus								
Device battery issue								
Device use error								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2016	12205144	EXPEDITED (15-DAY)		OT	US-TEVA-638234USA	47 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site swelling								
Dermatitis allergic								
Device battery issue								
Device leakage								
Drug effect incomplete								



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06-May-2016	12341617	EXPEDITED (15-DAY)		OT	US-TEVA-657345USA	24 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal		TEVA		
Application site erythema								
Application site pruritus								
Application site reaction								
Chemical Injury								
Incorrect drug administration duration								
Product adhesion issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2016	12342669	EXPEDITED (15-DAY)		OT	US-TEVA-657019USA	29 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal		TEVA		
Application site erythema								
Application site pain								
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2016	12345332	EXPEDITED (15-DAY)		OT	US-TEVA-657343USA	26 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal		TEVA		
Application site erythema								
Device battery issue								



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07-May-2016	12345333	EXPEDITED (15-DAY)		OT	US-TEVA-657729USA	38 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Product adhesion issue								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-May-2016	12052779	EXPEDITED (15-DAY)		OT	US-TEVA-632148USA	33 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Sunburn		ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Device leakage			C	Unknown				
Application site erythema								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-May-2016	12348358	EXPEDITED (15-DAY)		OT	US-TEVA-658893USA	39 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-May-2016	12184597	EXPEDITED (15-DAY)		OT	US-TEVA-642167USA	51 YR	Male	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pruritus								
Application site rash								
Device battery issue								



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10-May-2016	12353140	EXPEDITED (15-DAY)		OT	US-TEVA-657888USA	25 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY	S Transdermal			TEVA	
Application site rash								
Chemical burn of skin								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2016	12247922	NON-EXPEDITED			US-TEVA-629325USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discoloration			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Application site dermatitis								
Application site vesicles								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2016	12330578	EXPEDITED (15-DAY)		OT	US-TEVA-655551USA	27 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY	S Transdermal			TEVA	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site pruritus								
Device battery issue								
Device leakage								
Drug ineffective								
Wrong technique in product usage process								



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12-May-2016	12365116	EXPEDITED (15-DAY)		OT	US-TEVA-658852USA	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Device battery issue		ZECUITY	S	Transdermal			TEVA	
Application site discoloration								
Application site inflammation								
Application site pain								
Drug effect incomplete								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2016	12365669	DIRECT				48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECUITY MIGRAINE PATCHES, 6.5 MG	S	Topical	APPLIED AS MEDICATED PATCH TO SKIN		TEVA	
Application site pruritus		ZOLOF	C					
Application site vesicles		PERCOCET	C					
Dermatitis contact		XANAX	C					
Drug ineffective		MORPHINE	C					
Application site warmth		BENADRYL	C					
Application site pain		MULTI VITAMIN	C					
		B COMPLEX	C					
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2016	12366739	EXPEDITED (15-DAY)		OT	US-TEVA-659046USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site erythema								
Drug effect incomplete								



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16-May-2016	12372909	EXPEDITED (15-DAY)		OT	US-TEVA-658832USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2016	12359459	EXPEDITED (15-DAY)		OT	US-TEVA-659042USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Device battery issue								
Device failure								
Device issue								
Device use error								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2016	12378530	EXPEDITED (15-DAY)		OT	US-TEVA-659256USA	28 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site swelling		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site scab								
Application site vesicles								
Intentional product use issue								
Product physical issue								



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17-May-2016	12378850	EXPEDITED (15-DAY)		OT	OT		US-TEVA-658821USA	22 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn		ZECUITY		S	Transdermal			TEVA		
Application site erythema										
Application site pain										
Application site paraesthesia										
Dry skin										
Migraine										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2016	11980800	EXPEDITED (15-DAY)		OT	OT		US-TEVA-628673USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn		ZECUITY		S	Transdermal			TEVA		
Application site rash										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2016	12381214	EXPEDITED (15-DAY)		OT	OT		US-TEVA-660622USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn		ZECUITY		S	Transdermal			TEVA		
Application site erythema										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2016	12382170	EXPEDITED (15-DAY)		OT	OT		US-TEVA-660179USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site scar		ZECUITY		S	Transdermal			TEVA		
Sunburn										



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18-May-2016	12382830	EXPEDITED (15-DAY)		OT	US-TEVA-659629USA	60 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-May-2016	12382858	EXPEDITED (15-DAY)		OT	US-TEVA-659648USA	63 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Loss of consciousness		ZECUITY	S	Transdermal			TEVA	
Malaise								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-May-2016	12384821	DIRECT		Y		58 YR	Male	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site irritation		ZECUITY 6.5MG TRANSDERMAL	S	Topical	BID Topical/Patch		TEVA	
Application site erythema								
Application site pruritus								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-May-2016	11677537	EXPEDITED (15-DAY)		OT	US-TEVA-604001USA	50 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site discomfort								
Application site erythema								
Application site inflammation								
Application site irritation								
Drug effect incomplete								



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19-May-2016	11690829	EXPEDITED (15-DAY)		OT	US-TEVA-604818USA	38 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burns second degree		ZECURITY		S Transdermal			TEVA	
Application site burn								
Application site erythema								
Application site inflammation								
Application site pain								
Application site vesicles								
Drug effect decreased								
Sunburn								
Underdose								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2016	11720232	EXPEDITED (15-DAY)		OT	US-TEVA-606054USA	43 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site pain								
Device battery issue								
Device leakage								



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19-May-2016	11893465	EXPEDITED (15-DAY)		OT	US-TEVA-622628USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg/4 hr		TEVA	
Chemical burn of skin		SYNTHROID	C					
Application site bruise								
Application site discoloration								
Application site erythema								
Application site pain								
Application site pruritus								
Application site urticaria								
Device battery issue								
Device leakage								
Rash								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2016	12167991	EXPEDITED (15-DAY)		OT	US-TEVA-640288USA	41 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg/4 hours		TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site rash								
Application site warmth								
Chemical injury								
Device battery issue								



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19-May-2016	12208189	EXPEDITED (15-DAY)		OT	US-TEVA-644809USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	3 patches		TEVA	
Sunburn		EFFEXOR	C					
Application site pruritus		ALLEGRA	C					
Application site erythema		ProAir	C					
Product adhesion issue		PREVACID	C					
Application site discomfort								
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	11909452	EXPEDITED (15-DAY)		OT	US-TEVA-615119USA	35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site pain								



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20-May-2016	11966980	EXPEDITED (15-DAY)		OT	US-TEVA-628271USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal	6.5 mg / 4 hours		TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Application site rash								
Application site scab								
Application site swelling								
Dermatitis contact								
Device battery issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	12004762	EXPEDITED (15-DAY)		OT	US-TEVA-631695USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site pain								
Application site pruritus								
Application site warmth								
Device battery issue								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	12070085	EXPEDITED (15-DAY)		OT	US-TEVA-633674USA	37 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY		S Transdermal			TEVA	
Application site erythema		Maxalt		C				
Application site urticaria		AMITRIPTYLINE		C				
Erythema		Percocet		C				
Application site paraesthesia		Flomax		C				
Application site warmth		aspirin		C				
Application site discoloration		Zofran		C				
Application site pruritus		atorvastatin		C				
Application site pain		Trazodone		C				
Device adhesion issue		Lisinopril/Hctz		C				
		Xanax		C				
		Gabapentin		C				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	12155436	EXPEDITED (15-DAY)		OT	US-TEVA-640120USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site urticaria								
Product adhesion issue								
Product physical issue								



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20-May-2016	12155529	EXPEDITED (15-DAY)		OT	US-TEVA-629080USA	42 YR	Female	USA
Preferred Term								
Application site burn								
Application site pain								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Application site vesicles								
Headache								
EDA Received Date								
20-May-2016	12170617	EXPEDITED (15-DAY)		OT	US-TEVA-641676USA	26 YR	Female	USA
Preferred Term								
Application site burn								
Chemical injury								
Application site erythema								
Application site discoloration								
Application site dryness								
Application site pain								
Application site pruritus								
Application site warmth								
Device leakage								
Incorrect drug administration duration								
Product adhesion issue								



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20-May-2016	12205090	EXPEDITED (15-DAY)		OT	US-TEVA-644815USA	54 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn				S				TEVA
Sunburn				S				TEVA
Application site erythema				C				
Application site discoloration								
Application site dryness								
Application site pruritus								
Application site scab								
Device leakage								
Drug effect incomplete								
Migraine								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	12211361	EXPEDITED (15-DAY)		OT	US-TEVA-644784USA	55 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site scar				S				TEVA
Application site burn				S				TEVA
Application site pain				C				
Application site erythema				C				
Application site exfoliation				C				
Application site discoloration				C				
				C				
				C				



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20-May-2016	12215422	EXPEDITED (15-DAY)		OT	US-TEVA-646058USA	38 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Application site burn				S Transdermal				TEVA
Application site erythema								
Application site urticaria								
Burning sensation								
Device battery issue								
Product adhesion issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	12391056	EXPEDITED (15-DAY)		OT	US-TEVA-660406USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Application site burn				S Transdermal				TEVA
Application site erythema								
Application site scab								
Incorrect drug administration duration								
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	12391254	EXPEDITED (15-DAY)		OT	US-TEVA-660472USA	23 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Chemical injury				S Transdermal	6.5mg every 4 hours			TEVA
Application site erythema								
Application site pruritus								
Application site rash								
Pain in extremity								



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20-May-2016	12391264	EXPEDITED (15-DAY)		OT	US-TEVA-660377USA	36 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Migraine								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2016	12013007	EXPEDITED (15-DAY)		OT	US-TEVA-631304USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal			TEVA	
Cerebrovascular accident		ZECUITY	S	Transdermal			TEVA	
Application site rash		MAXXAL T	C					
Application site discoloration								
Application site erythema								
Application site paraesthesia								
Application site pruritus								
Application site reaction								
Application site swelling								
Application site warmth								
Device issue								
Miliaria								
Product physical issue								
Skin reaction								



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23-May-2016	12165408	EXPEDITED (15-DAY)		OT	US-TEVA-640932USA	28 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pruritus								
Device battery issue								
Device leakage								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-May-2016	12192624	EXPEDITED (15-DAY)		OT	US-TEVA-643951USA	32 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site urticaria								
Chemical injury								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-May-2016	12224072	EXPEDITED (15-DAY)		OT	US-TEVA-646682USA		Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site burn		ZECUITY	S	Transdermal	6:5 mg / 4 hours		TEVA	
Sunburn		ZECUITY	S	Transdermal	6:5 mg / 4 hours		TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Device leakage								



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23-May-2016	12226308	EXPEDITED (15-DAY)		OT	US-TEVA-647186USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Sunburn		ZECURITY		S Transdermal			TEVA	
Abdominal pain								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site urticaria								
Application site vesicles								
Diarrhoea								
Drug ineffective								
Nausea								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2016	12232471	EXPEDITED (15-DAY)		OT	US-TEVA-647765USA	27 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site erythema		ZECURITY		S Transdermal			TEVA	
Application site discoloration								
Application site dryness								
Application site exfoliation								
Application site pain								
Application site scar								
Device adhesion issue								
Device leakage								



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23-May-2016	12356200	EXPEDITED (15-DAY)		OT	US-TEVA-658028USA	53 YR	Female	USA
Preferred Term								
Application site burn								
Application site pain								
Application site pruritus								
Application site redness								
Application site swelling								
Application site warmth								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site redness								
Application site swelling								
Application site warmth								
Inappropriate schedule of drug administration								
Product adhesion issue								
<hr/>								
23-May-2016	12393684	EXPEDITED (15-DAY)		OT	US-TEVA-660766USA		Female	USA
Preferred Term								
Application site burn								
Application site pruritus								
Application site redness								
Application site swelling								
Application site warmth								
Inappropriate schedule of drug administration								
Product adhesion issue								
<hr/>								
23-May-2016	12394356	EXPEDITED (15-DAY)		OT	US-TEVA-660607USA	42 YR	Female	USA
Preferred Term								
Application site burn								
Application site discoloration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site redness								
Application site swelling								
Application site warmth								
Inappropriate schedule of drug administration								
Product adhesion issue								



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23-May-2016	12394483	EXPEDITED (15-DAY)		OT	US-TEVA-660616USA	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECUITY		S Transdermal				TEVA
Application site discoloration								
Application site erythema								
Product adhesion issue								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2016	11651595	EXPEDITED (15-DAY)		OT	US-TEVA-603309USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECUITY		S Transdermal				TEVA
Application site discoloration								
Application site vesicles								
Application site warmth								
Device battery issue								
Headache								
Nausea								



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24-May-2016	11720603	EXPEDITED (15-DAY)		OT	US-TEVA-606951USA	42 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug dependence		ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA	
Application site burn		ZECUITY	S	Transdermal	4 hours		TEVA	
Chemical burn of skin		ZECUITY	S	Transdermal	4 hours		TEVA	
Application site erosion								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site urticaria								
Device leakage								
Drug effect incomplete								
Drug ineffective								
Dry skin								
Incorrect product storage								
Sunburn								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2016	11920395	EXPEDITED (15-DAY)		OT	US-TEVA-625477USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA	
Application site necrosis		ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA	
Application site exfoliation		DYMISTA	C				TEVA	
Device battery issue		SINGULAIR	C					
Application site discoloration								
Application site erythema								



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24-May-2016	12085723	EXPEDITED (15-DAY)		OT	US-TEVA-634835USA	39 YR	Female	USA
Preferred Term								
Application site burn			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pain			ZECUITY	S	Transdermal			TEVA
Application site urticaria			ZECUITY	S	Transdermal			TEVA
Application site erythema			No Drug name	C				
Product adhesion issue								
Product physical issue								
Rash macular								
Wrong technique in product usage process								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2016	12147424	EXPEDITED (15-DAY)			US-TEVA-640223USA		Female	USA
Preferred Term								
Pain in extremity			Product	Role	Route	Dosage Text	Duration	Manufacturer
Muscle tightness			ZECUITY	S	Transdermal			TEVA
Application site erythema			Maxalt	C				
Muscle spasms								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-May-2016	12254739	EXPEDITED (15-DAY)		OT	US-TEVA-650136USA		Male	USA
Preferred Term								
Application site burn			Product	Role	Route	Dosage Text	Duration	Manufacturer
Device battery issue			ZECUITY	S	Transdermal			TEVA
Wrong technique in product usage process			Verapamil	C				
			Norco	C				



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24-May-2016	12257628	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-650267USA	64 YR	Male	USA		
Preferred Term												
Sunburn					S	Transdermal			TEVA			
Application site pain					C							
Application site erythema					C							
Application site rash												
<hr/>												
24-May-2016	12364198	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-658347USA		Male	USA		
Preferred Term												
Application site burn					S	Transdermal			TEVA			
Application site pain												
Application site scab												
<hr/>												
24-May-2016	12398165	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-660382USA	46 YR	Female	USA		
Preferred Term												
Application site burn					S	Transdermal			TEVA			
Application site paraesthesia												
Product physical issue												
<hr/>												
24-May-2016	12400218	DIRECT		OT	S	Topical	1 patch(es) As needed Applied as medicated patch to skin	39 YR	Female	USA		
Preferred Term												
ZECUITY					S	Topical			TEVA			
<hr/>												
Dermatitis contact												



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25-May-2016	11893312	EXPEDITED (15-DAY)		OT	US-TEVA-623376USA	45 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
Application site vesicles								
Application site warmth								
Burns second degree								
Device battery issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	11893466	EXPEDITED (15-DAY)		OT	US-TEVA-622662USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg/4 hours		TEVA	
Application site scar		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site papules								
Application site pruritus								
Application site urticaria								
Drug hypersensitivity								
Product adhesion issue								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12116475	EXPEDITED (15-DAY)		OT	US-TEVA-637286USA	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site erythema		TOPAMAX	C					
Application site swelling		SINGULAIR	C					
Application site pruritus		PROCARDIA	C					
Application site pain		DEXILANT	C					
Application site urticaria		ADVAIR	C					
Drug effect delayed		IMITREX	C					
Application site rash								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12128057	EXPEDITED (15-DAY)		OT	US-TEVA-638254USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	2 patches, 4 hrs 2 min apart		TEVA	
Application site erythema								
Application site pain								
Application site pruritus								
Device leakage								
Drug effect decreased								
Drug ineffective								
Nausea								



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25-May-2016	12142351	EXPEDITED (15-DAY)		OT	US-TEVA-635806USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
		ZECURITY		S Transdermal			TEVA	
Application site burn								
Application site erythema								
Application site haemorrhage								
Application site pain								
Application site vesicles								
Drug effect incomplete								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12160888	EXPEDITED (15-DAY)		OT	US-TEVA-64054USA	61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
		ZECURITY		S Transdermal			TEVA	
Application site burn								
Application site discolouration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site warmth								
Device adhesion issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12187270	EXPEDITED (15-DAY)		OT	US-TEVA-642868USA	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
		ZECURITY		S Transdermal			TEVA	
Sunburn								
Application site erythema								
Application site exfoliation								
Application site paraesthesia								
Application site urticaria								



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25-May-2016	12272458	EXPEDITED (15-DAY)		OT	US-TEVA-632777USA	47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECUITY	S	Transdermal	for 4 hours		TEVA		
Application site erythema								
Application site reaction								
Device battery issue								
Device leakage								
Product adhesion issue								
Skin reaction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12404299	EXPEDITED (15-DAY)		OT	US-TEVA-661516USA	30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site exfoliation								
Drug effect incomplete								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2016	12196480	EXPEDITED (15-DAY)		OT	US-TEVA-643991USA	43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site pain								
Application site pruritus								
Application site warmth								
Chemical Injury								
Drug administration error								
Drug effect incomplete								



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26-May-2016	12235322	EXPEDITED (15-DAY)		OT	US-TEVA-647802USA	26 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pain								
Application site scar								
Application site swelling								
Migraine								
Rash erythematous								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2016	12257923	EXPEDITED (15-DAY)		OT	US-TEVA-650174USA	47 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Device battery issue								
Sunburn								



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27-May-2016	12080905	EXPEDITED (15-DAY)		OT	US-TEVA-634245USA	51 YR	Female	USA
Preferred Term								
Application site vesicles								
Application site scar								
Application site erythema								
Application site irritation								
Application site pruritus								
Application site urticaria								
Application site warmth								
Product physical issue								
<hr/>								
27-May-2016	12410821	EXPEDITED (15-DAY)		OT	US-TEVA-662479USA		Unknown	USA
Preferred Term								
Application site burn								
Application site reaction								
<hr/>								
01-Jun-2016	12119648	EXPEDITED (15-DAY)		OT	US-TEVA-637313USA		Female	USA
Preferred Term								
Sunburn								
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site pain								
Application site pruritus								
Application site warmth								
Migraine								



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01-Jun-2016	12428737	DIRECT	Y				Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site urticaria				S Transdermal			TEVA	
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2016	12281734	EXPEDITED (15-DAY)		OT	US-TEVA-641654USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site rash				C				
Application site reaction								
Hypersensitivity								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2016	12433328	DIRECT	Y			59 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site dyyness				S	ZECURITY PAD 6.5MG/4H			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2016	12466191	EXPEDITED (15-DAY)		OT	US-TEVA-661836USA		Male	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site pain								



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03-Jun-2016	12155964	EXPEDITED (15-DAY)		OT	US-TEVA-639933USA	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECURITY		S Transdermal				TEVA
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
Application site vesicles								
Drug ineffective								
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2016	12235458	EXPEDITED (15-DAY)		OT	US-TEVA-647828USA	50 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Sunburn		ZECURITY		S Transdermal				TEVA
Application site erythema		ZECURITY		S Transdermal				TEVA
Application site urticaria		melatonin		C				
Application site pruritus		Nasonex		C				
Application site vesicles		Prevacid		C				
		Tizanidine		C				
		Topamax		C				
		Wellbutrin		C				



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03-Jun-2016	12235472	EXPEDITED (15-DAY)		OT	US-TEVA-647871USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site paraesthesia		TOPAMAX	C					
Application site pain		PROZAC	C					
Application site discoloration								
Application site dryness								
Application site erythema								
Device battery issue								
Device use error								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2016	12434296	EXPEDITED (15-DAY)		OT	US-TEVA-663335USA	50 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site irritation								
Application site pain								
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2016	12434666	EXPEDITED (15-DAY)		OT	US-TEVA-663425USA	30 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site warmth								



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03-Jun-2016	12436825	DIRECT		OT		60 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECURITY, 6.5 MG	S Topical	1 patch(es) as needed applied as medicated patch to skin		TEVA	
			TOPAMAX	C				
			TIZANIDINE	C				
			TRAZODONE	C				
			VITAMIN E	C				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2016	12466199	EXPEDITED (15-DAY)		OT	US-TEVA-662161USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site vesicles								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2016	12166347	EXPEDITED (15-DAY)		OT	US-TEVA-641826USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site irritation								
Application site pain								
Application site scab								
Chemical burn of skin								
Device leakage								



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05-Jun-2016	12169070	EXPEDITED (15-DAY)		OT	US-TEVA-641362USA	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site bruise								
Application site erythema								
Application site irritation								
Application site pain								
Device adhesion issue								
Incorrect drug administration duration								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2016	12192655	EXPEDITED (15-DAY)		OT	US-TEVA-643990USA	29 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal	6.5mg/4 hours		TEVA	
Application site burn		ZECURITY		S Transdermal	6.5mg/4 hours		TEVA	
Application site erythema								
Application site paraesthesia								
Application site warmth								
Device battery issue								
Device leakage								
Product quality issue								



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05-Jun-2016	12201022	EXPEDITED (15-DAY)		OT	US-TEVA-644363USA	50 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site irritation								
Application site pain								
Application site scar								
Application site vesicles								
Blood blister								
Complication of device removal								
Device use error								

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05-Jun-2016	12246542	EXPEDITED (15-DAY)		OT	US-TEVA-648544USA	21 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site vesicles								
Patient dissatisfaction with treatment								



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05-Jun-2016	12253659	EXPEDITED (15-DAY)		OT	US-TEVA-649845USA	34 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site discolouration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Application site swelling								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2016	12279908	EXPEDITED (15-DAY)		OT	US-TEVA-651717USA	35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal			TEVA	
Application site erythema		Norco	C					
Application site discolouration		Meloxicam	C					
Application site paraesthesia								
Application site warmth								



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06-Jun-2016	11899198	EXPEDITED (15-DAY)		OT	US-TEVA-623428USA	68 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical Injury		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site rash								
Application site vesicles								
Dermatitis contact								
Sunburn								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	11911399	EXPEDITED (15-DAY)		OT	US-TEVA-623642USA	43 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site vesicles		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site discomfort								
Application site erythema								
Application site pain								
Application site scab								
Chemical Injury								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12167960	EXPEDITED (15-DAY)		OT	US-TEVA-641295USA	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal	6.5 mg / 4 hours		TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site vesicles								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12203716	EXPEDITED (15-DAY)		OT	US-TEVA-644394USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site laceration								
Application site pain								
Application site scar								
Device adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12254762	EXPEDITED (15-DAY)		OT	US-TEVA-650094USA	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site pain								



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06-Jun-2016	12281003	EXPEDITED (15-DAY)		OT	US-TEVA-652201USA	67 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site pain		ACETAMINOPHEN HYDROCODONE BITARTRATE		C				
Application site erythema		NUCYNITA		C				
Application site exfoliation								
Application site urticaria								
Device battery issue								
Product adhesion issue								
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12436822	EXPEDITED (15-DAY)		OT	US-TEVA-664059USA	33 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site discolouration								
Application site dryness								
Application site pain								
Application site scab								
Application site vesicles								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12438346	EXPEDITED (15-DAY)		OT	US-TEVA-663732USA	50 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>			<u>Manufacturer</u>
Application site burn				S	Transdermal			TEVA
Application site erythema								
Application site inflammation								
Application site pain								
Product adhesion issue								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12438748	EXPEDITED (15-DAY)		OT	US-TEVA-661095USA	49 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>			<u>Manufacturer</u>
Application site scar				S	Transdermal			TEVA
Application site urticaria				S	Transdermal			TEVA
Application site discoloration								
Application site erythema								
Application site pain								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12439360	EXPEDITED (15-DAY)		OT	US-TEVA-663777USA		Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>			<u>Manufacturer</u>
Sunburn				S	Transdermal	6.5 mg over 4 hours		TEVA
Application site exfoliation								
Application site rash								
Product physical issue								



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06-Jun-2016	12442788	DIRECT				37 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site burn			ZECUITY	S	Topical	1 Patch(es) As Needed Applied as medicated patch to skin		TEVA
Application site pruritus			TOPAMAX	C				
Application site pain			NORTRIPTYLINE	C				
Application site erythema			ZOLOFT	C				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12443056	DIRECT		OT		23 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECUITY, 6.5 MG TEVA	S	Transdermal	4 Patch (es) As Needed Applied to a surface, usually the skin		TEVA
Application site pain			SUMMATRIPTAN	C				
Pain			ONDANSATRON	C				
			NAPROXEN	C				
			PRENATAL WITH FOLIC ACID	C				
Hyperaesthesia								
Pruritus								



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07-Jun-2016	12083595	EXPEDITED (15-DAY)		OT	US-TEVA-635765USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal	6.5 mg / 4 hours		TEVA	
Application site bruise								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site warmth								
Device battery issue								
Drug ineffective								
Product adhesion issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2016	12154238	EXPEDITED (15-DAY)		OT	US-TEVA-640175USA	37 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site urticaria								
Incorrect drug administration duration								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2016	12446803	DIRECT	Y			40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site burn			ZECUITY PAD 6.5MG/4H	S				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2016	12447424	DIRECT	Y	OT		39 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site burn			ZECUITY	S	Topical			
Application site erythema								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2016	12450576	DIRECT		OT		39 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site scar			ZECUITY SUMATRIPTAN IONTOPHORETI, 6.5 MG TEVA	S		1 patch Once a day Applied to a surface, usually the skin		TEVA
<u>Preferred Term</u>			LEVOTHYROXINE	C				
			AMERGE	C				
			MAGNESIUM	C				
			B2	C				
Application site burn								



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09-Jun-2016	12104348	EXPEDITED (15-DAY)		OT	US-TEVA-636141USA	44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site swelling								
Application site urticaria								
Chemical Injury								
Dermatitis contact								
Device leakage								
Drug effect Incomplete								
Hypersensitivity								
Product adhesion issue								
Rash								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2016	12451551	EXPEDITED (15-DAY)		OT	US-TEVA-665291USA	48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECURITY	S	Transdermal			TEVA		
Application site discolouration								
Application site erythema								
Application site pain								
Product adhesion issue								



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09-Jun-2016	12453331	EXPEDITED (15-DAY)		OT	US-TEVA-665383USA	41 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site pruritus								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2016	12454565	DIRECT		OT		43 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site urticaria			ZECUITY	S Topical			TEVA	
Application site pain			VIIBRYD	C				
Application site swelling			BACLOFEN	C				
Application site pruritus			CLONAZEPAM	C				
Application site warmth			VITAMIN B	C				
Application site inflammation			MAGNESIUM	C				
Application site vesicles			BIOTIN	C				
Application site discharge								
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2016	12456310	EXPEDITED (15-DAY)		OT	US-TEVA-665803USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY	S Transdermal			TEVA	
Application site discoloration								
Application site inflammation								
Application site pain								
Product physical issue								



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11-Jun-2016	12052508	EXPEDITED (15-DAY)		OT	US-TEVA-631846USA	40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECURITY	S	Transdermal	has used 5 or 6 patches		TEVA		
Application site erythema								
Application site pain								
Chest discomfort								
Chest pain								
Dizziness								
Drug ineffective								
Headache								
Palpitations								
Product adhesion issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2016	12191520	EXPEDITED (15-DAY)		OT	US-TEVA-643648USA	53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECURITY	S	Transdermal			TEVA		
Application site paraesthesia	ZECURITY	S	Transdermal			TEVA		
Application site pain	LEXAPRO	C		20 Milligram Daily;		TEVA		
Application site pruritus	SYNTHROID	C		daily				
Application site swelling	VALTREX	C		daily				
Application site erythema								
Contusion								
Product physical issue								



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13-Jun-2016	11706355	EXPEDITED (15-DAY)		OT	US-TEVA-601509USA	21 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site paraesthesia								
Application site scab								
Application site urticaria								
Application site warmth								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12185597	EXPEDITED (15-DAY)		OT	US-TEVA-642866USA	26 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site dysaesthesia								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site scab								
Application site swelling								
Application site urticaria								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12226364	EXPEDITED (15-DAY)		OT	US-TEVA-647190USA	53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Application site reaction								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12239159	EXPEDITED (15-DAY)		OT	US-TEVA-648152USA	20 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Application site rash								
Application site warmth								
Petechiae								
Skin texture abnormal								



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13-Jun-2016	12333925	EXPEDITED (15-DAY)		OT	US-TEVA-656378USA	53 YR	Male	USA
Preferred Term								
Application site burn								
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site vesicles								
Dermatitis contact								
Device battery issue								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12430276	EXPEDITED (15-DAY)		OT	US-TEVA-663993USA		Female	USA
Preferred Term								
Application site burn								
ZECURITY								
S Transdermal								
TEVA								
FDA Received Date								
13-Jun-2016								
Case #								
12459706								
Case Type								
EXPEDITED (15-DAY)								
Health Professional								
OT								
Outcomes								
OT								
Manufacturer Control #								
US-TEVA-665966USA								
Age								
26 YR								
Sex								
Female								
Country								
USA								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
26 YR								
Manufacturer								
TEVA								
Preferred Term								
Application site burn								
Application site discoloration								
Application site dryness								
Application site erythema								
Application site pain								
Wrong technique in product usage process								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12464227	DIRECT				25 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pruritus				S				
Burning sensation				C				
				C				
				C				
				C				
Application site burn								
Application site dryness								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12294898	EXPEDITED (15-DAY)		OT	US-TEVA-653091USA	28 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S				TEVA
Application site erythema								
Application site pain								
Application site pruritus								
Application site rash								
Application site swelling								
Application site urticaria								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12463549	EXPEDITED (15-DAY)		OT	US-TEVA-666031USA	41 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S				TEVA
Application site bruise								
Application site exfoliation								
Application site pain								
Application site pruritus								
Wrong technique in product usage process								



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14-Jun-2016	12465158	EXPEDITED (15-DAY)		OT	US-TEVA-666422USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal			TEVA	
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Product adhesion issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12465162	EXPEDITED (15-DAY)		OT	US-TEVA-666423USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical injury		ZECURITY	S	Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12467008	DIRECT		OT		31 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Medical device site pain		ZECURITY, 6.5 MG	S	Topical	1 Patch(es) As Needed Applied as medicated patch to skin		TEVA	
Application site burn		PEPCID	C					
Application site erythema		CLARITIN	C					
		AMBIEN	C					
		IMITREX	C					
		ZOFRAN	C					
		SKELAXIN	C					
		MULTI-VITAMIN	C					
		BIOTIN	C					
		ZINC	C					
		VIT C	C					



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14-Jun-2016	12467210	DIRECT	Y	OT		37 YR	Female	USA
<u>Preferred Term</u> Application site pain								
			<u>Product</u>	<u>Role</u>	<u>Route</u>			
			ZECURITY, 9.5MG/4H TEVA	S	Transdermal			
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12467263	DIRECT		OT		44 YR	Female	USA
<u>Preferred Term</u> Application site discoloration Application site erythema Application site pain								
			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
			ZECURITY, 6.5 MG TEVA	S		1 patch(es) applied as medicated patch to skin	20 MIN	TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12467524	DIRECT	Y	OT		36 YR	Female	USA
<u>Preferred Term</u> Application site vesicles Application site warmth Medical device site erythema								
			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
			ZECURITY, 6.5MG/4H TEVA	S	Transdermal			TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12467614	DIRECT	Y	OT		43 YR	Male	USA
<u>Preferred Term</u> Application site dryness Application site vesicles								
			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
			ZECURITY, 9.5MG/4H TEVA	S	Transdermal			TEVA



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14-Jun-2016	12467622	DIRECT	Y	OT		20 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain				S Transdermal			TEVA	
Application site scar								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12467637	DIRECT	Y	OT		56 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain				S Transdermal			TEVA	
Application site bruise								
Application site paraesthesia								
Chemical injury								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12467664	DIRECT	Y	OT		27 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12467674	DIRECT	Y	OT		36 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Skin exfoliation				S Transdermal			TEVA	
Application site burn								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12468073	DIRECT	Y	OT		32 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal			TEVA	
Device leakage								



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15-Jun-2016	12433292	EXPEDITED (15-DAY)		OT	US-TEVA-662814USA	41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Application site discolouration								
Application site vesicles								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2016	12468626	EXPEDITED (15-DAY)		OT	US-TEVA-666679USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Chemical injury								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2016	12469261	EXPEDITED (15-DAY)		OT	US-TEVA-667531USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Skin reaction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2016	12469269	EXPEDITED (15-DAY)		OT	US-TEVA-666660USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site oedema								
Application site pain								
Application site pruritus								
Application site rash								
Wrong technique in product usage process								



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15-Jun-2016	12469319	EXPEDITED (15-DAY)		OT			US-TEVA-667718USA		Female	USA
Preferred Term										
Application site burn				S	Transdermal					TEVA
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
15-Jun-2016	12469320	EXPEDITED (15-DAY)		OT			US-TEVA-667942USA	37 YR	Female	USA
Preferred Term							Dosage Text	Duration		Manufacturer
Application site burn				S	Transdermal		200 Milligram Daily;			TEVA
Application site exfoliation				C						
Application site vesicles										
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
15-Jun-2016	12469339	EXPEDITED (15-DAY)		OT			US-TEVA-667719USA		Female	USA
Preferred Term							Dosage Text	Duration		Manufacturer
Application site burn				S	Transdermal					TEVA
Application site discoloration										
Application site dryness										
Application site erythema										
Application site exfoliation										
Application site pain										
Application site rash										
Application site swelling										
Application site urticaria										
Application site vesicles										



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15-Jun-2016	12469345	EXPEDITED (15-DAY)		OT	US-TEVA-666786USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY	S	Transdermal		TEVA	
Application site pain			TRAMADOL	C				
Nausea			FIORICET	C				
Application site exfoliation			TORADOL	C				
Application site dryness								
Application site erythema								
Application site paraesthesia								
Application site swelling								
Dizziness								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2016	12470671	DIRECT				38 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burns first degree			ZECUITY	S	Topical		TEVA	
Application site pain			LAMICTAL	C				
Application site irritation			ZONISAMIDE	C				
Chemical injury								
Migraine								
Musculoskeletal stiffness								
Nausea								
Product adhesion issue								



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15-Jun-2016	12470760	DIRECT				36 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Pain in extremity			ZECURITY, 6.5 MG TEVA	S		1 patch(es) applied as medicated patch to skin		TEVA
			LEXAPRO	C				
			SINGULAR	C				
			FISH OIL	C				
			B COMPLEX	C				
			MULTIVITAMINS	C				
			PROBIOTIC	C				
			IRON	C				
Rash erythematous								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2016	12470769	DIRECT		OT		35 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Skin discolouration			ZECURITY PATCH	S		1 PATCH(ES) APPLIED TO A SURFACE, USUALLY THE SKIN		
Application site burn								



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15-Jun-2016	12470828	DIRECT		OT		33 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Erythema			ZECURITY	S				
Scar			PHENERGAN	C				
			EFFEXOR	C				
			TEGRETOL	C				
			VALIUM	C				
			LEVOTHYROXIN	C				
			NEXIUM	C				
Blister								
Burns second degree								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2016	12470834	DIRECT				32 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site vesicles			ZECURITY, 6.5 MG	S	4 Patch (es) once a day applied as medicated patch to skin			
Application site erythema								
GABAPENTIN								
C								
BOTOX								
C								
FISH OIL								
C								
VITAMIN C								
C								
VITAMIN B12								
C								
Application site burn								



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15-Jun-2016	12470866	DIRECT		OT		40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY FLEXERIL TOPAMAX FIORICET ELAVIL TRAZADONE NAPROXEN COMPazine	S C C C C C C C	1 patch for 4 hour		TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2016	12470892	DIRECT		OT		32 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burning sensation			ZECUITY TEVA PHARMACEUTICALS TROKENDI XR CALCIUM WITH D3 MAGNESIUM COQ10 B2	S C C C C C		TEVA		
Drug ineffective								
Impaired work ability								
Hyperaesthesia								
Tenderness								
Scar								
Application site erythema								
Application site pain								
Device leakage								
Scab								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2016	12471400	DIRECT		OT		38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY, 6.5 MG	S Transdermal			TEVA	



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16-Jun-2016	12434311	EXPEDITED (15-DAY)		OT	US-TEVA-664612USA	48 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical Injury		ZECUITY	S	Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site pain								
Application site pruritus								
Application site rash								
Drug effect incomplete								
Hypertidrosis								
Miliaria								
Skin texture abnormal								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2016	12471545	EXPEDITED (15-DAY)		OT	US-TEVA-666658USA	47 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Application site oedema								
Application site urticaria								
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2016	12473099	EXPEDITED (15-DAY)		OT	US-TEVA-667234USA	41 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Application site scar								



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16-Jun-2016	12473376	EXPEDITED (15-DAY)		OT	S	Transdermal		US-TEVA-667683USA	52 YR	Female	USA
Preferred Term											
Application site burn											
Application site discoloration											
Application site erythema											
Product											
ZECUITY											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country	
16-Jun-2016	12474351	DIRECT			S				32 YR	Female	USA
Preferred Term											
Migraine											
Application site pruritus											
Product											
ZECUITY, 6.5 MG											
Dosage Text											
2 Patch (es) Every 4 hours applied as medicated patch to skin											
Manufacturer Control #											
Age											
32 YR											
Sex											
Female											
Country											
USA											
Manufacturer											
TEVA											
Drug ineffective											
Dry skin											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
16-Jun-2016	12474355	DIRECT		OT	S				44 YR	Female	USA
Preferred Term											
Rash											
Application site vesicles											
Product											
ZECUITY											
Dosage Text											
As Needed Applied as medicated patch to skin											
Manufacturer Control #											
Age											
44 YR											
Sex											
Female											
Country											
USA											
Manufacturer											
TEVA											
Application site burn											



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16-Jun-2016	12474366	DIRECT				30 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECUITY TEVA PHARMACEUTICALS LABETALOL WELLBUTRIN FIORICET SUMATRIPTAN OMEPRAZOLE	S C C C C C C		applied as medication patch on skin	TEVA	
Application site pain								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2016	11647870	EXPEDITED (15-DAY)		OT	US-TEVA-602489USA	42 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Thermal burn			ZECUITY	S	Transdermal	apply one patch as needed		TEVA
Scar			ambien	C				
Electric shock			amlodipine	C				
Pain			Celexa	C				
Application site erythema			Iron	C				
Drug ineffective			Tramadol	C				
Paraesthesia			Keppra	C				
Application site discoloration								
Application site pain								
Incorrect drug administration duration								
Product physical issue								
Product quality issue								



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17-Jun-2016	12378896	EXPEDITED (15-DAY)		OT	US-TEVA-659875USA	47 YR	Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site pain			ZECUITY	S Transdermal	used 3 patches		TEVA	
Application site discoloration			Topamax	C				
Application site exfoliation			Floricet	C				
Application site erythema			Maxalt	C				
Incorrect drug administration duration								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
17-Jun-2016	12434297	EXPEDITED (15-DAY)		OT	US-TEVA-663333USA	54 YR	Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site scar								
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
17-Jun-2016	12467028	EXPEDITED (15-DAY)		OT	US-TEVA-666032USA	48 YR	Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site induration								
Application site inflammation								
Application site pain								
Incorrect drug administration duration								
Product physical issue								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2016	12476138	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-667944USA		Female	USA
Preferred Term											
Application site burn											
Application site erythema											
Application site pain											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
17-Jun-2016	12477239	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-667939USA	35 YR	Female	USA
Preferred Term											
Application site burn											
Application site dryness											
Application site erythema											
Application site pain											
Application site paraesthesia											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
17-Jun-2016	12477403	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-668002USA		Female	USA
Preferred Term											
Application site burn											
Application site discoloration											
Application site pain											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
17-Jun-2016	12477425	EXPEDITED (15-DAY)		OT		Transdermal		US-TEVA-668006USA	26 YR	Female	USA
Preferred Term											
Application site burn											
Application site erythema											
Application site pain											



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2016	12477433	EXPEDITED (15-DAY)		OT	US-TEVA-668394USA	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal			TEVA	
Application site pain								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2016	12461677	EXPEDITED (15-DAY)		OT	US-TEVA-666323USA	47 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site burn								
Application site erythema								
Application site exfoliation								
Application site pruritus								
Product adhesion issue								
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2016	12484245	DIRECT		OT		44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECUITY TEVA PHARMACEUTICALS	S				TEVA	
Application site pain								



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21-Jun-2016	12434157	EXPEDITED (15-DAY)		OT	US-TEVA-662792USA	36 YR	Female	USA
Preferred Term			Product	Role Route	Dosage Text	Duration	Manufacturer	
Sunburn			ZECUITY	S Transdermal			TEVA	
Application site bruise								
Application site discolouration								
Drug effect incomplete								
Migraine								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2016	12453335	EXPEDITED (15-DAY)		OT	US-TEVA-666418USA	43 YR	Female	USA
Preferred Term			Product	Role Route	Dosage Text	Duration	Manufacturer	
Sunburn			ZECUITY	S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site pain								
Application site pruritus								
Product physical issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jun-2016	12486964	DIRECT				36 YR	Female	USA
Preferred Term			Product	Role Route	Dosage Text	Duration	Manufacturer	
Erythema			ZECUITY TEVA PHARMACEUTICALS	S	1 Patch (es) As Needed Applied as medicated patch to skin		TEVA	
Skin burning sensation			ADVIL	C				
Photosensitivity reaction								
Product quality issue								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2016	12491914	DIRECT	Y			27 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		ZECURITY 6.5 MG/4HR	S	Transdermal	1			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12155569	EXPEDITED (15-DAY)		OT	US-TEVA-640967USA	26 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pruritus								
Device leakage								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12168873	EXPEDITED (15-DAY)		OT	US-TEVA-641683USA	33 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal	used 8-10 patches over the last couple months		TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site pruritus								
Application site swelling								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12174505	EXPEDITED (15-DAY)		OT	US-TEVA-639087USA	43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECURITY	S	Transdermal			TEVA		
Adverse event								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site rash								
Application site scab								
Application site swelling								
Drug ineffective								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12211174	EXPEDITED (15-DAY)		OT	US-TEVA-645010USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECURITY	S	Transdermal			TEVA		
Application site discolouration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site scab								
Application site vesicles								
Blister rupture								
Device use error								



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23-Jun-2016	12249953	EXPEDITED (15-DAY)		OT	US-TEVA-649353USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burns first degree		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site pain								
Application site swelling								
Application site urticaria								
Paraesthesia								
Sunburn								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12254576	EXPEDITED (15-DAY)		OT	US-TEVA-650102USA	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burns first degree		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site scar								
Application site warmth								
Product physical issue								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12312117	EXPEDITED (15-DAY)		OT	US-TEVA-654699USA	38 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Sunburn		LAMICTAL	C					
Application site scar		DILANTIN	C					
Application site erythema		ALLEGRA D	C					
Application site discoloration								
Application site rash								
Application site urticaria								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12492711	EXPEDITED (15-DAY)		OT	US-TEVA-668822USA	62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal			TEVA	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site irritation								
Application site pain								
Dry skin								
Incorrect drug administration duration								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12493377	EXPEDITED (15-DAY)		OT	US-TEVA-669090USA	20 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Application site pain								



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23-Jun-2016	12493403	EXPEDITED (15-DAY)		OT	US-TEVA-669091USA	42 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pruritus								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12493526	EXPEDITED (15-DAY)		OT	US-TEVA-668813USA	41 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY	S	Transdermal			TEVA	
Application site burn								
Application site discolouration								
Application site dryness								
Application site erythema								
Application site inflammation								
Application site pain								
Drug ineffective								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12493612	EXPEDITED (15-DAY)		OT	US-TEVA-668816USA	27 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site pain								
Application site scab								
Drug ineffective								
Migraine								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12493810	EXPEDITED (15-DAY)		OT	US-TEVA-669030USA	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site scab								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12493905	EXPEDITED (15-DAY)		OT	US-TEVA-669483USA	34 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site paraesthesia								
Application site urticaria								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2016	12499131	DIRECT		OT		29 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site burn			ZECUITY 6.5 MG/4 HOUR PATCH, 6.5 MG TEVA P HARMACEUTICALS NARATRIPTAN	S		4 Patch(es) as needed applied as medicated patch to skin		TEVA
Chemical Injury								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2016	12499216	DIRECT				69 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Device leakage			ZECUITY SUMATRIPTAN INOTOPHORETIC TRANSDERMAL SYSTEM	S				TEVA
Application site erythema			SIMV/STATIN	C				
Application site burn			WELLBUTRIN	C				
Application site scar			BONIVA	C				
			ZALEPLON	C				
			PERCOCET	C				
			PHENERGAN	C				
			PILCOGARPINE	C				
			AMLODOPINE	C				
			MULTIVITAMIN	C				
			CALCIUM	C				
			MELATONIN	C				
			VALLERIAN	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2016	12498058	EXPEDITED (15-DAY)		DE	US-TEVA-669823USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Death			ZECUITY	S				TEVA



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12432518	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-663275USA		Female	USA
Preferred Term										
Application site burn										
Application site scar										
Application site paraesthesia										
Application site pruritus										
Application site scab										
Application site warmth										
Burning sensation										
<hr/>										
27-Jun-2016	12476498	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-668847USA	41 YR	Female	USA
Preferred Term										
Application site burn										
Application site erythema										
Application site inflammation										
Application site pain										
Application site warmth										
Product physical issue										
<hr/>										
27-Jun-2016	12497956	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-669826USA		Female	USA
Preferred Term										
Application site scar										



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27-Jun-2016	12500229	EXPEDITED (15-DAY)		OT	US-TEVA-669115USA	51 YR	Female	USA
Preferred Term								
Sunburn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site dryness			ZECURITY	S Transdermal			TEVA	
Application site erythema								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jun-2016	12500567	EXPEDITED (15-DAY)		OT	US-TEVA-669890USA		Female	USA
Preferred Term								
Application site scar			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site bruise			ZECURITY	S Transdermal			TEVA	
Application site mass								
Application site pain								
Application site pruritus								
Application site rash								
Application site warmth								
Product adhesion issue								
Product physical issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jun-2016	12500600	EXPEDITED (15-DAY)		OT	US-TEVA-669745USA	32 YR	Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Application site inflammation								
Application site paraesthesia								
Application site rash								
Product physical issue								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12500855	EXPEDITED (15-DAY)		OT	US-TEVA-669775USA	51 YR	Female	USA
Preferred Term								
Sunburn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site erythema								
Application site oedema								
Application site pain								
Application site paraesthesia								
Application site urticaria								
Drug ineffective								
Skin fissures								
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
27-Jun-2016	12501169	EXPEDITED (15-DAY)		OT	US-TEVA-669925USA	48 YR	Female	USA
Preferred Term								
Application site burn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site inflammation								
Sunburn								
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
27-Jun-2016	12501577	EXPEDITED (15-DAY)		OT	US-TEVA-670259USA		Female	USA
Preferred Term								
Application site burn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site erythema								
Application site pain								
Product adhesion issue								
Product physical issue								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12501977	EXPEDITED (15-DAY)		OT	US-TEVA-669778USA	38 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal	6.5 mg over 4 hours		TEVA	
Application site discharge								
Application site discoloration								
Application site erythema								
Application site pain								
Application site pruritus								
Application site scar								
Application site vesicles								
Drug effect incomplete								
Inappropriate schedule of drug administration								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12502171	EXPEDITED (15-DAY)		OT	US-TEVA-669975USA		Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site scar								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12502543	EXPEDITED (15-DAY)		OT	US-TEVA-670247USA	33 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal	6.5mg/4hr		TEVA	
Application site exfoliation								
Application site paraesthesia								
Application site reaction								
Application site vesicles								
Drug effect incomplete								
Wrong technique in product usage process								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12502556	EXPEDITED (15-DAY)		OT			US-TEVA-670237USA	47 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site scar		ZECUITY		S	Transdermal	6.5mg/4hour		TEVA		
Application site pain										
Application site scab										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12502561	EXPEDITED (15-DAY)		OT			US-TEVA-670225USA	42 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn		ZECUITY		S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12503388	DIRECT						61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema		ZECUITY 6.5 MG TEVA PHARMACEUTICALS		S		applied as medicated patch to skin		TEVA		
Application site irritation		SUMA TRIPTAN		C						
		OMEPRAZOLE		C						
		PHENERGAN		C						
		TORADOL		C						
		APLENZIN		C						
		ELAVIL		C						
		INDERAL		C						
		CALCIUM		C						
		MAGNESIUM		C						

Application site swelling



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27-Jun-2016	12503533	DIRECT		OT		42 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site bruise		ZECUITY	S	Topical	1 patch as needed applied to a surface, usually the skin			
Application site rash		SUMATRIPTAN	C					
Application site pruritus		METROCHLOPRAMIDE	C					
		ADVIL	C					
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12503620	DIRECT		OT		37 YR	Unknown	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECUITY	S		As needed applied to a surface, usually the skin		TEVA	
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site paraesthesia								
Device leakage								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12449270	EXPEDITED (15-DAY)		OT	US-TEVA-665364USA	45 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg / 4 hours			
Application site erythema								
Application site pain								
Incorrect drug administration duration								



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28-Jun-2016	12503682	EXPEDITED (15-DAY)		OT	US-TEVA-669810USA	38 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site pain								
Application site paraesthesia								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12504395	EXPEDITED (15-DAY)		OT	US-TEVA-670294USA	34 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
Application site pain								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12505705	EXPEDITED (15-DAY)		OT	US-TEVA-670328USA	30 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site dryness								
Application site pain								
Application site pruritus								
Application site scab								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12505800	EXPEDITED (15-DAY)		OT	US-TEVA-670275USA	42 YR	Female	USA
Preferred Term								
Application site burn								
Application site discoloration								
Application site erythema								
Application site pruritus								
Application site rash								
Application site swelling								
Application site vesicles								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2016	12505802	EXPEDITED (15-DAY)		OT	US-TEVA-670313USA	55 YR	Female	USA
Preferred Term								
Application site scar								
Application site erythema								
Application site pain								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2016	12505821	EXPEDITED (15-DAY)		OT	US-TEVA-670289USA	32 YR	Female	USA
Preferred Term								
Application site scar								
Application site dryness								
Application site irritation								
Application site vesicles								
Wound								



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28-Jun-2016	12505900	EXPEDITED (15-DAY)		OT	US-TEVA-669931USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discharge								
Application site pain								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12505910	EXPEDITED (15-DAY)		OT	US-TEVA-669928USA	24 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site oedema								
Application site pain								



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28-Jun-2016	12505924	EXPEDITED (15-DAY)		OT	US-TEVA-672291USA	47 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECURITY		S Transdermal				TEVA
Application site discolouration								
Application site dryness								
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
Application site scar								
Application site urticaria								
Application site vesicles								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12506111	EXPEDITED (15-DAY)		HO,OT	US-TEVA-670194USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Cerebrovascular accident		ZECURITY		S Transdermal				TEVA
Adverse event								
Agitation								
Blood pressure increased								
Headache								
Intentional overdose								
Vomiting								



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28-Jun-2016	12506214	EXPEDITED (15-DAY)		OT	US-TEVA-669815USA	47 YR	Female	USA
Preferred Term								
Burns second degree								
Application site pain								
Application site erythema								
Application site pain								
Drug ineffective								
Product physical issue								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2016	12506418	EXPEDITED (15-DAY)		OT	US-TEVA-670600USA		Female	USA
Preferred Term								
Application site burn								
Application site pain								
Application site paraesthesia								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2016	12506619	EXPEDITED (15-DAY)		OT	US-TEVA-670477USA		Female	USA
Preferred Term								
Application site burn								
Application site dryness								
Application site pain								
Application site pruritus								
Application site rash								
Application site warmth								
Incorrect drug administration duration								



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28-Jun-2016	12507479	DIRECT	Y	OT		31 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Rash		ZECURITY, 6.5 MG TEVA	S	Cutaneous			TEVA	
Medical device site irritation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12507509	DIRECT				40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECURITY, 6.5 MG TEVA NEUROSCIENCE	S		1 Patch as needed applied as medicated patch to skin		TEVA	
Application site discomfort								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12177349	EXPEDITED (15-DAY)		OT	US-TEVA-642131USA	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site scab								
Application site vesicles								
Application site warmth								
Product adhesion issue								



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29-Jun-2016	12461678	EXPEDITED (15-DAY)		OT	US-TEVA-665971USA		Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site pain			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Application site erythema			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Application site pruritus								
Drug ineffective								
Product physical issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2016	12473370	EXPEDITED (15-DAY)		OT	US-TEVA-666725USA	60 YR	Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site erythema								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2016	12477265	EXPEDITED (15-DAY)		OT	US-TEVA-667691USA	36 YR	Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site hypersensitivity								
Application site irritation								
Application site pain								
Application site scab								
Application site swelling								
Application site warmth								
Incorrect product storage								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12486664	EXPEDITED (15-DAY)		OT	US-TEVA-668357USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site rash								
Application site reaction								
Application site urticaria								
Drug effect incomplete								
Incorrect drug administration duration								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12502250	EXPEDITED (15-DAY)		OT	US-TEVA-669977USA	22 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site vesicles								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12508639	EXPEDITED (15-DAY)		OT	US-TEVA-669929USA	50 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site vesicles								
Drug ineffective								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12509072	EXPEDITED (15-DAY)		OT	US-TEVA-670616USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12509740	EXPEDITED (15-DAY)		OT	US-TEVA-671016USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12509802	EXPEDITED (15-DAY)		OT	US-TEVA-671034USA	49 YR	Female	USA
Preferred Term								
Sunburn				Role Route	Dosage Text	Duration	Manufacturer	
Application site burn				S Transdermal			TEVA	
Application site discomfort				S Transdermal			TEVA	
Application site erythema								
Application site inflammation								
Application site pain								
Application site paraesthesia								
Application site urticaria								
Incorrect drug administration duration								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12509812	EXPEDITED (15-DAY)		OT	US-TEVA-671063USA		Female	USA
Preferred Term								
Application site burn				Role Route	Dosage Text	Duration	Manufacturer	
Application site inflammation				S Transdermal			TEVA	
Application site pain								
Application site reaction								
Incorrect drug administration duration								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12509816	EXPEDITED (15-DAY)		OT	US-TEVA-671065USA	21 YR	Female	USA
Preferred Term								
Application site scar				Role Route	Dosage Text	Duration	Manufacturer	
Application site burn				S Transdermal			TEVA	
Application site discoloration								
Application site scab								
Drug ineffective								
Migraine								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12510010	EXPEDITED (15-DAY)		OT	US-TEVA-670620USA	31 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Sunburn		ZECURITY		S Transdermal				TEVA
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site vesicles								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12510691	EXPEDITED (15-DAY)		OT	US-TEVA-671024USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Sunburn		ZECURITY		S Transdermal				TEVA
Application site burn								
Application site discolouration								
Application site dryness								
Application site erythema								
Application site inflammation								
Application site pain								
Application site paraesthesia								
Chest discomfort								
Product physical issue								
Throat tightness								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12510780	EXPEDITED (15-DAY)		OT	US-TEVA-669882USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site Inflammation								
Application site pain								
Application site pruritus								
Application site pustules								
Application site scab								
Application site vesicles								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12511111	EXPEDITED (15-DAY)		OT	US-TEVA-670958USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical injury		ZECURITY	S	Transdermal			TEVA	
Application site dryness								
Application site pain								
Drug ineffective								
Incorrect drug administration duration								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12511158	EXPEDITED (15-DAY)		OT	US-TEVA-670960USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12511382	EXPEDITED (15-DAY)		HO,OT	US-TEVA-670597USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Brain neoplasm		ZECUITY	S	Transdermal			TEVA	
Product adhesion issue								
Product physical issue								
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12510782	EXPEDITED (15-DAY)		OT	US-TEVA-670522USA	29 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal			TEVA	
Application site dryness								
Application site pain								
Application site vesicles								
Blood blister								
Incorrect drug administration duration								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12515686	EXPEDITED (15-DAY)		OT	US-TEVA-671360USA		Female	USA
Preferred Term								
Application site burn								
Application site discoloration								
Application site exfoliation								
Application site irritation								
Application site scar								
Application site vesicles								
Product physical issue								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
30-Jun-2016	12516765	EXPEDITED (15-DAY)		OT	US-TEVA-670880USA	33 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site paraesthesia								
Application site scar								
Application site vesicles								
Drug ineffective								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
30-Jun-2016	12517151	EXPEDITED (15-DAY)		OT	US-TEVA-671448USA	46 YR	Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site paraesthesia								
Application site warmth								
Inappropriate schedule of drug administration								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12517154	EXPEDITED (15-DAY)		OT	US-TEVA-670563USA	36 YR	Male	USA
Preferred Term								
Application site burn								
Application site bruise								
Application site discoloration								
Application site erythema								
Application site pruritus								
Product								
ZECUITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Age								
36 YR								
Sex								
Male								
Country								
USA								
Manufacturer Control #								
US-TEVA-670563USA								
Outcomes								
OT								
Health Professional								
Manufacturer Control #								
US-TEVA-671658USA								
Age								
Sex								
Female								
Country								
USA								
Duration								
6.5 mg over 4 hours								
Manufacturer								
TEVA								
Dosage Text								
6.5 mg over 4 hours								
Role Route								
S Transdermal								
Product								
ZECUITY								
Preferred Term								
Application site scar								
Application site discoloration								
Application site erythema								
Application site rash								
Application site exfoliation								
Drug ineffective								
Application site erythema								
Application site exfoliation								
Drug ineffective								
EDA Received Date								
30-Jun-2016								
Case #								
12517186								
Case Type								
EXPEDITED (15-DAY)								
Health Professional								
Outcomes								
OT								
Manufacturer Control #								
US-TEVA-671796USA								
Age								
Sex								
Female								
Country								
USA								
Duration								
6.5 mg over 4 hours								
Manufacturer								
TEVA								
Dosage Text								
6.5 mg over 4 hours								
Role Route								
S Transdermal								
Product								
ZECUITY								
Preferred Term								
Application site scar								
Application site discoloration								
Application site erythema								
Application site rash								
Application site exfoliation								
Drug ineffective								
Application site erythema								
Application site exfoliation								
Drug ineffective								



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30-Jun-2016	12517760	EXPEDITED (15-DAY)		OT	US-TEVA-670556USA	45 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal			TEVA	
Application site bruise								
Application site discolouration								
Application site erythema								
Application site Inflammation								
Application site pain								
Hyperhidrosis								
Incorrect drug administration duration								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12517840	EXPEDITED (15-DAY)		OT	US-TEVA-671076USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site scar								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12518229	EXPEDITED (15-DAY)		OT	US-TEVA-671067USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal	6.5mg/4hr		TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Drug ineffective								
Product physical issue								
Wrong technique in product usage process								



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30-Jun-2016	12518428	EXPEDITED (15-DAY)		OT	US-TEVA-671786USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical Injury		ZECUITY		S Transdermal			TEVA	
Application site discolouration								
Application site dryness								
Application site erythema								
Application site mass								
Application site pain								
Application site pruritus								
Application site rash								
Product adhesion issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12518432	EXPEDITED (15-DAY)		OT	US-TEVA-671799USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site pain								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12518493	EXPEDITED (15-DAY)		OT	US-TEVA-671787USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Administration site bruise								
Application site erythema								
Application site inflammation								
Application site pain								
Application site vesicles								
Incorrect drug administration duration								



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30-Jun-2016	12518503	EXPEDITED (15-DAY)		OT	US-TEVA-671788USA	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Sunburn		ZECURITY		S Transdermal				TEVA
Application site discolouration								
Application site dryness								
Application site erythema								
Application site pain								
Application site swelling								
Medication residue present								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12518518	EXPEDITED (15-DAY)		OT	US-TEVA-671789USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECURITY		S Transdermal				TEVA
Application site discolouration								
Application site dryness								
Application site erythema								
Application site paraesthesia								



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30-Jun-2016	12518622	EXPEDITED (15-DAY)		OT	US-TEVA-671074USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical Injury		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site irritation								
Application site mass								
Application site pain								
Application site pruritus								
Product physical issue								
Skin wrinkling								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12518739	EXPEDITED (15-DAY)		OT	US-TEVA-671431USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site urticaria								
Incorrect drug administration duration								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12519882	EXPEDITED (15-DAY)		OT	US-TEVA-672132USA	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site scar								
Drug effect incomplete								
Paraesthesia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12519917	EXPEDITED (15-DAY)		OT	US-TEVA-672149USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12519918	EXPEDITED (15-DAY)		OT	US-TEVA-672164USA	24 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pain								



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30-Jun-2016	12519972	EXPEDITED (15-DAY)		OT	US-TEVA-671232USA	32 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal			TEVA	
Application site paraesthesia				S Transdermal			TEVA	
Application site erythema								
Application site inflammation								
Application site pain								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12520065	EXPEDITED (15-DAY)		OT	US-TEVA-671336USA	22 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site erythema								
Application site rash								
Application site vesicles								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12520104	EXPEDITED (15-DAY)		OT	US-TEVA-671609USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal	has used 4 patches/ dates not provided		TEVA	
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
Application site urticaria								
Wrong technique in product usage process								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12520115	EXPEDITED (15-DAY)		OT	US-TEVA-671639USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site inflammation								
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12520116	EXPEDITED (15-DAY)		OT	US-TEVA-671651USA	25 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY	S	Transdermal	used 3 times		TEVA	
Application site discolouration								
Application site inflammation								
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12101822	EXPEDITED (15-DAY)		OT	US-TEVA-637327USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site injury								
Application site reaction								
Urticaria								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12116874	EXPEDITED (15-DAY)		OT	US-TEVA-636448USA	52 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal			TEVA	
Application site warmth				S Transdermal			TEVA	
Application site discomfort								
Application site erythema								
Application site exfoliation								
Application site pain								
Drug effect incomplete								
Drug ineffective								
Incorrect drug administration duration								
Product label confusion								
Therapeutic response delayed								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12224074	EXPEDITED (15-DAY)		OT	US-TEVA-646710USA	48 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site pain				S Transdermal			TEVA	
Application site discoloration								
Application site scab								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12356393	EXPEDITED (15-DAY)		OT	US-TEVA-658338USA	41 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site erythema								
Application site pain								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12493593	EXPEDITED (15-DAY)		OT	US-TEVA-669086USA	36 YR	Female	USA
Preferred Term								
Application site burn				Role Route	Dosage Text	Duration	Manufacturer	
Application site exfoliation			S	Transdermal			TEVA	
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2016	12501191	EXPEDITED (15-DAY)		OT	US-TEVA-669888USA	19 YR	Female	USA
Preferred Term								
Application site burn				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			S	Transdermal			TEVA	
Application site inflammation								
Application site pain								
Application site scab								
Application site scar								
Application site urticaria								
Application site warmth								
Product adhesion issue								
Product physical issue								
Skin disorder								
Wrong technique in product usage process								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2016	12509078	EXPEDITED (15-DAY)		OT	US-TEVA-670623USA	54 YR	Male	USA
Preferred Term								
Application site burn				Role Route	Dosage Text	Duration	Manufacturer	
Application site exfoliation			S	Transdermal	6.5 mg over 4 hours		TEVA	
Application site pain								
Application site scar								
Application site vesicles								
Product physical issue								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12520629	EXPEDITED (15-DAY)		OT	US-TEVA-672168USA	38 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Application site scab								
Application site urticaria								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12520680	EXPEDITED (15-DAY)		OT	US-TEVA-672224USA	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site vesicles								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12521003	EXPEDITED (15-DAY)		OT	US-TEVA-671446USA		Female	USA
Preferred Term								
Application site haemorrhage								
Application site erythema								
Application site paraesthesia								
Application site pruritus								
Application site swelling								
Application site vesicles								
Incorrect drug administration duration								
Scab								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12521014	EXPEDITED (15-DAY)		OT	US-TEVA-671441USA	38 YR	Female	USA
Preferred Term								
Application site burn								
Application site exfoliation								
Aura								
Vision blurred								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12521659	EXPEDITED (15-DAY)		OT	US-TEVA-671761USA	36 YR	Female	USA
Preferred Term								
Application site burn								
Application site vesicles								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12521685	EXPEDITED (15-DAY)		OT	US-TEVA-672306USA	24 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal	6.5 mg over 4 hours		TEVA	
Application site dryness								
Application site erythema								
Application site pruritus								
Application site reaction								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12521718	EXPEDITED (15-DAY)		OT	US-TEVA-672328USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site pain								
Incorrect drug administration duration								
Product adhesion issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12521996	EXPEDITED (15-DAY)		OT	US-TEVA-672665USA	53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Sunburn								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522051	EXPEDITED (15-DAY)		OT	US-TEVA-672314USA		Female	USA
Preferred Term								
Sunburn								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522059	EXPEDITED (15-DAY)		OT	US-TEVA-672317USA	43 YR	Male	USA
Preferred Term								
Chemical injury								
Application site discolouration								
Application site dryness								
Application site erythema								
Application site inflammation								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522121	EXPEDITED (15-DAY)		OT	US-TEVA-672382USA		Female	USA
Preferred Term								
Application site scar								
Application site erythema								
Application site inflammation								
Application site paraesthesia								
Application site pruritus								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522139	EXPEDITED (15-DAY)		OT	US-TEVA-672669USA	38 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site pain								
Application site pruritus								
Application site swelling								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522195	EXPEDITED (15-DAY)		OT	US-TEVA-672671USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY	S	Transdermal			TEVA	
Application site haemorrhage								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522349	EXPEDITED (15-DAY)		OT	US-TEVA-672657USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY	S	Transdermal			TEVA	
Application site eczema								
Application site rash								



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01-Jul-2016	12522355	EXPEDITED (15-DAY)		OT	US-TEVA-672304USA	22 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pain								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522361	EXPEDITED (15-DAY)		OT	US-TEVA-672301USA	36 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site urticaria								
Drug prescribing error								
Wrong technique in product usage process								



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EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2016	12522398	EXPEDITED (15-DAY)		OT	US-TEVA-672356USA	33 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site irritation								
Application site pain								
Application site pruritus								
Application site urticaria								
Drug ineffective								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2016	12522516	EXPEDITED (15-DAY)		OT	US-TEVA-672214USA	40 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Sunburn	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Drug ineffective								
Skin exfoliation								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2016	12522540	EXPEDITED (15-DAY)		OT	US-TEVA-672201USA	53 YR	Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Sunburn	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site pain								
Application site pruritus								
Application site warmth								
Skin exfoliation								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522570	EXPEDITED (15-DAY)		OT	US-TEVA-672334USA	30 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site discolouration								
Application site irritation								
Application site paraesthesia								
Application site pustules								
Application site vesicles								
Drug ineffective								
Wrong technique in product usage process								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522677	EXPEDITED (15-DAY)		OT	US-TEVA-672651USA	41 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY	S	Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site vesicles								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12522829	EXPEDITED (15-DAY)		OT	US-TEVA-671792USA	22 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Drug effect Incomplete								
Incorrect drug administration duration								
Product adhesion issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12523109	EXPEDITED (15-DAY)		OT	US-TEVA-672981USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical injury		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site dryness								
Application site erythema								
Application site scar								
Drug effect Incomplete								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12523115	EXPEDITED (15-DAY)		OT	US-TEVA-672982USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Throat tightness		ZECUITY	S	Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site scar								
Dyspnoea								
Electric shock								
Intentional product use issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12526034	DIRECT				43 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Hyperhidrosis		ZECUITY TEVA PHARMACEUTICALS	S		Applied as medicated patch to skin	3 HR	TEVA	
Migraine		ADDERALL	C					
Product adhesion issue		NORTRIPELINE	C					
Application site burn								
Fall								
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01-Jul-2016	12526298	DIRECT				43 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discolouration		ZECUITY	S	Topical	1 Patch(es) As Needed Applied as medicated patch to skin	1 MTH	TEVA	
		VITAMINS		C				



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02-Jul-2016	12523317	EXPEDITED (15-DAY)		OT	US-TEVA-671432USA	37 YR	Male	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site paraesthesia								
Product physical issue								
Product								
ZECUITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Age								
45 YR								
Sex								
Female								
Country								
USA								
Manufacturer Control #								
US-TEVA-672278USA								
Outcomes								
OT								
Health Professional								
Case Type								
EXPEDITED (15-DAY)								
Case #								
12523318								
FDA Received Date								
02-Jul-2016								
Preferred Term								
Application site burn								
Application site rash								
Application site pain								
Product								
ZECUITY								
Role Route								
S Transdermal								
Dosage Text								
#3								
TEVA								
Duration								
#2								
TEVA								
Manufacturer								
TEVA								
Manufacturer Control #								
#1								
Age								
41 YR								
Sex								
Female								
Country								
USA								
Manufacturer								
TEVA								
Duration								
41 YR								
Sex								
Female								
Country								
USA								
Manufacturer Control #								
US-TEVA-672605USA								
Outcomes								
OT								
Health Professional								
Case Type								
EXPEDITED (15-DAY)								
Case #								
12523349								
FDA Received Date								
02-Jul-2016								
Preferred Term								
Sunburn								
Application site erythema								
Application site pain								
Application site vesicles								
Application site warmth								
Drug ineffective								
Incorrect drug administration duration								
Scab								



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04-Jul-2016	12524554	EXPEDITED (15-DAY)		OT	US-TEVA-672368USA		Female	USA
Preferred Term								
Application site burn								
ZECURITY								
S Transdermal								
TEVA								
Adverse event								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Jul-2016	12524556	EXPEDITED (15-DAY)		OT	US-TEVA-672370USA	57 YR	Female	USA
Preferred Term								
Application site burn								
ZECURITY								
S Transdermal								
TEVA								
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site rash								
Application site scar								
Application site vesicles								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Jul-2016	12524557	EXPEDITED (15-DAY)		OT	US-TEVA-672372USA	34 YR	Female	USA
Preferred Term								
Application site burn								
ZECURITY								
S Transdermal								
TEVA								
Application site discolouration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site vesicles								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2016	12524566	EXPEDITED (15-DAY)		OT	US-TEVA-672644USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2016	12524578	EXPEDITED (15-DAY)		OT	US-TEVA-672958USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site discolouration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site warmth								
Drug ineffective								
Incorrect drug administration duration								
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2016	12524589	EXPEDITED (15-DAY)		OT	US-TEVA-672920USA	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Incorrect drug administration duration								
Paraesthesia								
Skin exfoliation								



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04-Jul-2016	12524925	EXPEDITED (15-DAY)		OT	US-TEVA-672369USA	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site burn								
Application site discolouration								
Application site erythema								
Application site mass								
Application site pain								
Drug ineffective								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2016	12524941	EXPEDITED (15-DAY)		OT	US-TEVA-672375USA	62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pruritus								
Application site scar								
Application site urticaria								



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04-Jul-2016	12524942	EXPEDITED (15-DAY)		OT	US-TEVA-672603USA		Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site pain								
Application site pruritus								
Application site urticaria								
Drug ineffective								
Dry skin								
EDA Received Date								
04-Jul-2016	12524981	EXPEDITED (15-DAY)		OT	US-TEVA-672941USA		Female	USA
Preferred Term								
Application site burn								
Application site discoloration								
Application site discomfort								
Application site erythema								
Application site pruritus								
Application site urticaria								
Product physical issue								



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04-Jul-2016	12524990	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-672963USA	46 YR	Male	USA		
Preferred Term												
Thermal burn												
Application site discolouration												
Application site erythema												
Application site Inflammation												
Application site pain												
Application site paraesthesia												
Application site pruritus												
Application site scab												
EDA Received Date												
Case #												
Case Type												
Health Professional												
Outcomes												
Role												
Route												
Dosage Text												
Duration												
Manufacturer												
Age												
Sex												
Country												
04-Jul-2016	12525002	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-672973USA		Female	USA		
Preferred Term												
Application site burn												
Application site scar												
Application site discolouration												
Application site erythema												
Application site pain												
Drug ineffective												
Incorrect drug administration duration												
EDA Received Date												
Case #												
Case Type												
Health Professional												
Outcomes												
Role												
Route												
Dosage Text												
Duration												
Manufacturer												
Age												
Sex												
Country												
04-Jul-2016	12525003	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-672645USA	43 YR	Female	USA		
Preferred Term												
Application site burn												
Application site erythema												
Drug ineffective												



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04-Jul-2016	12525028	EXPEDITED (15-DAY)		OT	US-TEVA-672643USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site pain								
Application site pruritus								
Application site urticaria								
Erythema								
Skin exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2016	12525184	EXPEDITED (15-DAY)		OT	US-TEVA-673004USA	34 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site discolouration								
Application site pain								
Application site scar								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2016	12525214	EXPEDITED (15-DAY)		OT	US-TEVA-673340USA	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pain								
Application site pruritus								
Incorrect drug administration duration								



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04-Jul-2016	12525234	EXPEDITED (15-DAY)		OT	US-TEVA-673343USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site exfoliation								
Application site irritation								
Application site pain								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2016	12525321	EXPEDITED (15-DAY)		OT	US-TEVA-672934USA	63 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY		S Transdermal			TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
Application site scab								
Incorrect drug administration duration								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2016	12525337	EXPEDITED (15-DAY)		OT	US-TEVA-672639USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burns first degree		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site pain								
Sunburn								



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04-Jul-2016	12525460	EXPEDITED (15-DAY)		OT	US-TEVA-673634USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal			TEVA	
Application site bruise								
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site scab								
Application site vesicles								
Incorrect drug administration duration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2016	12495457	EXPEDITED (15-DAY)		OT	US-TEVA-669121USA	38 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical injury		ZECUITY	S	Transdermal			TEVA	
Application site exfoliation								
Application site pain								
Application site rash								
Sunburn								



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05-Jul-2016	12497012	EXPEDITED (15-DAY)		OT	US-TEVA-669092USA	26 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal	6.5 mg over 4 hours		TEVA	
Application site discolouration								
Application site paraesthesia								
Dry skin								
Hyperkeratosis								
Product physical issue								
Sticky skin								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2016	12504333	EXPEDITED (15-DAY)		OT	US-TEVA-670182USA	37 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
Application site scar								
Application site urticaria								
Application site warmth								



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05-Jul-2016	12522437	EXPEDITED (15-DAY)		OT	US-TEVA-672329USA	58 YR	Female	USA
Preferred Term								
Sunburn								
Application site burn								
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site paraesthesia								
Application site scar								
Product adhesion issue								
Product physical issue								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2016	12527438	EXPEDITED (15-DAY)		OT	US-TEVA-673632USA	57 YR	Female	USA
Preferred Term								
Application site burn								
Application site discolouration								
Application site erythema								
Application site paraesthesia								
Incorrect drug administration duration								



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05-Jul-2016	12528724	EXPEDITED (15-DAY)		OT	US-TEVA-673598USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site pain								
Application site pruritus								
Hypersensitivity								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2016	12528762	EXPEDITED (15-DAY)		OT	US-TEVA-673603USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2016	12528963	EXPEDITED (15-DAY)		OT	US-TEVA-673617USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Throat irritation								



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06-Jul-2016	12342497	EXPEDITED (15-DAY)		OT	US-TEVA-657842USA	35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site scab		Riboflavin		C Unknown				
		women one daily multivitamin		C Unknown				
		magnesium		C Unknown				
		CO Q10		C				
		zofran		C				
		Reglan		C				
		Relpax		C Unknown				
		MAXALT		C				
		AMERGE		C Unknown				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12529498	EXPEDITED (15-DAY)		OT	US-TEVA-672984USA	30 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site vesicles								



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06-Jul-2016	12529501	EXPEDITED (15-DAY)		OT	US-TEVA-672994USA	61 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site dermatitis								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pain								
Application site warmth								
Drug effect incomplete								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12529820	EXPEDITED (15-DAY)		OT	US-TEVA-673361USA	60 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site pain								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12531739	EXPEDITED (15-DAY)		OT	US-TEVA-672985USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site pain								
Chemical injury								



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06-Jul-2016	12531775	EXPEDITED (15-DAY)		OT	US-TEVA-672991USA	45 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site inflammation								
Hypertidrosis								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12531792	EXPEDITED (15-DAY)		OT	US-TEVA-672996USA	21 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12477244	EXPEDITED (15-DAY)		OT	US-TEVA-667700USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site pain		ZECUITY		S Transdermal			TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site scab								
Drug administered at inappropriate site								



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07-Jul-2016	12535503	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-673289USA		Female	USA
Preferred Term										
Application site burn										
Application site discoloration										
Application site erythema										
Application site pain										
Application site scar										
Application site swelling										
Incorrect drug administration duration										
Product physical issue										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12535756	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-673297USA		Female	USA
Preferred Term										
Sunburn										
Application site dryness										
Application site erythema										
Application site exfoliation										
Application site irritation										
Application site warmth										
Drug effect incomplete										
Product adhesion issue										
Product physical issue										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12538024	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-673791USA	45 YR	Female	USA
Preferred Term										
Application site burn										
Application site pain										



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07-Jul-2016	12538194	EXPEDITED (15-DAY)		OT	US-TEVA-673294USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal			TEVA	
Application site eczema								
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
Application site urticaria								
Dry skin								
Incorrect drug administration duration								
Product adhesion issue								
Rash generalised								
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12538200	EXPEDITED (15-DAY)		OT	US-TEVA-674736USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site scar								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12538237	EXPEDITED (15-DAY)		OT	US-TEVA-674487USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site scar								



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07-Jul-2016	12538364	EXPEDITED (15-DAY)		OT	US-TEVA-673592USA	35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Sunburn		ZECUITY		S Transdermal				TEVA
Application site erythema								
Application site pain								
Incorrect drug administration duration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	11909384	NON-EXPEDITED			US-TEVA-604820USA	62 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective		ZECUITY		S Transdermal				TEVA
Device battery issue								



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08-Jul-2016	12245110	NON-EXPEDITED			US-TEVA-627559USA	49 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECUIITY	S	Transdermal	6.5 mg / 4 hours		TEVA
Application site discoloration			ZECUIITY	S	Transdermal			TEVA
Device leakage			ZECUIITY	S	Transdermal			TEVA
Application site pain			ZECUIITY	S				TEVA
			NUVARING	C				
			ZOFRAN	C				
			TENORMIN	C				
			ZANNAFLEX	C				
			SYNTHROID	C				
			CYTOMEL	C				
			PHENERGAN	C				
			ZONEGRAN	C				
			ALBUTEROL	C				
			KETOPROFEN	C				
			REGLAN	C				
			ZANTAC	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12247944	NON-EXPEDITED			US-TEVA-629492USA	53 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECUIITY	S	Transdermal			TEVA
			ZECUIITY	S	Transdermal			TEVA



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08-Jul-2016	12247978	NON-EXPEDITED			US-TEVA-630492USA	45 YR	Female	USA
Preferred Term								
Application site pain			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal			TEVA
Application site pain								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12247989	NON-EXPEDITED			US-TEVA-630491USA	44 YR	Female	USA
Preferred Term								
Application site pain			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pain			ZECUITY	S	Transdermal			TEVA
Application site pain								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12277202	NON-EXPEDITED			US-TEVA-635795USA	46 YR	Female	USA
Preferred Term								
Paraesthesia			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA
Application site irritation								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12277248	NON-EXPEDITED			US-TEVA-639065USA	28 YR	Male	USA
Preferred Term								
Application site warmth			Product	Role	Route	Dosage Text	Duration	Manufacturer
Underdose			ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA
Device battery issue			LEXAPRO	C				
Product quality issue			PRILOSEC	C				
			PROPRANLOL	C				
			TRAZODONE	C				



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08-Jul-2016	12277275	NON-EXPEDITED			US-TEVA-636935USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Device leakage	PROTONIX	C						
Device battery issue	KETAMINE	C						
Incorrect product storage	Gralise	C						
Application site swelling	Depfin	C						
	VITAMIN D	C						
	MAGNESIUM OXIDE	C						
	Vyvanse	C						
	TIZANIDINE	C						
	ZOFIRAN	C						
	PHENERGAN	C						
	ZOLOFT	C						
	OXYCONTIN	C						
	TRAMADOL	C						
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12277283	NON-EXPEDITED			US-TEVA-636387USA	39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site exfoliation	ZECURITY	S	Transdermal			TEVA		
Application site acne								
Application site erythema								
Application site pain								
Application site pruritus								
Application site swelling								



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08-Jul-2016	12277322	NON-EXPEDITED			US-TEVA-640277USA	63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash Application site erythema Application site pruritus	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12281731	NON-EXPEDITED			US-TEVA-641849USA	43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug effect decreased Drug ineffective	ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12284687	NON-EXPEDITED			US-TEVA-646010USA	29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective Device battery issue Muscular weakness Product physical issue	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12284695	NON-EXPEDITED			US-TEVA-645963USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site oedema Application site pain Application site pruritus Drug effect incomplete	ZECURITY	S	Transdermal	6.5mg/4 hours		TEVA		



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08-Jul-2016	12284700	NON-EXPEDITED			S	Transdermal	US-TEVA-646346USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECURITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12284833	NON-EXPEDITED					US-TEVA-647797USA	52 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECURITY		S	Transdermal				TEVA
Application site exfoliation			ZECURITY		S	Transdermal				TEVA
Application site exfoliation										
Application site pruritus										
Application site rash										
Application site swelling										
Device battery issue										
Device issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12284841	NON-EXPEDITED					US-TEVA-648090USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECURITY		S					TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12284845	NON-EXPEDITED					US-TEVA-647792USA	63 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Dizziness			ZECURITY		S	Transdermal				TEVA
Abdominal discomfort										
Drug ineffective										



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08-Jul-2016	12522680	NON-EXPEDITED			S	Transdermal	US-TEVA-653976USA	35 YR	Female	USA
Preferred Term										
Application site vesicles										
Application site erythema										
Device battery issue										
Device leakage										
Product adhesion issue										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540509	NON-EXPEDITED			S	Transdermal	US-TEVA-649443USA	30 YR	Female	USA
Preferred Term										
Application site pain										
ZECURITY										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540510	NON-EXPEDITED			S	Transdermal	US-TEVA-633872USA	40 YR	Female	USA
Preferred Term										
Paraesthesia										
Application site erythema										
Application site papules										
Application site pruritus										
Application site rash										
Device battery issue										
Device leakage										



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08-Jul-2016	12540511	NON-EXPEDITED			S	Transdermal	US-TEVA-635740USA	28 YR	Female	USA
Preferred Term			Product				Dosage Text	Duration	Manufacturer	
Application site pain			ZECUITY						TEVA	
Application site erythema										
Application site paraesthesia										
Application site urticaria										
Drug ineffective										
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540512	NON-EXPEDITED			S	Transdermal	US-TEVA-649319USA	51 YR	Female	USA
Preferred Term			Product				Dosage Text	Duration	Manufacturer	
Drug effect incomplete			ZECUITY						TEVA	
Drug effect decreased										
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540513	NON-EXPEDITED			S	Transdermal	US-TEVA-635745USA		Female	USA
Preferred Term			Product				Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY						TEVA	
Application site swelling										
Device leakage			SEPTRA							
Product adhesion issue										
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540514	NON-EXPEDITED			S	Transdermal	US-TEVA-649439USA	31 YR	Female	USA
Preferred Term			Product				Dosage Text	Duration	Manufacturer	
Application site vesicles			ZECUITY						TEVA	
Application site erythema										
Application site oedema										
Application site pain										
Application site paraesthesia										



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08-Jul-2016	12540515	NON-EXPEDITED			S	Transdermal	US-TEVA-649278USA	42 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY						TEVA	
Application site pain										
Application site pain										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540516	NON-EXPEDITED			S	Transdermal	US-TEVA-650092USA	22 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY						TEVA	
Application site erythema										
Drug ineffective										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540517	NON-EXPEDITED			S	Transdermal	US-TEVA-649280USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECURITY						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540518	NON-EXPEDITED			S	Transdermal	US-TEVA-649767USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Palpitations			ZECURITY						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540519	NON-EXPEDITED			S	Transdermal	US-TEVA-649785USA	28 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY						TEVA	



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08-Jul-2016	12540520	NON-EXPEDITED			S	Transdermal	US-TEVA-649284USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain	ZECURITY								TEVA	
Application site bruise										
Application site erythema										
Product physical issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540521	NON-EXPEDITED			S	Transdermal	US-TEVA-649399USA	45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Feeling abnormal	ZECURITY								TEVA	
Application site erythema										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540522	NON-EXPEDITED			S	Transdermal	US-TEVA-649275USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema	ZECURITY								TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540523	NON-EXPEDITED			S	Transdermal	US-TEVA-650103USA	64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective	ZECURITY								TEVA	
Application site pain										
Application site pruritus										



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08-Jul-2016	12540525	NON-EXPEDITED			US-TEVA-649323USA	29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site exfoliation Wrong technique in product usage process	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540526	NON-EXPEDITED			US-TEVA-649272USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash Application site erythema Application site swelling	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540528	NON-EXPEDITED			US-TEVA-649717USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Vomiting	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540529	NON-EXPEDITED			US-TEVA-649879USA	53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site reaction	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540530	NON-EXPEDITED			US-TEVA-649421USA	45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema	ZECURITY	S	Transdermal			TEVA		



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08-Jul-2016	12540537	NON-EXPEDITED			US-TEVA-649857USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Heart rate increased Chest pain	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540538	NON-EXPEDITED			US-TEVA-649283USA	36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540539	NON-EXPEDITED			US-TEVA-649394USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site dryness	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540540	NON-EXPEDITED			US-TEVA-650290USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site dryness Application site exfoliation	ZECUITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540545	NON-EXPEDITED			US-TEVA-650090USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug effect decreased Application site erythema Incorrect drug administration duration	ZECUITY	S	Transdermal			TEVA		



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EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540546	NON-EXPEDITED			US-TEVA-649430USA	43 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540548	NON-EXPEDITED			US-TEVA-649793USA	30 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective	ZECUITY	S				TEVA		
Device leakage								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540549	NON-EXPEDITED			US-TEVA-650286USA	45 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site pain								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540550	NON-EXPEDITED			US-TEVA-649842USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site discoloration	ZECUITY	S	Transdermal			TEVA		
Device battery issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540552	NON-EXPEDITED			US-TEVA-649848USA	19 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site warmth	ZECUITY	S	Transdermal			TEVA		
Application site erythema								



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08-Jul-2016	12540579	NON-EXPEDITED			US-TEVA-650295USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540580	NON-EXPEDITED			US-TEVA-650293USA	53 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540581	NON-EXPEDITED			US-TEVA-650705USA	65 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal	6.5 mg over 6 hours		TEVA	
			Trokendi XR	C				
			Application site pain					
			Application site erythema					
			Application site irritation					
			Dermatitis contact					
			Drug ineffective					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540582	NON-EXPEDITED			US-TEVA-650661USA	17 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal	6.5 mg ove four hours		TEVA	



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08-Jul-2016	12540583	NON-EXPEDITED			US-TEVA-650663USA	58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		ZECUITY	S	Transdermal	6.5 mg ove 4 hours		TEVA	
Application site erythema								
Application site irritation								
Application site papules								
Application site pruritus								
Dizziness								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540584	NON-EXPEDITED			US-TEVA-651014USA	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Somnolence		ZECUITY	S	Transdermal	6.5mg/4h		TEVA	
Device battery issue								
Drug ineffective								
Fatigue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540585	NON-EXPEDITED			US-TEVA-651416USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Application site inflammation								
Application site pruritus								
Application site vesicles								
Drug effect incomplete								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540586	NON-EXPEDITED			US-TEVA-650296USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECUITY	S	Transdermal			TEVA	



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08-Jul-2016	12540590	NON-EXPEDITED			US-TEVA-650932USA		Female	USA
Preferred Term								
Application site paraesthesia			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site rash			ZECURITY	S	Transdermal	605 mg over 4 hours		TEVA
Application site erythema			ASPIRIN	C				
Application site discoloration			PLAVIX	C				
			IBUPROFEN	C				
			MAGNESIUM OXIDE	C				
			Topiragen	C				
<hr/>								
08-Jul-2016	12540591	NON-EXPEDITED			US-TEVA-651426USA	63 YR	Male	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective			ZECURITY	S	Transdermal			TEVA
Application site pain			ZECURITY	S	Transdermal			TEVA
Application site rash								
Drug hypersensitivity								
Incorrect drug administration duration								
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08-Jul-2016	12540592	NON-EXPEDITED			US-TEVA-650655USA		Male	USA
Preferred Term								
Application site reaction			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Application site irritation								
Application site pruritus								
Application site urticaria								



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08-Jul-2016	12540596	NON-EXPEDITED			S	Transdermal		US-TEVA-651005USA	20 YR	Female	USA
Preferred Term											
Application site erythema											
Application site irritation											
Application site rash											
Device battery issue											
Drug ineffective											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540597	NON-EXPEDITED			S	Transdermal		US-TEVA-650656USA	41 YR	Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Inappropriate schedule of drug administration											
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540598	NON-EXPEDITED			S	Transdermal		US-TEVA-651440USA	53 YR	Female	USA
Preferred Term											
Palpitations											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540599	NON-EXPEDITED			S	Transdermal		US-TEVA-650649USA	59 YR	Female	USA
Preferred Term											
Application site urticaria											
Application site discoloration											
Application site discomfort											
Application site erythema											



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08-Jul-2016	12540600	NON-EXPEDITED			S	Transdermal		US-TEVA-651789USA	48 YR	Female	USA
Preferred Term											
Application site pruritus											
Application site erythema											
Application site pain											
Migraine											
08-Jul-2016	12540601	NON-EXPEDITED						US-TEVA-651778USA	46 YR	Female	USA
Preferred Term											
Application site bruise											
Application site discoloration											
Application site reaction											
Drug ineffective											
Product adhesion issue											
08-Jul-2016	12540602	NON-EXPEDITED						US-TEVA-650997USA	39 YR	Female	USA
Preferred Term											
Application site erythema											
Device leakage											
08-Jul-2016	12540603	NON-EXPEDITED						US-TEVA-651755USA		Female	USA
Preferred Term											
Application site erythema											
Device battery issue											
Product physical issue											



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08-Jul-2016	12540605	NON-EXPEDITED			US-TEVA-651460USA	55 YR	Male	USA
Preferred Term								
Application site erythema								
Application site pruritus								
Drug effect incomplete								
Drug ineffective								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540606	NON-EXPEDITED			US-TEVA-650980USA		Female	USA
Preferred Term								
Application site erythema								
Application site discoloration								
Device adhesion issue								
Device leakage								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540607	NON-EXPEDITED			US-TEVA-651784USA	70 YR	Female	USA
Preferred Term								
Skin irritation								
Application site bruise								
Application site erythema								
Drug ineffective								
Product adhesion issue								



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08-Jul-2016	12540608	NON-EXPEDITED			S	Transdermal	US-TEVA-651823USA	40 YR	Female	USA
Preferred Term										
Application site pain										
Application site discoloration										
Application site erythema										
Application site irritation										
Application site paraesthesia										
<hr/>										
08-Jul-2016	12540609	NON-EXPEDITED					US-TEVA-650633USA		Female	USA
Preferred Term										
Application site urticaria										
<hr/>										
08-Jul-2016	12540610	NON-EXPEDITED			S	Transdermal	US-TEVA-651535USA		Female	USA
Preferred Term										
Headache										
Nausea										
Weight decreased										
Device adhesion issue										
Device leakage										
Device use error										
<hr/>										
Product										
ZECUITY										
Product										
ZECUITY										
Health Professional										
Outcomes										
S										
Role										
S										
Route										
Transdermal										
Dosage Text										
Manufacturer Control #										
US-TEVA-651535USA										
Age										
Sex										
Female										
Country										
USA										
Dosage Text										
6.5 mg per 4 hours										
Duration										
Manufacturer										
TEVA										
Product										
ZECUITY										
Product										
ZECUITY										
Product										
ARIPIPRAZOLE										
Product										
Vyvanase										
Product										
TOPIRAMATE										
Product										
FLUOXETINE										
Product										
CLONAZEPAM										
Product										
PROPRANOLOL										
Product										
SUMATRIPTAN										
Product										
DEXAMETHASONE										
Product										
amphetamine/dextroamphetamine										



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08-Jul-2016	12540612	NON-EXPEDITED			US-TEVA-651413USA		Female	USA
Preferred Term								
Drug ineffective								
Device battery issue								
Product								
ZECURITY								
Role Route								
S								
Dosage Text								
TEVA								
Duration								
Manufacturer								
TEVA								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540613	NON-EXPEDITED			US-TEVA-651425USA	32 YR	Female	USA
Preferred Term								
Application site pain								
Application site inflammation								
Device battery issue								
Product adhesion issue								
Product								
ZECURITY								
Role Route								
S								
Dosage Text								
TEVA								
Duration								
Manufacturer								
TEVA								



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08-Jul-2016	12540614	NON-EXPEDITED			US-TEVA-652691USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUITY	S Transdermal				TEVA
			LO LOESTRIN	C				
			MELOXICAM	C				
			TIROSINT	C				
			CYCLOBENZAPRINE	C				
			SUMATRIPTAN	C				
			ATORVASTATIN	C				
			MICROGESTIN	C				
			VOLTAREN	C				
			HYDROXYZINE	C				
			CHLORZOXAZON	C				
			CLINDAMYCIN	C				
			NITROFURANTOIN	C				
			AMETHIA	C				
			DOXYCYCLINE	C				
			ONDANSETRON	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540616	NON-EXPEDITED			US-TEVA-651466USA	38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site urticaria			ZECUITY	S Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540617	NON-EXPEDITED			US-TEVA-651842USA	64 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY	S Transdermal				TEVA
Device battery issue								



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08-Jul-2016	12540618	NON-EXPEDITED			S	Transdermal	US-TEVA-651433USA		TEVA		Female	USA
Preferred Term Application site rash												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540619	NON-EXPEDITED			S	Transdermal	US-TEVA-652223USA		TEVA	33 YR	Female	USA
Preferred Term Application site erythema												
Application site pain												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540620	NON-EXPEDITED			S	Transdermal	US-TEVA-651851USA		TEVA		Female	USA
Preferred Term Drug effect increased Disturbance in attention Dizziness Feeling abnormal Incorrect drug administration duration												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540621	NON-EXPEDITED			S	Transdermal	US-TEVA-651553USA		TEVA		Female	USA
Preferred Term Application site reaction Application site discoloration Application site pain Application site paraesthesia												



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08-Jul-2016	12540622	NON-EXPEDITED			US-TEVA-652313USA		Unknown	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site bruise			ZECUITY	S	over 4 hours		TEVA	
Device battery issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540623	NON-EXPEDITED			US-TEVA-651101USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Feeling abnormal			ZECUITY	S	6.5 mg over 4 hours		TEVA	
Inappropriate schedule of drug administration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540624	NON-EXPEDITED			US-TEVA-653984USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect incomplete			ZECUITY	S			TEVA	
Contraindicated drug administered								
Intentional product misuse								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540625	NON-EXPEDITED			US-TEVA-651410USA	38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S			TEVA	
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540626	NON-EXPEDITED			US-TEVA-651551USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S	6.5 mg over 4 hours		TEVA	
Application site discoloration								
Application site erythema								



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08-Jul-2016	12540629	NON-EXPEDITED			US-TEVA-651011USA	39 YR	Female	USA
Preferred Term								
Application site irritation			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECUITY	S	Transdermal			TEVA
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
08-Jul-2016	12540630	NON-EXPEDITED			US-TEVA-651036USA	38 YR	Female	USA
Preferred Term								
Application site pain			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site discomfort			ZECUITY	S	Transdermal			TEVA
Application site erythema								
Application site pain								
Application site swelling								
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
08-Jul-2016	12540631	NON-EXPEDITED			US-TEVA-651806USA	54 YR	Female	USA
Preferred Term								
Application site erythema			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECUITY	S	Transdermal			TEVA
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
08-Jul-2016	12540633	NON-EXPEDITED			US-TEVA-651491USA		Female	USA
Preferred Term								
Application site erythema			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Device leakage			ZECUITY	S	Transdermal			TEVA
Device use error								



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08-Jul-2016	12540634	NON-EXPEDITED			US-TEVA-652686USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540635	NON-EXPEDITED			US-TEVA-650992USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECURITY	S	Transdermal			TEVA	
Application site pain								
Device adhesion issue								
Device leakage								
Drug effect incomplete								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540636	NON-EXPEDITED			US-TEVA-652683USA	42 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Heart rate increased		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site paraesthesia								
Chills								
Nausea								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540637	NON-EXPEDITED			US-TEVA-651497USA	27 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECURITY	S	Transdermal			TEVA	
Device battery issue								
Device leakage								



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08-Jul-2016	12540638	NON-EXPEDITED			US-TEVA-653457USA	59 YR	Female	USA
Preferred Term								
Application site paraesthesia			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pain			ZECUITY	S	Transdermal			TEVA
Application site erythema			ZECUITY	S	Transdermal			TEVA
Application site urticaria			ZECUITY	S	Transdermal			TEVA
Application site bruise								
Application site discoloration								
Application site exfoliation								
Wrong technique in product usage process								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540639	NON-EXPEDITED			US-TEVA-651549USA		Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site swelling			ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540640	NON-EXPEDITED			US-TEVA-653910USA		Female	USA
Preferred Term								
Application site pain			Product	Role	Route	Dosage Text	Duration	Manufacturer
			ZECUITY	S	Transdermal			TEVA



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08-Jul-2016	12540643	NON-EXPEDITED			US-TEVA-651502USA		Female	USA
<u>Preferred Term</u>								
Application site urticaria								
	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
	ZECUITY	S	Transdermal	6.5 mg per 4 hours, 4 patches a month		TEVA		
	ALPRAZOLAM	C						
	KETOROLAC	C						
	AZITHROMYCIN	C						
	TIZANIDINE	C						
	TRAMADOL	C						
	SUMA TRIPTAN	C						
	Matzim LA	C						
	HYDROXYZINE	C						
	PROCHLORPERAZINE	C						
	Cambia	C						
	PROMETHAZINE	C						
	METOCLOPRAMIDE	C						
	ACETAMINOPHEN	C						
	VHYDROCODONE BITARTRATE	C						
	ondansetron	C						
	methylphenidate	C						
	chlorpromazine	C						
	sertraline	C						
	VITAMIN D	C						
	fluconazole	C						
	duloxetine	C						
	INDOMETHACIN	C						
	SULFAMETHOXAZOLE w/ TRIMETHOPRIM	C						



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08-Jul-2016	12540644	NON-EXPEDITED			US-TEVA-652277USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540645	NON-EXPEDITED			US-TEVA-653667USA	54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Chest pain	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540646	NON-EXPEDITED			US-TEVA-651890USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema Application site irritation Application site pruritus Application site swelling Device leakage Device use error	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540647	NON-EXPEDITED			US-TEVA-651803USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash Device battery issue Drug ineffective	ZECUITY	S	Transdermal			TEVA		



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08-Jul-2016	12540648	NON-EXPEDITED			US-TEVA-651877USA	33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site discomfort								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540649	NON-EXPEDITED			US-TEVA-653036USA	63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site warmth								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540650	NON-EXPEDITED			US-TEVA-651787USA	48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Burning sensation	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site urticaria								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540651	NON-EXPEDITED			US-TEVA-652689USA	52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site pain								
Application site pruritus								



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08-Jul-2016	12540663	NON-EXPEDITED			S	Transdermal	US-TEVA-652695USA	59 YR	Female	USA
Preferred Term										
Application site erythema										
Application site irritation										
Application site pruritus										
Application site urticaria										
Application site warmth										
<hr/>										
08-Jul-2016	12540664	NON-EXPEDITED			S	Transdermal	US-TEVA-653696USA		Female	USA
Preferred Term										
Application site pain										
Application site discomfort										
Application site erythema										
<hr/>										
08-Jul-2016	12540665	NON-EXPEDITED			S	Transdermal	US-TEVA-651849USA		Female	USA
Preferred Term										
Dysgeusia										
<hr/>										
08-Jul-2016	12540666	NON-EXPEDITED			S	Transdermal	US-TEVA-654708USA		Female	USA
Preferred Term										
Application site reaction										
Application site erythema										
Application site pain										
Drug ineffective										



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08-Jul-2016	12540667	NON-EXPEDITED			S	Transdermal	US-TEVA-653069USA	23 YR	Female	USA
Preferred Term										
Application site erythema										
Application site paraesthesia										
Application site swelling										
Application site warmth										
<hr/>										
08-Jul-2016	12540668	NON-EXPEDITED			S	Transdermal	US-TEVA-653074USA	32 YR	Female	USA
Preferred Term										
Application site pain										
Device leakage										
<hr/>										
08-Jul-2016	12540669	NON-EXPEDITED			S	Transdermal	US-TEVA-654700USA	61 YR	Female	USA
Preferred Term										
Application site irritation										
Device battery issue										
<hr/>										
08-Jul-2016	12540670	NON-EXPEDITED			S	Transdermal	US-TEVA-653650USA	44 YR	Female	USA
Preferred Term										
Application site erythema										
<hr/>										
Product										
ZECURITY										
propранолол										
Imitrex										
Ambien										
oxybutynin										
Celexa										



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08-Jul-2016	12540671	NON-EXPEDITED			US-TEVA-653972USA	55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site dryness Application site bruise Device leakage	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540672	NON-EXPEDITED			US-TEVA-654704USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema Application site pain Device leakage	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540674	NON-EXPEDITED			US-TEVA-653134USA	25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site pruritus Asthma	ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540675	NON-EXPEDITED			US-TEVA-653988USA	59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site urticaria Application site erythema Application site exfoliation Device battery issue	ZECUITY	S	Transdermal			TEVA		



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08-Jul-2016	12540676	NON-EXPEDITED			S	Transdermal	US-TEVA-654212USA	39 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site bruise										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540677	NON-EXPEDITED			S	Transdermal	US-TEVA-653979USA		Female	USA
<u>Preferred Term</u> Application site paraesthesia Device battery issue										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540678	NON-EXPEDITED			S	Transdermal	US-TEVA-654953USA	46 YR	Female	USA
<u>Preferred Term</u> Palpitations										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540679	NON-EXPEDITED			S	Transdermal	US-TEVA-653484USA	66 YR	Female	USA
<u>Preferred Term</u> Application site pain Application site paraesthesia										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540680	NON-EXPEDITED			S	Transdermal	US-TEVA-653998USA	33 YR	Female	USA
<u>Preferred Term</u> Application site vesicles Application site erythema Application site pain										



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08-Jul-2016	12540681	NON-EXPEDITED			S	Transdermal		US-TEVA-654702USA		Female	USA
Preferred Term											
Application site swelling											
Application site erythema											
Incorrect drug administration duration											
08-Jul-2016	12540682	NON-EXPEDITED			S	Transdermal		US-TEVA-653093USA		Female	USA
Preferred Term											
Application site erythema											
Application site discoloration											
Application site dryness											
Application site pain											
Application site pruritus											
08-Jul-2016	12540683	NON-EXPEDITED			S	Transdermal		US-TEVA-652770USA		Female	USA
Preferred Term											
Drug ineffective											
Device battery issue											
08-Jul-2016	12540684	NON-EXPEDITED			S	Transdermal		US-TEVA-659214USA	35 YR	Female	USA
Preferred Term											
Application site erythema											
Application site discoloration											
Application site exfoliation											
Application site swelling											



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08-Jul-2016	12540685	NON-EXPEDITED			US-TEVA-654706USA	30 YR	Female	USA
Preferred Term								
Application site pruritus				Role Route	Dosage Text	Duration	Manufacturer	
Application site urticaria				S Transdermal	6.5 mg/4 hours		TEVA	
Application site erythema				S Transdermal	6.5 mg/4 hours		TEVA	
Application site pain								
Product physical issue								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540686	NON-EXPEDITED			US-TEVA-654008USA	42 YR	Female	USA
Preferred Term								
Skin reaction				Role Route	Dosage Text	Duration	Manufacturer	
Application site discolouration				S			TEVA	
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540687	NON-EXPEDITED			US-TEVA-654540USA	51 YR	Female	USA
Preferred Term								
Application site pain				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema				S Transdermal	6.5 mg over 4 hours		TEVA	
Device battery issue								
Device leakage								
Inappropriate schedule of drug administration								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540688	NON-EXPEDITED			US-TEVA-654707USA		Female	USA
Preferred Term								
Application site erythema				Role Route	Dosage Text	Duration	Manufacturer	
Skin irritation				S Transdermal			TEVA	



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08-Jul-2016	12540689	NON-EXPEDITED			S	Transdermal	US-TEVA-653990USA	51 YR	Female	USA
Preferred Term										
Application site urticaria										
Application site erythema										
Product adhesion issue										
Product physical issue										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540690	NON-EXPEDITED			S		US-TEVA-654009USA	44 YR	Male	USA
Preferred Term										
Application site paraesthesia										
Inappropriate schedule of drug administration										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540691	NON-EXPEDITED			S	Transdermal	US-TEVA-653657USA		Female	USA
Preferred Term										
Wrong technique in product usage process										
Drug ineffective										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540692	NON-EXPEDITED			S	Transdermal	US-TEVA-655133USA	46 YR	Female	USA
Preferred Term										
Application site reaction										
Device battery issue										
Skin disorder										



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08-Jul-2016	12540693	NON-EXPEDITED			US-TEVA-654006USA	56 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site rash	ZECURITY	S				TEVA		
Application site erythema								
Application site inflammation								
Application site pruritus								
Device battery issue								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540694	NON-EXPEDITED			US-TEVA-654177USA		Unknown	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site vesicles	ZECURITY	S	Transdermal			TEVA		
Application site erythema								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540695	NON-EXPEDITED			US-TEVA-654692USA	59 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site discoloration								
Application site papules								
Application site pruritus								
Device battery issue								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12540696	NON-EXPEDITED			US-TEVA-653973USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECURITY	S	Transdermal			TEVA		



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08-Jul-2016	12540697	NON-EXPEDITED			US-TEVA-654701USA	45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective Migraine	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540698	NON-EXPEDITED			US-TEVA-654211USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site dermatitis Application site erythema Application site pruritus	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540699	NON-EXPEDITED			US-TEVA-653991USA	48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site laceration Application site erythema Application site pain Skin sensitisation	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12540708	NON-EXPEDITED			US-TEVA-654694USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site dryness Application site pruritus	ZECUITY	S	Transdermal			TEVA		



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08-Jul-2016	12540709	NON-EXPEDITED			US-TEVA-654240USA	41 YR	Female	USA
Preferred Term								
Application site rash								
Application site pain								
Application site papules								
Device leakage								
Drug ineffective								
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08-Jul-2016	12540710	NON-EXPEDITED			US-TEVA-654264USA	24 YR	Female	USA
Preferred Term								
Application site pain								
Application site bruise								
Application site discoloration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site swelling								
Device leakage								
<hr/>								
08-Jul-2016	12540711	NON-EXPEDITED			US-TEVA-654270USA	47 YR	Female	USA
Preferred Term								
Application site erythema								
Application site urticaria								
Application site exfoliation								
Application site pain								



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08-Jul-2016	12541184	EXPEDITED (15-DAY)		OT	US-TEVA-673596USA	40 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site burn	ZECURITY	S	Transdermal			TEVA		
Application site erythema								
Application site Induration								
Application site pain								
Application site paraesthesia								
Application site swelling								
Application site urticaria								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12541244	EXPEDITED (15-DAY)		OT	US-TEVA-673662USA	52 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Sunburn	ZECURITY	S	Transdermal			TEVA		
Application site burn								
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Product physical issue								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jul-2016	12541636	NON-EXPEDITED		OT	US-TEVA-673595USA	59 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Seizure	ZECURITY	S	Transdermal			TEVA		
Application site erythema								
Application site pain								
Incorrect drug administration duration								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12542030	EXPEDITED (15-DAY)		OT	US-TEVA-674475USA	36 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal			TEVA	
Application site discolouration								
Application site dryness								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12542254	EXPEDITED (15-DAY)		OT	US-TEVA-674485USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Incorrect drug administration duration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12542452	EXPEDITED (15-DAY)		OT	US-TEVA-674486USA	39 YR	Male	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site paraesthesia								
Application site scab								
Drug ineffective								
Wrong technique in product usage process								



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08-Jul-2016	12543581	DIRECT		OT		23 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY TRANSDERMAL PATCH, 6.5 MG TEVA PHARMACEUTICALS	S	2 patch(es) As needed	4 MTH	TEVA	
Application site scar			PACEMAKER	C				
Application site pain			NORTRIPTYLINE	C				
			DILTIA XR	C				
			PANTOPRAZOLE	C				
			SPRINTEC	C				
			LAMICTAL	C				
			BUPROPION	C				
			DOMPERIDONE	C				
			FISH OIL	C				
			SUPER B-COMPLEX	C				
			SWISS KRISS	C				
			CALCIUM/MAGNESIUM	C				
			ZINC	C				
			GREEN TEA	C				
Application site bruise								
Application site rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2016	12542933	EXPEDITED (15-DAY)		OT	US-TEVA-673307USA		Unknown	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn			ZECUITY	S	Transdermal		TEVA	
Product physical issue								



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11-Jul-2016	12493552	EXPEDITED (15-DAY)		OT	US-TEVA-669085USA	37 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site discolouration								
Application site dryness								
Application site erythema								
Application site exfoliation								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12500568	EXPEDITED (15-DAY)		OT	US-TEVA-669884USA	29 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Thermal burn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site scab								
Application site scar								
Incorrect drug administration duration								



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11-Jul-2016	12500864	EXPEDITED (15-DAY)		OT	US-TEVA-669771USA	60 YR	Female	USA
Preferred Term								
Application site burn								
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site oedema								
Application site rash								
Product adhesion issue								
Product physical issue								
<hr/>								
11-Jul-2016	12503708	EXPEDITED (15-DAY)		OT	US-TEVA-669813USA	44 YR	Female	USA
Preferred Term								
Application site burn								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site vesicles								
<hr/>								
11-Jul-2016	12504349	EXPEDITED (15-DAY)		OT	US-TEVA-670248USA	42 YR	Female	USA
Preferred Term								
Application site scar								
<hr/>								



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11-Jul-2016	12509081	EXPEDITED (15-DAY)		OT	US-TEVA-670657USA	47 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal	6.5 mg over 4 hours		TEVA	
Application site scar		TOPIRAMATE		C				
Application site pruritus		VERAPAMIL		C				
		OMEPRAZOLE		C				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12511399	EXPEDITED (15-DAY)		OT	US-TEVA-670661USA	51 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site scar		ZECUITY		S Transdermal			TEVA	
		LEXAPRO		C				
		RELPAK		C				
		NEURONTIN		C				
		LOPRESSOR		C				
		NORCO		C				
		FLEXERIL		C				
		MOBIC		C				



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11-Jul-2016	12519827	EXPEDITED (15-DAY)		OT	US-TEVA-671679USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg/hour		TEVA	
Application site scar		SPIRONOLACTONE	C					
Application site erythema		VALIUM	C					
Application site exfoliation		WELLBUTRIN	C					
Application site discoloration		TOPROL	C					
		PREVACID	C					
		HYDROXYCHLOROQUINE	C					
		TOPAMAX	C					
		INDOCIN	C					
		NADLOL	C					
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12545489	EXPEDITED (15-DAY)		OT	US-TEVA-675149USA	22 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site paraesthesia								
Incorrect drug administration duration								



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11-Jul-2016	12546247	EXPEDITED (15-DAY)		OT	US-TEVA-674863USA	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site pruritus		Gabapentin	C		unknown form strength			
Application site discoloration								
Application site inflammation								
Application site vesicles								
Drug ineffective								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12546847	EXPEDITED (15-DAY)		OT	US-TEVA-675487USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site pain								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12546855	EXPEDITED (15-DAY)		OT	US-TEVA-675478USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site exfoliation								



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11-Jul-2016	12546880	EXPEDITED (15-DAY)		OT	US-TEVA-675482USA		Female	USA
Preferred Term								
Application site burn								
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site reaction								
Application site vesicles								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12547100	EXPEDITED (15-DAY)		OT	US-TEVA-675635USA		Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site pain								
Incorrect drug administration duration								
Wrong technique in product usage process								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12547109	EXPEDITED (15-DAY)		OT	US-TEVA-675466USA		Female	USA
Preferred Term								
Application site scar								
Application site erythema								
Application site inflammation								
Application site paraesthesia								
Application site urticaria								
Pruritus								



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11-Jul-2016	12547215	EXPEDITED (15-DAY)		OT	US-TEVA-674670USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	11909469	EXPEDITED (15-DAY)		OT	US-TEVA-615830USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal			TEVA	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Application site bruise								
Application site discoloration								
Application site pain								
Application site pruritus								
Device use error								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12284734	EXPEDITED (15-DAY)		OT	US-TEVA-644812USA	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site pain		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pruritus								
Skin exfoliation								



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12-Jul-2016	12540627	EXPEDITED (15-DAY)		OT	US-TEVA-652692USA	31 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY		S Transdermal			TEVA	
Abasia								
Application site discoloration								
Application site erythema								
Application site pain								
Application site scab								
Application site urticaria								
Wound secretion								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12549620	EXPEDITED (15-DAY)		OT	US-TEVA-675491USA	35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site irritation								
Application site paraesthesia								
Application site scab								
Application site warmth								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12549691	EXPEDITED (15-DAY)		OT	US-TEVA-675526USA	38 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site pain								



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12-Jul-2016	12549726	EXPEDITED (15-DAY)		OT	US-TEVA-675629USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12549829	EXPEDITED (15-DAY)		OT	US-TEVA-675489USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
Application site pain								
Application site vesicles								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12550757	EXPEDITED (15-DAY)		OT	US-TEVA-675631USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burns first degree		ZECURITY	S	Transdermal	used 4 patches in the last 3 months		TEVA	
Application site erythema								
Drug effect incomplete								
Product use issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12551684	DIRECT		HO		35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site vesicles		ZECURITY	S		applied to a surface, usually the skin		TEVA	
Application site pain								



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13-Jul-2016	12247927	NON-EXPEDITED			US-TEVA-627876USA	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECURITY		S Transdermal	6.5 mg / 4 hours		TEVA	
Device battery issue								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12270837	NON-EXPEDITED			US-TEVA-633684USA	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Allodynia		ZECURITY		S Transdermal			TEVA	
Application site vesicles		penicillin		C				
Incorrect drug administration duration		morphine		C				
Application site erythema		Norvasc		C				
		lisinopril		C				
		lopressor		C				
		Zanaflex		C	1 every 6 hours as needed			
		Requip		C				
		Cymbalta		C	60 Milligram Daily;			
		Diovan		C	320-25 mg			
		Lipitor		C				
		Aspirin		C				
		Aspirin		C				
		Zofran		C	1 as needed			
		Dicyclomine		C	20 Milligram Daily;			
		Lamictal		C	400 Milligram Daily;			
		Arthrotec		C	75-0.2mg			
		Klonopin		C				
		Bystolic		C	2.5 Milligram Daily;			
		Topamax		C	100 Milligram Daily;			
		Trazodone		C	150 Milligram Daily;			



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<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
	Progesterone Sr	C		50 Milligram Daily; at bedtime				
	Fluticasone	C	Nasal	1 to 2 sprays daily each nostril				
	Montelukast Sodium	C	Oral	10 Milligram Daily;				
	Omeprazole	C	Oral	20 Milligram Daily;				
	Gabapentin	C	Oral					
	Volaren	C	Transdermal	as directed				
	Cipro	C	Oral	1000 Milligram Daily;				
	Medrol	C		as directed				
	Epi Pen	C		as directed				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12277188	NON-EXPEDITED			US-TEVA-636107USA	55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Palpitations	ZECURITY	S	Transdermal			TEVA		
Anxiety	ZOMIG	C						
Tremor								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12277301	EXPEDITED (15-DAY)		OT	US-TEVA-637423USA	45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECURITY	S	Transdermal			TEVA		
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
Drug ineffective								
Product physical issue								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12281743	NON-EXPEDITED			S	Transdermal	US-TEVA-641687USA	53 YR	Female	USA
Preferred Term			Product				Dosage Text	Duration		Manufacturer
Drug effect incomplete			ZECUITY							TEVA
Application site erythema										
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12281763	NON-EXPEDITED			S		US-TEVA-644498USA		Female	USA
Preferred Term			Product				Dosage Text	Duration		Manufacturer
Application site discolouration			ZECUITY							TEVA
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12284711	NON-EXPEDITED			S	Transdermal	US-TEVA-646655USA	37 YR	Female	USA
Preferred Term			Product				Dosage Text	Duration		Manufacturer
Application site pain			ZECUITY							TEVA
			AMITRIPTYLINE							
			WELLBUTRIN							
			PROMETHAZINE							
			ZYRTEC							
			MOTRIN							



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13-Jul-2016	12284861	NON-EXPEDITED			US-TEVA-648503USA	53 YR	Female	USA
Preferred Term								
Application site irritation			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site rash			ZECUITY	S	Transdermal			TEVA
Application site discoloration			LIBRIUM	C				
Application site erythema								
Application site paraesthesia								
Application site pruritus								
Application site urticaria								
Drug effect incomplete								
Drug hypersensitivity								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12284864	NON-EXPEDITED			US-TEVA-647438USA	62 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site inflammation			ZECUITY	S	Transdermal			TEVA
Application site irritation								
Application site pain								
Application site pruritus								
Application site rash								
Dizziness								

FDA Received Date **Case #** **Case Type** **Health Professional** **Outcomes** **Manufacturer Control #** **Age** **Sex** **Country**
13-Jul-2016 12284887 NON-EXPEDITED OT US-TEVA-648814USA 25 YR Female USA

Preferred Term **Product** **Role** **Route** **Dosage Text** **Duration** **Manufacturer**
Application site discoloration ZECUITY S Transdermal 75 Milligram Daily;
Topamax C Unknown nightly TEVA



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13-Jul-2016	12506613	EXPEDITED (15-DAY)		OT	US-TEVA-670457USA	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Adverse event								
Application site erythema								
Application site pain								
Application site pruritus								
Drug ineffective								
Erythema								
Nausea								
Wrong technique in product usage process								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12510950	EXPEDITED (15-DAY)		OT	US-TEVA-670896USA	36 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site haemorrhage								
Application site pain								
Application site pruritus								
Application site rash								
Application site urticaria								



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13-Jul-2016	12511396	EXPEDITED (15-DAY)		OT	US-TEVA-670608USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site pain								
Application site pruritus								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12515685	EXPEDITED (15-DAY)		OT	US-TEVA-671351USA	45 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site burn								
Application site discolouration								
Application site dryness								
Application site pain								
Application site pruritus								
Spider vein								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12516668	EXPEDITED (15-DAY)		OT	US-TEVA-670862USA	53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY		S Transdermal			TEVA	
Application site discharge								
Application site vesicles								



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13-Jul-2016	12518002	EXPEDITED (15-DAY)		OT	US-TEVA-670560USA	36 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal		TEVA		
Application site discolouration								
Application site exfoliation								
Application site pain								
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12518230	EXPEDITED (15-DAY)		OT	US-TEVA-671069USA	42 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal		TEVA		
Application site warmth				S Transdermal		TEVA		
Application site discolouration								
Application site erythema								
Application site pruritus								
Dizziness								
Incorrect drug administration duration								
Nausea								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12518422	EXPEDITED (15-DAY)		OT	US-TEVA-671782USA	34 YR	Male	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal		TEVA		
Application site erythema								
Application site vesicles								
Electrical burn								
Rash								
Rash macular								



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13-Jul-2016	12518641	EXPEDITED (15-DAY)		OT	US-TEVA-671415USA		Female	USA
Preferred Term								
Sunburn				Role Route S Transdermal	Dosage Text	Duration	Manufacturer	TEVA
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site reaction								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12518765	EXPEDITED (15-DAY)		OT	US-TEVA-671790USA	23 YR	Female	USA
Preferred Term								
Sunburn				Role Route S Transdermal	Dosage Text	Duration	Manufacturer	TEVA
Application site discolouration								
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12522058	EXPEDITED (15-DAY)		OT	US-TEVA-672322USA	38 YR	Female	USA
Preferred Term								
Sunburn				Role Route S Transdermal	Dosage Text	Duration	Manufacturer	TEVA
Application site scar								
Application site erythema								
Application site pain								
Application site vesicles								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12522247	EXPEDITED (15-DAY)		OT	US-TEVA-672670USA	42 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12540524	NON-EXPEDITED			US-TEVA-649365USA	33 YR	Male	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site paraesthesia		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Heart rate increased								
Intentional product use issue								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12540535	NON-EXPEDITED			US-TEVA-650137USA	28 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Drug ineffective		ZECUITY	S	Transdermal			TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site irritation								
Application site pain								
Device battery issue								
Incorrect drug administration duration								



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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12540547	NON-EXPEDITED			S	Transdermal	US-TEVA-649887USA	42 YR	Female	USA
Preferred Term			Product				Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY						TEVA	
Application site rash										
Dermatitis contact										
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12540632	NON-EXPEDITED			S	Transdermal	US-TEVA-652202USA	44 YR	Female	USA
Preferred Term			Product				Dosage Text	Duration	Manufacturer	
Drug ineffective			ZECUITY						TEVA	
Device battery issue										
Device leakage										
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551241	NON-EXPEDITED			S	Transdermal	US-TEVA-654893USA	42 YR	Female	USA
Preferred Term			Product				Dosage Text	Duration	Manufacturer	
Application site irritation			ZECUITY						TEVA	
Application site erythema										
Application site pruritus										
Application site urticaria										
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551242	NON-EXPEDITED			S	Transdermal	US-TEVA-654911USA	42 YR	Female	USA
Preferred Term			Product				Dosage Text	Duration	Manufacturer	
Drug ineffective			ZECUITY						TEVA	



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551243	NON-EXPEDITED			S	Transdermal	US-TEVA-654841USA	48 YR	Female	USA
Preferred Term										
Wrong technique in product usage process										
Application site erythema										
Device battery issue										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
13-Jul-2016										
12551244										
NON-EXPEDITED										
ZECUITY										
S										
Transdermal										
US-TEVA-654910USA										
26 YR										
Female										
USA										
Preferred Term										
Application site pain										
Device leakage										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
13-Jul-2016										
12551245										
NON-EXPEDITED										
ZECUITY										
S										
Transdermal										
US-TEVA-655173USA										
40 YR										
Female										
USA										
Preferred Term										
Application site pain										
Device battery issue										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
13-Jul-2016										
12551246										
NON-EXPEDITED										
ZECUITY										
S										
Transdermal										
US-TEVA-654929USA										
40 YR										
Female										
USA										
Preferred Term										
Application site erythema										
Application site pruritus										
Device battery issue										
Product use issue										



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13-Jul-2016	12551247	NON-EXPEDITED			S	Transdermal	US-TEVA-654912USA	47 YR	Female	USA
Preferred Term										
Application site pain										
Device battery issue										
Device leakage										
Drug ineffective										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551248	NON-EXPEDITED			S	Transdermal	US-TEVA-654934USA	34 YR	Female	USA
Preferred Term										
Application site erythema										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551249	NON-EXPEDITED			S	Transdermal	US-TEVA-655192USA		Female	USA
Preferred Term										
Application site erythema										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551250	NON-EXPEDITED			S	Transdermal	US-TEVA-654897USA	36 YR	Female	USA
Preferred Term										
Paraesthesia										
Nausea										
Vomiting										



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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551251	NON-EXPEDITED			US-TEVA-654810USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site irritation	nivaliripian	C						
Application site discoloration								
Application site scab								
Device battery issue								
Drug ineffective								
Migraine								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551252	NON-EXPEDITED			US-TEVA-654915USA	54 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Vomiting	ZECUITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551253	NON-EXPEDITED			US-TEVA-654913USA	46 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site bruise								
Application site erythema								
Application site exfoliation								
Application site fissure								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551254	NON-EXPEDITED			US-TEVA-654932USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551255	NON-EXPEDITED			S	Transdermal	US-TEVA-655219USA	48 YR	Female	USA
Preferred Term										
Application site erythema										
Application site bruise										
Application site pain										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
Preferred Term										
Drug ineffective										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
Preferred Term										
Drug ineffective										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
Preferred Term										
Migraine										
Device battery issue										
Application site bruise										
Application site erythema										
Device battery issue										
Drug ineffective										



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551259	NON-EXPEDITED			US-TEVA-655210USA	61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Device leakage Product adhesion issue	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551260	NON-EXPEDITED			US-TEVA-655200USA	48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551261	NON-EXPEDITED			US-TEVA-655225USA	58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site discomfort Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551263	NON-EXPEDITED			US-TEVA-655231USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site pruritus	ZECUITY	S	Transdermal			TEVA		



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13-Jul-2016	12551264	NON-EXPEDITED			S	Transdermal	US-TEVA-655163USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective Application site dryness Application site exfoliation Skin discoloration Wrong technique in product usage process	ZECUITY								TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551265	NON-EXPEDITED			S	Transdermal	US-TEVA-654928USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Palpitations	ZECUITY								TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551266	NON-EXPEDITED			S	Transdermal	US-TEVA-655057USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site urticaria Application site irritation Application site pain	ZECUITY								TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551267	NON-EXPEDITED			S	Transdermal	US-TEVA-655197USA	43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema Application site paraesthesia Application site discoloration	ZECUITY ZECUITY				S S	Transdermal Transdermal			TEVA TEVA	



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13-Jul-2016	12551268	NON-EXPEDITED			S	Transdermal	US-TEVA-655146USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain Somnolence			ZECUITY						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551270	NON-EXPEDITED			S		US-TEVA-655198USA	55 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551271	NON-EXPEDITED			S	Transdermal	US-TEVA-655495USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Diarrhoea Nausea Vomiting Application site erythema Application site pain Muscle spasms			ZECUITY SEROQUEL Pristiq						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551274	NON-EXPEDITED			S	Transdermal	US-TEVA-655253USA	60 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain Device leakage Drug effect Incomplete			ZECUITY						TEVA	



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13-Jul-2016	12551275	NON-EXPEDITED			US-TEVA-655218USA	58 YR	Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Drug effect incomplete								
Headache								
Nausea								
Photophobia								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551276	NON-EXPEDITED			US-TEVA-655466USA		Female	USA
Preferred Term								
Rash								
Device battery issue								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551277	NON-EXPEDITED			US-TEVA-655226USA	36 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site erythema								
Application site exfoliation								
Application site pruritus								



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13-Jul-2016	12551278	NON-EXPEDITED			S	Transdermal	US-TEVA-656660USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dry mouth			ZECURITY						TEVA	
Application site erythema										
Application site pruritus										
Application site urticaria										
Application site warmth										
Device battery issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551279	NON-EXPEDITED			S	Transdermal	US-TEVA-656627USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Migraine			ZECURITY						TEVA	
Device battery issue										
Wrong technique in product usage process										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551280	NON-EXPEDITED			S	Transdermal	US-TEVA-655494USA	36 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECURITY				6.5 mg over 4 hours		TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551282	NON-EXPEDITED			S	Transdermal	US-TEVA-656670USA	59 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect decreased			ZECURITY						TEVA	



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13-Jul-2016	12551283	NON-EXPEDITED			US-TEVA-65662USA	52 YR	Female	USA
Preferred Term								
Application site erythema								
Application site pruritus								
Application site pruritus								
Product								
ZECUITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Manufacturer Control #								
US-TEVA-65662USA								
Age								
52 YR								
Sex								
Female								
Country								
USA								
Outcomes								
Health Professional								
Case Type								
NON-EXPEDITED								
Case #								
12551283								
EDA Received Date								
13-Jul-2016								
Preferred Term								
Drug ineffective								
Application site discolouration								
Application site erythema								
Application site irritation								
Application site pain								
Application site pruritus								
Application site pruritus								
Product								
ZECUITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Manufacturer Control #								
US-TEVA-656633USA								
Age								
43 YR								
Sex								
Female								
Country								
USA								
Outcomes								
Health Professional								
Case Type								
NON-EXPEDITED								
Case #								
12551285								
EDA Received Date								
13-Jul-2016								
Preferred Term								
Application site erythema								
Application site irritation								
Application site pain								
Application site pruritus								
Application site rash								
Product use issue								



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13-Jul-2016	12551286	NON-EXPEDITED			US-TEVA-656599USA	47 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECURITY	S Transdermal			TEVA	
Application site exfoliation								
Drug ineffective								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551287	NON-EXPEDITED			US-TEVA-655569USA	47 YR	Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Application site swelling								
Application site warmth								
Product adhesion issue								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551288	NON-EXPEDITED			US-TEVA-655806USA		Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site warmth			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Device battery issue								



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13-Jul-2016	12551289	NON-EXPEDITED			US-TEVA-655537USA	31 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site irritation								
Application site pruritus								
Drug ineffective								
Product adhesion issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551290	NON-EXPEDITED			US-TEVA-655684USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Muscular weakness								
Drug ineffective								
Nausea								
Product odour abnormal								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551291	NON-EXPEDITED			US-TEVA-655846USA	52 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site pruritus								
Device use error								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551292	NON-EXPEDITED			US-TEVA-655837USA	25 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								



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13-Jul-2016	12551293	NON-EXPEDITED			US-TEVA-656413USA	16 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site irritation								
Drug administered to patient of inappropriate age								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551294	NON-EXPEDITED			US-TEVA-655543USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site pruritus								
Application site rash								
Application site swelling								
Drug hypersensitivity								
Incorrect drug administration duration								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551295	NON-EXPEDITED			US-TEVA-655534USA	44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site discoloration								
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551296	NON-EXPEDITED			US-TEVA-655829USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
	ZECUITY	S	Transdermal			TEVA		



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13-Jul-2016	12551297	NON-EXPEDITED			S	Transdermal	US-TEVA-655830USA	21 YR	Female	USA
<u>Preferred Term</u> Application site erythema Skin disorder										
<u>Product</u> ZECURITY										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551298	NON-EXPEDITED			S	Transdermal	US-TEVA-656687USA	40 YR	Female	USA
<u>Preferred Term</u> Application site vesicles Application site erythema Application site pain										
<u>Product</u> ZECURITY										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551299	NON-EXPEDITED			S	Transdermal	US-TEVA-655857USA	64 YR	Female	USA
<u>Preferred Term</u> Application site pain										
<u>Product</u> ZECURITY										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551300	NON-EXPEDITED			S	Transdermal	US-TEVA-655848USA		Female	USA
<u>Preferred Term</u> Application site pruritus Application site erythema Application site urticaria Incorrect drug administration duration										
<u>Product</u> ZECURITY										



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13-Jul-2016	12551301	NON-EXPEDITED			S	Transdermal	100 Milligram Daily;	US-TEVA-655780USA	55 YR	Male	USA
Preferred Term											
Application site rash											
Application site pruritus											
Application site swelling											
Application site pain											
Incorrect drug administration duration											
Intentional product misuse											
<hr/>											
13-Jul-2016	12551302	NON-EXPEDITED			S	Transdermal		US-TEVA-656398USA	39 YR	Female	USA
Preferred Term											
Application site erythema											
Application site pain											
<hr/>											
13-Jul-2016	12551303	NON-EXPEDITED			S	Transdermal		US-TEVA-655573USA		Female	USA
Preferred Term											
Application site erythema											
<hr/>											
13-Jul-2016	12551305	NON-EXPEDITED			S	Transdermal	has used 3 different patches	US-TEVA-656204USA	49 YR	Female	USA
Preferred Term											
Application site erythema											
<hr/>											
13-Jul-2016	12551306	NON-EXPEDITED			S	Transdermal		US-TEVA-655900USA		Female	USA
Preferred Term											
Application site erythema											



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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551307	NON-EXPEDITED			US-TEVA-655800USA	52 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551308	NON-EXPEDITED			US-TEVA-655579USA	52 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site urticaria	ZECURITY	S	Transdermal			TEVA		
Application site discolouration								
Application site erythema								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551309	NON-EXPEDITED			US-TEVA-655775USA	46 YR	Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site laceration								
Application site pain								
Application site scab								
Application site swelling								
Oedema								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551310	NON-EXPEDITED			US-TEVA-655827USA	41 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective	ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Application site dryness								
Application site erythema								
Application site exfoliation								



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13-Jul-2016	12551311	NON-EXPEDITED			US-TEVA-655858USA	60 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia Application site discoloration Application site erythema Application site irritation Drug effect incomplete Therapeutic response unexpected	ZECURITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551314	NON-EXPEDITED			US-TEVA-656364USA	40 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective	ZECURITY	S	Transdermal	6.5 mg/4 hours, onset of migraine, to upper arm or thigh		TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551315	NON-EXPEDITED			US-TEVA-658356USA	51 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Application site pain	ZECURITY	S	Transdermal			TEVA		



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13-Jul-2016	12551316	NON-EXPEDITED			US-TEVA-658346USA	45 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site discoloration								
Application site erythema								
Application site hyperaesthesia								
Application site pain								
Application site pruritus								
Application site warmth								
Drug ineffective								
Tension headache								
Preferred Term								
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551317	NON-EXPEDITED			US-TEVA-656357USA	41 YR	Female	USA
Preferred Term								
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551318	NON-EXPEDITED			US-TEVA-656386USA	35 YR	Female	USA
Preferred Term								
Application site erythema								
Application site pain								



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13-Jul-2016	12551319	NON-EXPEDITED			S	Transdermal	US-TEVA-658884USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia Application site dryness Application site erythema Application site pain Application site vesicles	ZECUITY								TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551320	NON-EXPEDITED			S	Transdermal	US-TEVA-656392USA	23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain Application site erythema	ZECUITY								TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551321	NON-EXPEDITED			S	Transdermal	US-TEVA-656349USA	28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia Application site pain	ZECUITY								TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551322	NON-EXPEDITED			S	Transdermal	US-TEVA-656377USA	36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect incomplete	ZECUITY								TEVA	



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13-Jul-2016	12551323	NON-EXPEDITED			S	Transdermal	US-TEVA-656384USA		Female	USA
Preferred Term Drug ineffective Application site erythema Application site pruritus										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551325	NON-EXPEDITED			S	Transdermal	US-TEVA-656387USA	35 YR	Female	USA
Preferred Term Application site erythema Product physical issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551327	NON-EXPEDITED			S	Transdermal	US-TEVA-656348USA		Female	USA
Preferred Term Application site dryness Device battery issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551328	NON-EXPEDITED			S	Transdermal	US-TEVA-656390USA	58 YR	Female	USA
Preferred Term Drug effect incomplete Incorrect drug administration duration Product substitution issue										



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13-Jul-2016	12551329	NON-EXPEDITED			US-TEVA-658025USA	40 YR	Female	USA
Preferred Term								
Application site rash				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain				S Transdermal			TEVA	
Application site discoloration				S Transdermal			TEVA	
Application site erythema								
Device leakage								
Incorrect drug administration duration								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551330	NON-EXPEDITED			US-TEVA-658345USA		Female	USA
Preferred Term								
Application site erythema				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discoloration				S Transdermal			TEVA	
Application site pain								
Application site pruritus								
Application site reaction								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551332	NON-EXPEDITED			US-TEVA-658354USA	45 YR	Female	USA
Preferred Term								
Application site erythema				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site irritation				S Transdermal			TEVA	



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13-Jul-2016	12551333	NON-EXPEDITED			US-TEVA-657738USA	37 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia Application site erythema Application site pain Application site warmth Flushing Incorrect drug administration duration	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551334	NON-EXPEDITED			US-TEVA-658320USA	46 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia Application site discolouration Application site erythema	ZECUITY	S				TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551335	NON-EXPEDITED			US-TEVA-658022USA	51 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia Application site pain Incorrect drug administration duration Migraine	ZECUITY	S	Transdermal			TEVA		
ZECUITY		S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551336	NON-EXPEDITED			US-TEVA-658353USA	46 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Migraine Drug ineffective	ZECUITY	S	Transdermal			TEVA		



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13-Jul-2016	12551337	NON-EXPEDITED			US-TEVA-656379USA	56 YR	Female	USA
Preferred Term			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site dryness			ZECUITY	S	Transdermal			TEVA
Application site erythema								
Application site pruritus								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551338	NON-EXPEDITED			US-TEVA-658831USA	28 YR	Unknown	USA
Preferred Term			Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective			ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA
Device battery issue								
Product adhesion issue								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551339	NON-EXPEDITED			US-TEVA-658863USA	26 YR	Female	USA
Preferred Term			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pain			ZECUITY	S	Transdermal			TEVA
Application site erythema								
Product physical issue								
Wrong technique in product usage process								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551340	NON-EXPEDITED			US-TEVA-656370USA		Female	USA
Preferred Term			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pain			ZECUITY	S	Transdermal			TEVA
Application site erythema								
Application site vesicles								



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13-Jul-2016	12551341	NON-EXPEDITED			US-TEVA-658386USA	52 YR	Female	USA
<u>Preferred Term</u>								
Urticaria			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECURITY	S	Transdermal	6.5mg/4hours		TEVA
Administration site warmth			ZECURITY	S	Transdermal	6.5mg/4hours		TEVA
Drug ineffective								
<hr/>								
13-Jul-2016	12551342	NON-EXPEDITED			US-TEVA-658021USA	33 YR	Female	USA
<u>Preferred Term</u>								
Application site pain			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site pain			ZECURITY	S	Transdermal			TEVA
Application site pain			Verapamil	C				
Application site pain			Doxepin	C				
Application site urticaria			Butalbital	C				
			Methotrexate	C				
			Alprazolam	C				
			Cyclobenzaprine	C				
			Spirolactone	C				
<hr/>								
13-Jul-2016	12551344	NON-EXPEDITED			US-TEVA-657329USA	42 YR	Female	USA
<u>Preferred Term</u>								
Application site bruise			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site bruise			ZECURITY	S	Transdermal			TEVA
<hr/>								
13-Jul-2016	12551345	NON-EXPEDITED			US-TEVA-657945USA		Female	USA
<u>Preferred Term</u>								
Application site paraesthesia			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site irritation			ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA
Device battery issue								



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13-Jul-2016	12551346	NON-EXPEDITED			US-TEVA-658358USA	47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Application site erythema Application site pain Device battery issue Product adhesion issue	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551347	NON-EXPEDITED			US-TEVA-658030USA	52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Nausea Inappropriate schedule of drug administration Vomiting	ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551348	NON-EXPEDITED			US-TEVA-657341USA	26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Burning sensation	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551349	NON-EXPEDITED			US-TEVA-658027USA	24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site warmth Application site erythema Application site rash Incorrect drug administration duration	ZECURITY	S	Transdermal			TEVA		



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13-Jul-2016	12551350	NON-EXPEDITED			US-TEVA-658889USA	48 YR	Male	USA
Preferred Term								
Application site erythema			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site irritation			ZECUITY	S	Transdermal			TEVA
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551351	NON-EXPEDITED			US-TEVA-658888USA	18 YR	Female	USA
Preferred Term								
Drug ineffective			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site discolouration			ZECUITY	S	Transdermal			TEVA
Application site erythema								
Application site pruritus								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551352	NON-EXPEDITED			US-TEVA-657746USA	49 YR	Female	USA
Preferred Term								
Application site pain			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECUITY	S	Transdermal			TEVA
Application site rash								
Application site swelling								



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13-Jul-2016	12551353	NON-EXPEDITED			S	Transdermal	US-TEVA-658349USA		Male	USA
Preferred Term	Product						Dosage Text	Duration	Manufacturer	
Application site vesicles Application site dryness Application site erythema Application site irritation Application site pruritus Application site rash Application site warmth	ZECUITY								TEVA	
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551354	NON-EXPEDITED			S		US-TEVA-658328USA		Female	USA
Preferred Term	Product						Dosage Text	Duration	Manufacturer	
Drug ineffective	ZECUITY								TEVA	
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551355	NON-EXPEDITED			S	Transdermal	US-TEVA-658036USA	23 YR	Female	USA
Preferred Term	Product						Dosage Text	Duration	Manufacturer	
Drug effect incomplete Application site erythema Application site pruritus	ZECUITY						6.5 mg over 4 hours		TEVA	
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551356	NON-EXPEDITED			S	Transdermal	US-TEVA-658853USA	47 YR	Female	USA
Preferred Term	Product						Dosage Text	Duration	Manufacturer	
Drug ineffective	ZECUITY								TEVA	



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13-Jul-2016	12551357	NON-EXPEDITED			US-TEVA-658334USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Hot flush Feeling hot	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551358	NON-EXPEDITED			US-TEVA-658858USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site irritation Application site erythema Application site inflammation Drug ineffective	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551359	NON-EXPEDITED			US-TEVA-658321USA	49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug effect incomplete Application site paraesthesia Device battery issue	ZECUITY	S				TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551360	NON-EXPEDITED			US-TEVA-657051USA	50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Hypersensitivity Application site erythema Application site pain Application site pruritus	ZECUITY	S	Transdermal			TEVA		



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13-Jul-2016	12551361	NON-EXPEDITED			US-TEVA-658825USA	29 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551362	NON-EXPEDITED			US-TEVA-657743USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site pain								
Device leakage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551363	NON-EXPEDITED			US-TEVA-658326USA	32 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S			TEVA	
Application site exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551365	NON-EXPEDITED			US-TEVA-658034USA	38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site discoloration								
Incorrect drug administration duration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551366	NON-EXPEDITED			US-TEVA-656984USA	37 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Eyelid ptosis			ZECUITY	S Transdermal			TEVA	
Insomnia								



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13-Jul-2016	12551367	NON-EXPEDITED			S	Transdermal	US-TEVA-658847USA		Male	USA
<u>Preferred Term</u>										
Application site urticaria										
Application site discoloration										
Application site erythema										
Application site pain										
<u>EDA Received Date</u>										
<u>Case #</u>										
<u>Case Type</u>										
<u>Health Professional</u>										
<u>Outcomes</u>										
<u>Role</u>										
<u>Route</u>										
<u>Manufacturer Control #</u>										
<u>Age</u>										
<u>Sex</u>										
<u>Country</u>										
<u>Preferred Term</u>										
Application site erythema										
Product physical issue										
<u>EDA Received Date</u>										
<u>Case #</u>										
<u>Case Type</u>										
<u>Health Professional</u>										
<u>Outcomes</u>										
<u>Role</u>										
<u>Route</u>										
<u>Manufacturer Control #</u>										
<u>Age</u>										
<u>Sex</u>										
<u>Country</u>										
<u>Preferred Term</u>										
Application site paraesthesia										
Application site discoloration										
Application site erythema										
Application site pruritus										
Application site swelling										
Application site warmth										
<u>EDA Received Date</u>										
<u>Case #</u>										
<u>Case Type</u>										
<u>Health Professional</u>										
<u>Outcomes</u>										
<u>Role</u>										
<u>Route</u>										
<u>Manufacturer Control #</u>										
<u>Age</u>										
<u>Sex</u>										
<u>Country</u>										
<u>Preferred Term</u>										
Application site pain										
Application site erythema										
Device leakage										
Product adhesion issue										



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13-Jul-2016	12551371	NON-EXPEDITED			US-TEVA-6558343USA	63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Headache	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551372	NON-EXPEDITED			US-TEVA-657962USA	30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Device battery issue Product use issue	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551373	NON-EXPEDITED			US-TEVA-656807USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site irritation Drug interaction Nausea	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551374	NON-EXPEDITED			US-TEVA-656956USA	37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		



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13-Jul-2016	12551375	NON-EXPEDITED			S	Transdermal		US-TEVA-656983USA	59 YR	Female	USA
Preferred Term											
Application site paraesthesia											
Application site discoloration											
Application site erythema											
Application site swelling											
Device battery issue											
<hr/>											
13-Jul-2016	12551376	NON-EXPEDITED			S	Transdermal		US-TEVA-656962USA	50 YR	Female	USA
Preferred Term											
Application site hypoaesthesia											
Palpitations											
<hr/>											
13-Jul-2016	12551377	NON-EXPEDITED			S	Transdermal		US-TEVA-657012USA	50 YR	Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Application site paraesthesia											
Application site rash											
Intentional product misuse											
Product use issue											
<hr/>											
13-Jul-2016	12551378	NON-EXPEDITED			S	Transdermal		US-TEVA-656964USA	26 YR	Female	USA
Preferred Term											
Application site pain											



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13-Jul-2016	12551379	NON-EXPEDITED			US-TEVA-657330USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Dysgeusia Application site erythema Application site swelling Drug effect incomplete Parosmia	ZECURITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551380	NON-EXPEDITED			US-TEVA-657394USA	34 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia Application site erosion Application site erythema Application site irritation Application site pain Application site scab Device battery issue Menstruation delayed	ZECURITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551381	NON-EXPEDITED		OT	US-TEVA-657454USA	29 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECURITY	S	Transdermal	6.5mg every 4 hours		TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jul-2016	12551382	NON-EXPEDITED			US-TEVA-657389USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug effect incomplete Therapeutic response unexpected	ZECURITY	S	Transdermal			TEVA		



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13-Jul-2016	12551383	NON-EXPEDITED			S	Transdermal	US-TEVA-658024USA	27 YR	Female	USA
Preferred Term										
Application site pain										
Application site discoloration										
Application site erythema										
Application site laceration										
Application site macule										
Incorrect drug administration duration										
<hr/>										
13-Jul-2016	12551384	NON-EXPEDITED			S	Transdermal	US-TEVA-658332USA	50 YR	Female	USA
Preferred Term										
Dysgeusia										
Device battery issue										
Product quality issue										
<hr/>										
13-Jul-2016	12551385	NON-EXPEDITED			S	Transdermal	US-TEVA-656979USA	23 YR	Female	USA
Preferred Term										
Application site erythema										
Application site pain										
Application site warmth										
<hr/>										
13-Jul-2016	12551386	NON-EXPEDITED			S		US-TEVA-658324USA	45 YR	Female	USA
Preferred Term										
Application site paraesthesia										
Device battery issue										
Product odour abnormal										



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13-Jul-2016	12551387	NON-EXPEDITED			S	Transdermal		US-TEVA-657013USA	41 YR	Female	USA
Preferred Term											
Application site coldness											
Application site discoloration											
Application site erythema											
Product adhesion issue											
Product physical issue											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551388	NON-EXPEDITED			S	Transdermal		US-TEVA-657698USA	53 YR	Male	USA
Preferred Term											
Drug ineffective											
Migraine											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551389	NON-EXPEDITED		OT				US-TEVA-657708USA		Female	USA
Preferred Term											
Application site vesicles											
Application site erythema											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551396	NON-EXPEDITED			S	Transdermal		US-TEVA-657699USA		Female	USA
Preferred Term											
Application site warmth											
Application site discoloration											
Application site erythema											
Application site pruritus											



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13-Jul-2016	12551397	NON-EXPEDITED					US-TEVA-657704USA	51 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>			<u>Manufacturer</u>
Drug ineffective			ZECUITY		S	Transdermal	6.5 mg /4 hours			TEVA
Device battery issue										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551398	NON-EXPEDITED					US-TEVA-657490USA	41 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site irritation			ZECUITY		S	Transdermal				TEVA
Application site rash			CITALOPRAM		C					
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551400	NON-EXPEDITED					US-TEVA-659858USA	31 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUITY		S	Transdermal	used for one month			TEVA
			ADVIL		C					
			TYLENOL		C					
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551401	NON-EXPEDITED					US-TEVA-659041USA	51 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site bruise			ZECUITY		S	Transdermal				TEVA
Application site irritation										
Device battery issue										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551403	NON-EXPEDITED					US-TEVA-659044USA	39 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site discoloration			ZECUITY		S	Transdermal				TEVA
Application site pain										



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13-Jul-2016	12551405	NON-EXPEDITED			S	Transdermal	US-TEVA-657705USA	35 YR	Female	USA
Preferred Term										
Application site paraesthesia										
Application site dryness										
Application site erythema										
Application site pruritus										
Drug ineffective										
<hr/>										
13-Jul-2016	12551406	NON-EXPEDITED			S	Transdermal	US-TEVA-657733USA		Female	USA
Preferred Term										
Application site bruise										
Application site pruritus										
Drug ineffective										
<hr/>										
13-Jul-2016	12551407	NON-EXPEDITED			S	Transdermal	US-TEVA-659258USA		Female	USA
Preferred Term										
Drug ineffective										
<hr/>										
13-Jul-2016	12551408	NON-EXPEDITED			S	Transdermal	US-TEVA-657692USA	56 YR	Female	USA
Preferred Term										
Application site erythema										
Application site discoloration										
Application site dryness										
Application site papules										
Application site paraesthesia										
Application site pruritus										
Application site swelling										
Drug ineffective										



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13-Jul-2016	12551409	NON-EXPEDITED			S	Transdermal	US-TEVA-659269USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash			ZECUITY						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551410	NON-EXPEDITED			S	Transdermal	US-TEVA-658933USA	57 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dizziness			ZECUITY		S	Transdermal			TEVA	
Nausea			SEROQUEL		S	Unknown				
Dysarthria			CELEXA		S	Unknown				
Application site erythema										
Application site pruritus										
Drug interaction										
Product physical issue										
Vision blurred										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551411	NON-EXPEDITED			S	Transdermal	US-TEVA-657700USA	51 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY		S	Transdermal			TEVA	
Application site discoloration										
Application site pruritus										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551412	NON-EXPEDITED			S	Transdermal	US-TEVA-659607USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device battery issue			ZECUITY		S	Transdermal			TEVA	
Application site erythema										
Application site pain										



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13-Jul-2016	12551414	NON-EXPEDITED			S	Transdermal	US-TEVA-658945USA	53 YR	Male	USA
Preferred Term Application site pain Application site paraesthesia										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551417	NON-EXPEDITED			S	Transdermal	US-TEVA-659637USA	43 YR	Female	USA
Preferred Term Drug ineffective Device battery issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551418	NON-EXPEDITED			S	Transdermal	US-TEVA-659613USA	59 YR	Female	USA
Preferred Term Application site rash Application site erythema Application site pain Device battery issue Product physical issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551419	NON-EXPEDITED			S	Transdermal	US-TEVA-659644USA	64 YR	Female	USA
Preferred Term Application site pain Application site erythema Application site reaction										



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13-Jul-2016	12551420	NON-EXPEDITED			S	Transdermal	US-TEVA-659687USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective	ZECUITY								TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551421	NON-EXPEDITED			S	Transdermal	US-TEVA-660145USA		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site reaction	ZECUITY								TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551422	NON-EXPEDITED			S	Transdermal	US-TEVA-665221USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective	ZECUITY								TEVA	
Product physical issue										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551423	NON-EXPEDITED			S	Transdermal	US-TEVA-659320USA	56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site irritation	ZECUITY								TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551424	NON-EXPEDITED			S	Transdermal	US-TEVA-659368USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective	ZECUITY								TEVA	
Application site erythema										
Application site pain										
Application site pruritus										
Application site swelling										



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13-Jul-2016	12551425	NON-EXPEDITED			US-TEVA-659690USA	37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site inflammation								
Application site pruritus								
Application site swelling								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551426	NON-EXPEDITED			US-TEVA-659373USA	41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S				TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551427	NON-EXPEDITED			US-TEVA-659466USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site swelling	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551430	NON-EXPEDITED			US-TEVA-667827USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug effect incomplete	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551431	NON-EXPEDITED			US-TEVA-660156USA		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site reaction	ZECUITY	S	Transdermal			TEVA		
Rash								



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13-Jul-2016	12552769	NON-EXPEDITED			US-TEVA-657323USA		Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Application site exfoliation								
Application site pruritus								
Application site rash								
Device battery issue								
Drug effect incomplete								
Incorrect drug administration duration								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12553336	EXPEDITED (15-DAY)		OT	US-TEVA-671427USA	44 YR	Female	USA
Preferred Term								
Application site scar								
Application site discolouration								
Application site erythema								
Incorrect drug administration duration								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12556436	DIRECT	Y			46 YR	Female	USA
Preferred Term								
Application site rash								
Paraesthesia								



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14-Jul-2016	12502568	EXPEDITED (15-DAY)		OT	US-TEVA-670196USA	46 YR	Female	USA
Preferred Term		Product		Role Route	Dosage Text	Duration	Manufacturer	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jul-2016	12517140	EXPEDITED (15-DAY)		OT	US-TEVA-671447USA	45 YR	Female	USA
Preferred Term		Product		Role Route	Dosage Text	Duration	Manufacturer	
Sunburn		ZECUITY		S Transdermal	6.5 mg over 4 hours		TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Incorrect drug administration duration								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jul-2016	12519876	EXPEDITED (15-DAY)		OT	US-TEVA-672126USA	34 YR	Male	USA
Preferred Term		Product		Role Route	Dosage Text	Duration	Manufacturer	
Chemical injury		ZECUITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site paraesthesia								
Migraine								
Product adhesion issue								
Product physical issue								



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14-Jul-2016	12519983	EXPEDITED (15-DAY)		OT	US-TEVA-671334USA	54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn Application site burn Application site discolouration Application site erythema Migraine	ZECURITY	S	Transdermal			TEVA		
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2016	12524921	EXPEDITED (15-DAY)		OT	US-TEVA-672215USA	50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Burns first degree Application site erythema Application site hypoaesthesia Application site irritation Application site pain Application site pruritus Application site scar Application site vesicles Dysgeusia Product physical issue Skin exfoliation Sunburn	ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Wrong technique in product usage process								



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14-Jul-2016	12528859	EXPEDITED (15-DAY)		OT	US-TEVA-673599USA	52 YR	Female	USA
Preferred Term								
Sunburn				<u>Role Route</u> S Transdermal	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u> TEVA	
Application site discolouration								
Application site erythema								
Application site warmth								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2016	12538130	EXPEDITED (15-DAY)		OT	US-TEVA-673825USA	44 YR	Female	USA
Preferred Term								
Application site burn				<u>Role Route</u> S Transdermal	<u>Dosage Text</u> 6.5 mg / 4 hours	<u>Duration</u>	<u>Manufacturer</u> TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site reaction								
Application site vesicles								
Application site warmth								
Inappropriate schedule of drug administration								
Product adhesion issue								
Product physical issue								
Sunburn								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2016	12554831	EXPEDITED (15-DAY)		OT	US-TEVA-675861USA		Female	USA
Preferred Term								
Application site burn				<u>Role Route</u> S Transdermal	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u> TEVA	
Application site pain								
Application site vesicles								
Incorrect drug administration duration								



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14-Jul-2016	12556455	NON-EXPEDITED			US-TEVA-655049USA		Unknown	USA
Preferred Term								
Application site urticaria								
Product physical issue								
Product								
ZECUIITY								
Role Route								
S Transdermal								
Dosage Text								
6.5MG/4HR								
Manufacturer								
TEVA								
Duration								
EDA Received Date								
14-Jul-2016								
Case #								
12557259								
Case Type								
EXPEDITED (15-DAY)								
Health Professional								
Outcomes								
OT								
Manufacturer Control #								
US-TEVA-676533USA								
Age								
41 YR								
Sex								
Male								
Country								
USA								
Preferred Term								
Application site scar								
Application site discoloration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Product physical issue								
Product								
ZECUIITY								
Role Route								
S Transdermal								
Dosage Text								
Manufacturer								
TEVA								
Duration								
EDA Received Date								
14-Jul-2016								
Case #								
12557401								
Case Type								
EXPEDITED (15-DAY)								
Health Professional								
Outcomes								
OT								
Manufacturer Control #								
US-TEVA-672595USA								
Age								
45 YR								
Sex								
Female								
Country								
USA								
Preferred Term								
Sunburn								
Application site discoloration								
Application site erythema								
Application site exfoliation								
Drug ineffective								



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14-Jul-2016	12560485	DIRECT		OT		38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Skin Irritation			ZECUITY	S	1 patch(es) Once a day Applied as medicated patch to skin			
Application site pruritus			TOPAMAX	C				
Application site pain			FLORICET	C				
Device malfunction			INDOMETHACIN	C				
			XANMAX	C				
Application site pain								
Application site scar								
Application site urticaria								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12254604	NON-EXPEDITED		OT	US-TEVA-650631USA	53 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn			ZECUITY	S			TEVA	
Application site pain			PREMPRO	C				
Application site erythema			NASOCORT	C				
Application site discoloration			BENADRYL	C				
Application site discoloration								
Device leakage								
Drug ineffective								
Dry skin								



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15-Jul-2016	12281701	NON-EXPEDITED			US-TEVA-641331USA	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		ZECURITY	S	Transdermal			TEVA	
Dizziness								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12281725	NON-EXPEDITED			US-TEVA-641736USA	38 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Discomfort		ZECURITY	S	Transdermal			TEVA	
Dysstasia								
Palpitations								
Paraesthesia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12281727	NON-EXPEDITED			US-TEVA-641719USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECURITY	S	Transdermal			TEVA	
Application site pruritus								
Application site rash								



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15-Jul-2016	12281757	NON-EXPEDITED			US-TEVA-642159USA	51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUIITY	S	Transdermal			TEVA		
Device leakage	ZECUIITY	S	Transdermal			TEVA		
Application site paraesthesia	ZECUIITY	S	Transdermal			TEVA		
Underdose	ZECUIITY	S	Transdermal			TEVA		
Product adhesion issue	ZECUIITY	S	Transdermal			TEVA		
Application site pain	ZECUIITY	S	Transdermal			TEVA		
Application site erythema	sumatriptan	C						
Application site irritation	Calcium with vitamin D3	C		600mg with D3				
	Gabapentin	C		2700 Milligram Daily;				
	B-12	C	Oral					
	omeprazole	C						
	trazadone	C		QHS				
	Cymbalta	C						
	Toradol	C		PRN				
	Phenergan	C		PRN				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12281764	NON-EXPEDITED			US-TEVA-641841USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Migraine	ZECUIITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
Application site erythema								
Device battery issue								
Device leakage								
Drug ineffective								



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15-Jul-2016	12281781	NON-EXPEDITED			S	Transdermal	US-TEVA-644705USA		Female	USA
Preferred Term Application site erythema Application site pruritus										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12281782	NON-EXPEDITED			S	Transdermal	US-TEVA-644007USA	49 YR	Female	USA
Preferred Term Drug ineffective Application site erythema Application site discoloration Application site dryness Application site pruritus										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12281786	NON-EXPEDITED			S	Transdermal	US-TEVA-643685USA	30 YR	Female	USA
Preferred Term Application site pain Device battery issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12281821	NON-EXPEDITED			S	Transdermal	US-TEVA-643918USA	44 YR	Female	USA
Preferred Term Drug effect incomplete Product physical issue Wrong technique in product usage process										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
					S	Transdermal			TEVA	



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15-Jul-2016	12281822	NON-EXPEDITED			US-TEVA-642482USA	29 YR	Female	USA
Preferred Term								
Application site warmth								
Application site erythema								
Application site inflammation								
Application site pain								
Incorrect drug administration duration								
<hr/>								
15-Jul-2016	12284709	NON-EXPEDITED			US-TEVA-645021USA	49 YR	Female	USA
Preferred Term								
Application site rash								
Application site irritation								
Application site pain								
<hr/>								
15-Jul-2016	12284748	NON-EXPEDITED			US-TEVA-646715USA	56 YR	Female	USA
Preferred Term								
Myocardial infarction								
Application site erythema								
Application site pruritus								
Chest pain								
Hypoaesthesia								
Pain								



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15-Jul-2016	12284853	NON-EXPEDITED			US-TEVA-648169USA	36 YR	Female	USA
Preferred Term								
Wound				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site rash								
Skin abrasion								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
15-Jul-2016	12342644	EXPEDITED (15-DAY)		OT	US-TEVA-656797USA		Female	USA
Preferred Term								
Application site burn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site bruise								
Application site erythema								
Application site pain								
Application site scab								
Application site swelling								
Drug ineffective								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
15-Jul-2016	12501124	EXPEDITED (15-DAY)		OT	US-TEVA-669920USA		Female	USA
Preferred Term								
Application site burn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site pruritus								



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15-Jul-2016	12510136	EXPEDITED (15-DAY)		OT	US-TEVA-670933USA		Female	USA
Preferred Term								
Application site burn								
Application site discomfort								
Application site pain								
Application site paraesthesia								
Application site vesicles								
Application site warmth								
Sunburn								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12538118	EXPEDITED (15-DAY)		OT	US-TEVA-673824USA		Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site discoloration								
Application site pain								
Application site vesicles								
Application site warmth								
Incorrect drug administration duration								
Product physical issue								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12540541	NON-EXPEDITED			US-TEVA-649764USA	34 YR	Female	USA
Preferred Term								
Application site discoloration								
Drug effect incomplete								
Drug ineffective								
Product physical issue								



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15-Jul-2016	12540611	NON-EXPEDITED			S	Transdermal	US-TEVA-651820USA		Female	USA
Preferred Term										
Application site discomfort										
Application site coldness										
Application site erythema										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12551273	NON-EXPEDITED			S	Transdermal	US-TEVA-655222USA	69 YR	Female	USA
Preferred Term										
Application site erythema										
Product physical issue										
Application site pain										
Application site bruise										
Application site oedema										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12551312	NON-EXPEDITED			S	Transdermal	US-TEVA-656169USA		Female	USA
Preferred Term										
Application site pain										
Application site rash										
Incorrect drug administration duration										
Product adhesion issue										
Product physical issue										



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EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12551331	NON-EXPEDITED			US-TEVA-657795USA	33 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECUIITY	S	Transdermal	she had used 7-8 TDS previously		TEVA		
Application site rash	ZECUIITY	S	Transdermal			TEVA		
Application site dryness								
Product adhesion issue								
Product physical issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12551364	NON-EXPEDITED			US-TEVA-658865USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECUIITY	S	Transdermal			TEVA		
Product physical issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12551402	NON-EXPEDITED			US-TEVA-659305USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Device battery issue	ZECUIITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Application site erythema								
Application site pain								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12551413	NON-EXPEDITED			US-TEVA-659253USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia	ZECUIITY	S	Transdermal			TEVA		
Product quality issue								



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15-Jul-2016	12551416	NON-EXPEDITED			US-TEVA-659467USA	42 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY	S Transdermal	6.5 mg/4 hours		TEVA	
			TOPAMAX	C				
			ALBUTEROL	C				
			BOTOX	C				
			MAXALT	C				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12551428	NON-EXPEDITED			US-TEVA-658911USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECUITY	S Transdermal			TEVA	
Application site dryness								
Application site erythema								
Drug effect incomplete								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559018	NON-EXPEDITED			US-TEVA-660128USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site discoloration								
Application site exfoliation								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559019	NON-EXPEDITED			US-TEVA-660140USA	62 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site irritation								
Application site pruritus								
Application site rash								



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15-Jul-2016	12559020	NON-EXPEDITED			US-TEVA-660147USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema Product physical issue Wrong technique in product usage process	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559021	NON-EXPEDITED			US-TEVA-660134USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective Product physical issue	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559022	NON-EXPEDITED			US-TEVA-661011USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Product physical issue	ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559023	NON-EXPEDITED			US-TEVA-660614USA	48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pruritus Application site erythema Application site rash	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559024	NON-EXPEDITED			US-TEVA-660129USA	37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA		



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15-Jul-2016	12559025	NON-EXPEDITED			S	Transdermal	US-TEVA-660063USA		Female	USA
Preferred Term										
Application site inflammation										
Application site erythema										
Application site pain										
Application site paraesthesia										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559026	NON-EXPEDITED			S	Transdermal	US-TEVA-661091USA		Female	USA
Preferred Term										
Application site erythema										
Application site pain										
Intentional product use issue										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559027	NON-EXPEDITED			S	Transdermal	US-TEVA-660142USA		Female	USA
Preferred Term										
Application site urticaria										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559028	NON-EXPEDITED			S	Transdermal	US-TEVA-660941USA	22 YR	Female	USA
Preferred Term										
Application site pain										
Application site bruise										
Application site erythema										
Application site swelling										
Chest discomfort										
Discomfort										
Dizziness										



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15-Jul-2016	12559029	NON-EXPEDITED			S	Transdermal	US-TEVA-660612USA	54 YR	Female	USA
Preferred Term										
Application site erythema										
Application site reaction										
Application site swelling										
Drug ineffective										
Product adhesion issue										
<hr/>										
15-Jul-2016	12559030	NON-EXPEDITED			S	Transdermal	US-TEVA-660141USA		Male	USA
Preferred Term										
Application site erythema										
Application site pain										
Drug effect incomplete										
Product physical issue										
<hr/>										
15-Jul-2016	12559031	NON-EXPEDITED			S	Transdermal	US-TEVA-660132USA	47 YR	Female	USA
Preferred Term										
Application site rash										
Application site pain										
Application site pruritus										
<hr/>										
15-Jul-2016	12559032	NON-EXPEDITED			S	Transdermal	US-TEVA-660371USA	44 YR	Female	USA
Preferred Term										
Application site pain										
Application site paraesthesia										
Device battery issue										
Product adhesion issue										



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15-Jul-2016	12559033	NON-EXPEDITED			US-TEVA-660953USA	45 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Application site erythema				S Transdermal	4 hours			TEVA
Application site pain								
Application site pruritus								
Application site swelling								
Device adhesion issue								
Device battery issue								
Device defective								
Parasthesia								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559034	NON-EXPEDITED			US-TEVA-660982USA	65 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Application site erythema				S Transdermal	6.5 mg over 4 hours			TEVA
Application site pain								
Application site swelling								
Application site urticaria								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559035	NON-EXPEDITED			US-TEVA-660137USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>			<u>Manufacturer</u>
Application site erythema				S Transdermal	6.5 mg over 4 hours			TEVA
Application site bruise								
Application site laceration								
Application site pain								
Application site pruritus								
Application site swelling								



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15-Jul-2016	12559036	NON-EXPEDITED			US-TEVA-660143USA	52 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY	S Transdermal			TEVA	
			ZECURITY	S Transdermal			TEVA	
<u>EDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559037	NON-EXPEDITED			US-TEVA-660394USA	43 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECURITY	S Transdermal	2 or 3 patches since March 2016		TEVA	
Application site erythema								
Application site urticaria								
<u>EDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559038	NON-EXPEDITED			US-TEVA-660952USA	65 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY	S Transdermal	4 hours		TEVA	
Application site pain								
Device battery issue								
Drug effect incomplete								
Product physical issue								
<u>EDA Received Date</u> <th><u>Case #</u></th> <th><u>Case Type</u></th> <th><u>Health Professional</u></th> <th><u>Outcomes</u></th> <th><u>Manufacturer Control #</u></th> <th><u>Age</u></th> <th><u>Sex</u></th> <th><u>Country</u></th>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559039	NON-EXPEDITED			US-TEVA-660373USA	44 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect incomplete			ZECURITY	S Transdermal			TEVA	
Application site pain								
Application site pruritus								



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15-Jul-2016	12559040	NON-EXPEDITED			US-TEVA-660130USA	22 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559041	NON-EXPEDITED			US-TEVA-661078USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
			Application site warmth	C Unknown				
			Application site erythema					
			Application site pain					
			Application site swelling					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559042	NON-EXPEDITED			US-TEVA-660605USA	44 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
			Application site erythema					
			Device battery issue					
			Product adhesion issue					
			Product physical issue					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559043	NON-EXPEDITED			US-TEVA-660764USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
			Application site discoloration					



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15-Jul-2016	12559044	EXPEDITED (15-DAY)		OT	US-TEVA-660948USA		Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Application site rash								
Application site urticaria								
Application site vesicles								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559045	NON-EXPEDITED			US-TEVA-660609USA	37 YR	Male	USA
Preferred Term								
Drug prescribing error								
Drug effect incomplete								
Intentional product misuse								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559046	NON-EXPEDITED			US-TEVA-660386USA	34 YR	Female	USA
Preferred Term								
Drug effect incomplete								
Product physical issue								



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15-Jul-2016	12559047	NON-EXPEDITED			US-TEVA-660135USA	44 YR	Male	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Device leakage				S Transdermal	6.5 mg over 4 hours			TEVA
Application site erythema								
Application site pain								
Application site pruritus								
Application site warmth								
Device battery issue								
Paraesthesia								
Product adhesion issue								
Skin disorder								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559048	NON-EXPEDITED			US-TEVA-660552USA		Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Wound				S Transdermal	from 12-Feb-2016 to current - dates and number of patches used not provided			TEVA
Application site inflammation								
Application site vesicles								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559049	NON-EXPEDITED			US-TEVA-661092USA		Male	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema				S Transdermal	6.5 mg over 4 hours			TEVA
Application site discomfort								
Application site pain								
Application site pruritus								
Application site urticaria								



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15-Jul-2016	12559050	NON-EXPEDITED			S	Transdermal	US-TEVA-660984USA	39 YR	Female	USA
Preferred Term										
Application site pain										
ZECUITY										
Adverse event										
Application site erythema										
Application site swelling										
<hr/>										
15-Jul-2016	12559051	NON-EXPEDITED			S	Transdermal	US-TEVA-660380USA	34 YR	Female	USA
Preferred Term										
Application site erythema										
ZECUITY										
Device battery issue										
<hr/>										
15-Jul-2016	12559052	NON-EXPEDITED			S	Transdermal	US-TEVA-660412USA		Female	USA
Preferred Term										
Drug ineffective										
ZECUITY										
<hr/>										
15-Jul-2016	12559055	NON-EXPEDITED			S	Transdermal	US-TEVA-660617USA	44 YR	Female	USA
Preferred Term										
Application site rash										
ZECUITY										
Application site erythema										
Application site pruritus										
Drug effect incomplete										
Product physical issue										
Somnolence										



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15-Jul-2016	12559056	NON-EXPEDITED					US-TEVA-660771USA		Female	USA
Preferred Term										
Application site erythema										
					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
					S	Transdermal	6.5 mg over 4 hours		TEVA	
15-Jul-2016	12559057	NON-EXPEDITED					US-TEVA-660944USA		Female	USA
Preferred Term										
Application site urticaria										
Application site pruritus										
					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
					S	Transdermal			TEVA	
15-Jul-2016	12559060	NON-EXPEDITED					US-TEVA-661097USA	49 YR	Female	USA
Preferred Term										
Chest discomfort										
					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
					S	Transdermal			TEVA	
					S	Unknown				
15-Jul-2016	12559062	NON-EXPEDITED					US-TEVA-660978USA	52 YR	Female	USA
Preferred Term										
Drug ineffective										
Intentional product use issue										
Product adhesion issue										
Product physical issue										
					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
					S	Transdermal			TEVA	
15-Jul-2016	12559063	NON-EXPEDITED					US-TEVA-661360USA		Female	USA
Preferred Term										
Tachycardia										
Incorrect drug administration duration										
Palpitations										
					<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
					S	Transdermal			TEVA	



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15-Jul-2016	12559064	NON-EXPEDITED			US-TEVA-661368USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site irritation Device adhesion issue Device battery issue	ZECUITY	S		6.5 mg / 4 hours		TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559066	NON-EXPEDITED			US-TEVA-660809USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Hypersensitivity	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559067	NON-EXPEDITED			US-TEVA-660973USA	65 YR	Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia Application site discoloration Application site erythema	ZECUITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559068	NON-EXPEDITED			US-TEVA-660935USA	36 YR	Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site discomfort Application site discoloration Application site erythema Application site reaction Application site warmth Paraesthesia	ZECUITY	S	Transdermal			TEVA		



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15-Jul-2016	12559069	NON-EXPEDITED			US-TEVA-660768USA	23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site dryness Application site dryness Application site pruritus	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559070	NON-EXPEDITED			US-TEVA-661080USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash Application site dryness Application site pain Application site pruritus Application site swelling Drug effect incomplete	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559071	NON-EXPEDITED			US-TEVA-660934USA	55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site exfoliation Application site pain	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559072	NON-EXPEDITED			US-TEVA-661212USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site discoloration	ZECUITY	S	Transdermal			TEVA		



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15-Jul-2016	12559074	NON-EXPEDITED			S	Transdermal	US-TEVA-661372USA	38 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site exfoliation										
Device leakage										
<hr/>										
15-Jul-2016	12559075	NON-EXPEDITED			S	Transdermal	US-TEVA-661381USA	46 YR	Female	USA
Preferred Term										
Migraine										
Product physical issue										
<hr/>										
15-Jul-2016	12559076	NON-EXPEDITED			S	Transdermal	US-TEVA-661580USA		Female	USA
Preferred Term										
Application site urticaria										
Application site bruise										
Application site pruritus										
Application site warmth										
<hr/>										
15-Jul-2016	12559077	NON-EXPEDITED			S	Transdermal	US-TEVA-661434USA	50 YR	Female	USA
Preferred Term										
Application site erythema										
Drug hypersensitivity										
Rash macular										



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15-Jul-2016	12559078	NON-EXPEDITED					US-TEVA-661378USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECURITY		S					TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559079	NON-EXPEDITED					US-TEVA-661389USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECURITY		S	Transdermal				TEVA
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559080	NON-EXPEDITED					US-TEVA-661795USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site reaction			ZECURITY		S	Transdermal				TEVA
Application site erythema										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559081	NON-EXPEDITED					US-TEVA-661469USA	51 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug effect incomplete			ZECURITY		S	Transdermal				TEVA
Application site discoloration										
Application site erythema										
Application site pain										
Application site paraesthesia										
Product physical issue										
Wrong technique in product usage process										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559084	NON-EXPEDITED					US-TEVA-661431USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECURITY		S	Transdermal				TEVA



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15-Jul-2016	12559090	NON-EXPEDITED			US-TEVA-661550USA	31 YR	Female	USA
Preferred Term								
Application site erythema								
Application site discomfort								
Application site rash								
Application site warmth								
Device leakage								
Paraesthesia								
<hr/>								
15-Jul-2016	12559091	NON-EXPEDITED			US-TEVA-661829USA	42 YR	Female	USA
Preferred Term								
Application site erythema								
Application site irritation								
Incorrect drug administration duration								
Product adhesion issue								
Product physical issue								
Skin reaction								
<hr/>								
15-Jul-2016	12559092	NON-EXPEDITED			US-TEVA-661578USA		Female	USA
Preferred Term								
Application site swelling								
Application site erythema								
Application site irritation								
Drug ineffective								
Product physical issue								



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15-Jul-2016	12559093	NON-EXPEDITED			US-TEVA-661840USA	16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site reaction Application site erythema Application site pruritus Incorrect drug administration duration	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559094	NON-EXPEDITED			US-TEVA-661430USA	68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug effect incomplete	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559095	NON-EXPEDITED		OT	US-TEVA-661435USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Dyspnoea Dizziness Heart rate increased	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559096	NON-EXPEDITED			US-TEVA-661848USA	38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site irritation	ZECUITY	S	Transdermal			TEVA		



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15-Jul-2016	12559098	NON-EXPEDITED			US-TEVA-661831USA	37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site erythema Application site exfoliation Product physical issue	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559099	NON-EXPEDITED			US-TEVA-661566USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site discoloration Skin hyperpigmentation	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559100	NON-EXPEDITED			US-TEVA-661841USA	40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Panic attack	ZECUITY XANAX	S C	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559101	NON-EXPEDITED			US-TEVA-661513USA	57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site pain Application site pruritus	ZECUITY	S	Transdermal			TEVA		



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15-Jul-2016	12559102	NON-EXPEDITED			S	Transdermal	US-TEVA-661498USA	34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema	ZECURITY								TEVA	
Application site pain										
Application site swelling										
Device adhesion issue										
Paraesthesia										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559103	NON-EXPEDITED			S	Transdermal	US-TEVA-661845USA	58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema	ZECURITY				S	Transdermal			TEVA	
Application site pruritus	ZECURITY				S	Transdermal			TEVA	
Wrong technique in product usage process										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559105	NON-EXPEDITED			S	Transdermal	US-TEVA-661842USA	33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema	ZECURITY				S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559106	NON-EXPEDITED			S	Transdermal	US-TEVA-661852USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>						<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug hypersensitivity	ZECURITY				S	Transdermal			TEVA	



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15-Jul-2016	12559108	NON-EXPEDITED			S	Transdermal	US-TEVA-661857USA	30 YR	Female	USA
Preferred Term										
Application site irritation										
Application site discoloration										
Application site pruritus										
Wrong technique in product usage process										
<hr/>										
15-Jul-2016	12559109	NON-EXPEDITED			S	Transdermal	US-TEVA-662126USA		Female	USA
Preferred Term										
Drug effect incomplete										
<hr/>										
15-Jul-2016	12559110	NON-EXPEDITED			S	Transdermal	US-TEVA-662016USA		Female	USA
Preferred Term										
Application site erythema										
Application site pruritus										
<hr/>										
15-Jul-2016	12559111	NON-EXPEDITED			S	Transdermal	US-TEVA-662101USA	26 YR	Female	USA
Preferred Term										
Application site pain										
Application site coldness										
Application site erythema										



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15-Jul-2016	12559112	NON-EXPEDITED			US-TEVA-662129USA	49 YR	Female	USA
Preferred Term								
Application site paraesthesia			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site pruritus			ZECUITY	S Transdermal			TEVA	
Device battery issue								
Product adhesion issue								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559113	NON-EXPEDITED			US-TEVA-662104USA		Female	USA
Preferred Term								
Pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site rash								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559114	NON-EXPEDITED			US-TEVA-664620USA	42 YR	Female	USA
Preferred Term								
Application site irritation			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site rash			ZECUITY	S Transdermal			TEVA	
Drug ineffective								



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15-Jul-2016	12559115	EXPEDITED (15-DAY)		OT	US-TEVA-664818USA	46 YR	Female	USA
Preferred Term								
Application site burn			Product		Dosage Text		Duration	Manufacturer
Application site scar			ZECUITY				TEVA	
Application site discoloration			S Transdermal				TEVA	
Application site erythema			S Transdermal					
Application site inflammation								
Application site pain								
Application site paraesthesia								
Application site swelling								
Application site urticaria								
Application site vesicles								
Drug ineffective								
Product quality issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559116	NON-EXPEDITED			US-TEVA-664826USA	49 YR	Female	USA
Preferred Term								
Vomiting			Product		Dosage Text		Duration	Manufacturer
Drug effect increased			ZECUITY				TEVA	
			S Transdermal					
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559117	NON-EXPEDITED			US-TEVA-664830USA	13 YR	Female	USA
Preferred Term								
Application site exfoliation			Product		Dosage Text		Duration	Manufacturer
Application site erythema			ZECUITY				TEVA	
Drug administered to patient of inappropriate age			S Transdermal					



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15-Jul-2016	12559118	NON-EXPEDITED			US-TEVA-664834USA	19 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site discoloration								
Application site erythema								
Application site pruritus								
Application site warmth								
Muscle tightness								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559119	NON-EXPEDITED			US-TEVA-665222USA	27 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia	ZECUITY	S	Transdermal			TEVA		
Application site dryness								
Application site irritation								
Application site pain								
Dry skin								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559120	NON-EXPEDITED			US-TEVA-665287USA	36 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site rash	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site urticaria								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559121	NON-EXPEDITED			US-TEVA-663440USA		Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug effect incomplete	ZECUITY	S	Transdermal			TEVA		



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15-Jul-2016	12559123	NON-EXPEDITED			US-TEVA-663443USA	37 YR	Female	USA
Preferred Term								
Drug ineffective				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Paraesthesia				S Transdermal			TEVA	
Application site discolouration				S Transdermal			TEVA	
Application site dyyness								
Application site erythema								
Application site exfoliation								
Incorrect drug administration duration								
Preferred Term								
Application site erythema				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discolouration				S Transdermal			TEVA	
Application site inflammation								
Application site pruritus								
Product physical issue								
FDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
15-Jul-2016	12559125	NON-EXPEDITED			US-TEVA-663430USA	65 YR	Female	USA
Preferred Term								
Application site erythema				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema				S Transdermal	6.5 mg/4 hours: on upper arm or thigh		TEVA	
Application site pruritus								



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15-Jul-2016	12559126	NON-EXPEDITED			S	Transdermal	6.5 mg over 4 hours		US-TEVA-663779USA	53 YR	Female	USA
Preferred Term Drug effect incomplete Migraine												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559128	NON-EXPEDITED			S	Transdermal			US-TEVA-663490USA	24 YR	Female	USA
Preferred Term Application site pain Application site erythema Application site irritation Application site rash Application site warmth Incorrect drug administration duration												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559129	NON-EXPEDITED			S	Transdermal			US-TEVA-663359USA		Female	USA
Preferred Term Application site erythema												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559130	NON-EXPEDITED			S	Transdermal			US-TEVA-664590USA	49 YR	Female	USA
Preferred Term Application site erythema Application site inflammation Wrong technique in product usage process												



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15-Jul-2016	12559131	NON-EXPEDITED			US-TEVA-663353USA	60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Application site pain								
Application site pruritus								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559132	NON-EXPEDITED			US-TEVA-663436USA	58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site pruritus								
Application site urticaria								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559133	NON-EXPEDITED			US-TEVA-663778USA	70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Application site erythema								
Application site urticaria								
Incorrect drug administration duration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559134	NON-EXPEDITED			US-TEVA-663485USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal	6.5mg/4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559135	NON-EXPEDITED			US-TEVA-663612USA		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		



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15-Jul-2016	12559136	NON-EXPEDITED			S	Transdermal		US-TEVA-664596USA	46 YR	Female	USA
Preferred Term											
Application site erythema											
Application site mass											
Application site rash											
Wrong technique in product usage process											
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15-Jul-2016	12559137	NON-EXPEDITED			S	Transdermal		US-TEVA-663744USA		Female	USA
Preferred Term											
Application site inflammation											
Application site dryness											
Application site rash											
<hr/>											
15-Jul-2016	12559138	NON-EXPEDITED			S			US-TEVA-663793USA	53 YR	Female	USA
Preferred Term											
Pain											
Application site erythema											
Application site irritation											
Application site pain											
Application site reaction											
Medication overuse headache											
Product physical issue											



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15-Jul-2016	12559139	NON-EXPEDITED			S	Transdermal	US-TEVA-664060USA	52 YR	Female	USA
Preferred Term										
Application site discoloration										
Application site exfoliation										
Application site paraesthesia										
Skin papilloma										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559140	NON-EXPEDITED			S	Transdermal	US-TEVA-663995USA	28 YR	Female	USA
Preferred Term										
Application site inflammation										
Application site rash										
Application site urticaria										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559141	NON-EXPEDITED			S	Transdermal	US-TEVA-663735USA	41 YR	Female	USA
Preferred Term										
Application site erythema										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559142	NON-EXPEDITED			S	Transdermal	US-TEVA-664616USA	59 YR	Female	USA
Preferred Term										
Application site erythema										
Product physical issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559143	NON-EXPEDITED			S	Transdermal	US-TEVA-664165USA	21 YR	Female	USA
Preferred Term										
Application site pain										



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15-Jul-2016	12559144	NON-EXPEDITED			S	Transdermal	US-TEVA-664609USA	61 YR	Male	USA
Preferred Term										
Application site erythema										
Application site rash										
Product adhesion issue										
Wrong technique in product usage process										
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559145	NON-EXPEDITED			S	Transdermal	US-TEVA-662180USA		Female	USA
Preferred Term										
Palpitations										
Application site rash										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559146	NON-EXPEDITED			S	Transdermal	US-TEVA-664494USA	56 YR	Female	USA
Preferred Term										
Dermatitis contact										
Application site rash										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559147	NON-EXPEDITED			S	Transdermal	US-TEVA-664450USA		Female	USA
Preferred Term										
Application site erythema										
Adverse event										
Fatigue										
Product physical issue										



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15-Jul-2016	12559148	NON-EXPEDITED			US-TEVA-662170USA	17 YR	Female	USA
Preferred Term								
Application site erythema				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site inflammation				S Transdermal	6.5 mg over 4 hours		TEVA	
Migraine								
Product use issue								
Somnolence								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559149	NON-EXPEDITED			US-TEVA-663991USA	25 YR	Female	USA
Preferred Term								
Application site pain				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discoloration				S Unknown			TEVA	
Application site erythema								
Application site pain								
Feeling abnormal								
Incorrect drug administration duration								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559150	NON-EXPEDITED			US-TEVA-664602USA	49 YR	Female	USA
Preferred Term								
Application site erythema				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discoloration				S Transdermal			TEVA	
Application site inflammation								
Application site mass								
Application site pruritus								



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15-Jul-2016	12559151	NON-EXPEDITED			S	Transdermal	US-TEVA-662809USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUIITY							TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559152	NON-EXPEDITED			S	Transdermal	US-TEVA-664592USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site exfoliation			ZECUIITY							TEVA
Application site erythema										
Application site pruritus										
Application site rash										
Drug effect incomplete										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559153	NON-EXPEDITED			S	Transdermal	US-TEVA-663994USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Burning sensation			ZECUIITY				6.5 mg ober 4 hours			TEVA
Application site warmth										
Incorrect drug administration duration										
Nausea										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559154	NON-EXPEDITED			S	Transdermal	US-TEVA-662167USA	32 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUIITY							TEVA
Application site inflammation			ZECUIITY							TEVA
Application site rash			ZECUIITY							TEVA
Application site pruritus			ZECUIITY							TEVA
Migraine										
Product physical issue										



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15-Jul-2016	12559155	NON-EXPEDITED			US-TEVA-662134USA	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea		ZECURITY	S	Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559156	NON-EXPEDITED			US-TEVA-664599USA	36 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site inflammation								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Flushing								
Hypersensitivity								
Incorrect drug administration duration								
Product physical issue								
Pruritus generalised								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559157	NON-EXPEDITED			US-TEVA-664469USA	35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECURITY	S	Transdermal			TEVA	
Application site erythema								



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15-Jul-2016	12559158	NON-EXPEDITED			S	Transdermal	US-TEVA-662533USA	50 YR	Female	USA
Preferred Term										
Application site warmth										
Application site erythema										
Application site pain										
Incorrect drug administration duration										
<hr/>										
15-Jul-2016	12559159	NON-EXPEDITED			S	Transdermal	US-TEVA-662178USA		Male	USA
Preferred Term										
Application site pruritus										
Dizziness										
<hr/>										
15-Jul-2016	12559160	NON-EXPEDITED			S	Transdermal	US-TEVA-662803USA		Female	USA
Preferred Term										
Application site rash										
<hr/>										
15-Jul-2016	12559161	NON-EXPEDITED			S	Transdermal	US-TEVA-664597USA	59 YR	Male	USA
Preferred Term										
Application site erythema										
Application site inflammation										
Application site pain										
Drug effect incomplete										
Product physical issue										
Wrong technique in product usage process										



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15-Jul-2016	12559162	NON-EXPEDITED			S	Transdermal	US-TEVA-662163USA	55 YR	Female	USA
Preferred Term										
Application site pruritus										
Application site erythema										
Application site urticaria										
Drug ineffective										
<hr/>										
15-Jul-2016	12559163	NON-EXPEDITED					US-TEVA-662685USA		Female	USA
Preferred Term										
Application site discoloration										
<hr/>										
15-Jul-2016	12559164	NON-EXPEDITED			S	Transdermal	US-TEVA-664600USA	40 YR	Female	USA
Preferred Term										
Application site urticaria										
Application site discoloration										
Application site pain										
Incorrect drug administration duration										
<hr/>										
15-Jul-2016	12559165	NON-EXPEDITED					US-TEVA-662328USA		Female	USA
Preferred Term										
Application site rash										



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15-Jul-2016	12559166	NON-EXPEDITED			US-TEVA-662166USA		Female	USA
Preferred Term								
Product physical issue								
Application site erythema								
Product physical issue								
Product physical issue								
Preferred Term								
Product physical issue								
Application site erythema								
Product physical issue								
Product physical issue								
Wrong technique in product usage process								
<hr/>								
15-Jul-2016	12559167	NON-EXPEDITED			US-TEVA-662683USA		Female	USA
Preferred Term								
Application site erythema								
ZECUITY								
ZECUITY								
Preferred Term								
Application site erythema								
ZECUITY								
ZECUITY								
Wrong technique in product usage process								
<hr/>								
15-Jul-2016	12559169	NON-EXPEDITED			US-TEVA-662874USA	56 YR	Female	USA
Preferred Term								
Application site erythema								
Application site pruritus								
Application site urticaria								
Application site vesicles								
Product physical issue								
Wrong technique in product usage process								



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EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559170	NON-EXPEDITED			S	Transdermal	US-TEVA-662521USA	50 YR	Female	USA
Preferred Term	Product	Dosage Text	Duration	Manufacturer						
Application site rash	ZECUITY			TEVA						
Application site pruritus										
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559171	NON-EXPEDITED			S	Transdermal	US-TEVA-662864USA	53 YR	Female	USA
Preferred Term	Product	Dosage Text	Duration	Manufacturer						
Drug effect incomplete	ZECUITY			TEVA						
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559172	NON-EXPEDITED			S	Transdermal	US-TEVA-662536USA	22 YR	Female	USA
Preferred Term	Product	Dosage Text	Duration	Manufacturer						
Drug ineffective	ZECUITY			TEVA						
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559173	NON-EXPEDITED			S	Transdermal	US-TEVA-662581USA	54 YR	Female	USA
Preferred Term	Product	Dosage Text	Duration	Manufacturer						
Drug ineffective	ZECUITY			TEVA						
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
15-Jul-2016	12559174	NON-EXPEDITED			S	Transdermal	US-TEVA-664604USA	42 YR	Female	USA
Preferred Term	Product	Dosage Text	Duration	Manufacturer						
Application site erythema	ZECUITY			TEVA						
Application site pain										
Drug hypersensitivity										
Product adhesion issue										
Product physical issue										



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15-Jul-2016	12559175	NON-EXPEDITED			US-TEVA-662471USA	28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Application site bruise Application site Inflammation Application site pain Application site pruritus Application site rash Product adhesion issue Product physical issue Wrong technique in product usage process	ZECURITY ZECURITY ZECURITY	S S	Transdermal			TEVA TEVA		

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15-Jul-2016	12559176	NON-EXPEDITED			US-TEVA-662131USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash Application site induration	ZECURITY	S	Transdermal			TEVA		

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559177	NON-EXPEDITED			US-TEVA-662573USA	48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECURITY	S	Transdermal			TEVA		

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15-Jul-2016	12559178	NON-EXPEDITED			US-TEVA-662635USA	58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECURITY	S	Transdermal			TEVA		



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15-Jul-2016	12559179	NON-EXPEDITED			S	Transdermal	US-TEVA-662502USA	44 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug effect incomplete			ZECUITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559180	NON-EXPEDITED					US-TEVA-662687USA	60 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Erythema			ZECUITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559181	NON-EXPEDITED					US-TEVA-662578USA	32 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site pain			ZECUITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559182	NON-EXPEDITED					US-TEVA-662836USA	49 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY		S	Transdermal				TEVA
Product physical issue			ZECUITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559183	NON-EXPEDITED					US-TEVA-663345USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site rash			ZECUITY		S	Transdermal	6.5 mg over 4 hours			TEVA
Application site dryness										
Application site erythema										
Application site pain										
Drug effect incomplete										



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15-Jul-2016	12559184	NON-EXPEDITED			US-TEVA-662866USA	37 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site coldness								
Product physical issue								
Product ZECURITY								
Role Route S Transdermal								
Dosage Text TEVA								
Duration								
Manufacturer								
Country								
FDA Received Date								
Case #								
Case Type								
Health Professional								
Outcomes								
Manufacturer Control #								
Age								
Sex								
Country								
Preferred Term								
Application site erythema								
Application site discoloration								
Application site inflammation								
Application site pruritus								
Application site urticaria								
Product ZECURITY								
Role Route S Transdermal								
Dosage Text TEVA								
Duration								
Manufacturer								
Country								
FDA Received Date								
Case #								
Case Type								
Health Professional								
Outcomes								
Manufacturer Control #								
Age								
Sex								
Country								
Preferred Term								
Application site paraesthesia								
Application site erythema								
Product physical issue								
Product ZECURITY								
Role Route S Transdermal								
Dosage Text TEVA								
Duration								
Manufacturer								
Country								
FDA Received Date								
Case #								
Case Type								
Health Professional								
Outcomes								
Manufacturer Control #								
Age								
Sex								
Country								
Preferred Term								
Drug effect incomplete								
Product ZECURITY								
Role Route S Transdermal								
Dosage Text 6.5 mg over 4 hours								
Duration								
Manufacturer TEVA								
Country								



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15-Jul-2016	12559188	NON-EXPEDITED			US-TEVA-663292USA	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Pain		ZECUITY	S	Transdermal			TEVA	
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559189	NON-EXPEDITED			US-TEVA-663292USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Dermatitis contact		ZECUITY	S	Transdermal	at onset of migraine; apply patch to underarm or thigh		TEVA	
Application site erythema								
Application site irritation								
Application site pruritus								
Application site urticaria								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559190	NON-EXPEDITED			US-TEVA-665299USA	59 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site paraesthesia								
Product adhesion issue								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559191	NON-EXPEDITED			US-TEVA-665305USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site rash		ZECUITY	S	Transdermal			TEVA	



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15-Jul-2016	12559192	NON-EXPEDITED			S	Transdermal	US-TEVA-662489USA	52 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY						TEVA	
Device battery issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559193	NON-EXPEDITED			S	Transdermal	US-TEVA-662907USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559194	NON-EXPEDITED			S	Transdermal	US-TEVA-662889USA	23 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY						TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559195	NON-EXPEDITED			S	Transdermal	US-TEVA-662854USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY						TEVA	
Application site discoloration										
Application site erythema										
Incorrect drug administration duration										
Product physical issue										



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15-Jul-2016	12559196	NON-EXPEDITED			S	Transdermal		US-TEVA-662899USA	17 YR	Male	USA
Preferred Term											
Application site erythema											
Application site inflammation											
Application site paraesthesia											
Product use issue											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559197	NON-EXPEDITED			S	Transdermal		US-TEVA-662537USA	54 YR	Female	USA
Preferred Term											
Drug ineffective											
ZECURITY											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559198	NON-EXPEDITED			S	Transdermal		US-TEVA-665417USA	28 YR	Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Dysgeusia											
Nausea											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559199	NON-EXPEDITED			S	Transdermal		US-TEVA-666649USA	32 YR	Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Drug ineffective											
Headache											



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15-Jul-2016	12559200	NON-EXPEDITED			S	Transdermal	US-TEVA-665409USA	25 YR	Female	USA
Preferred Term										
Application site erythema										
Application site discoloration										
Application site exfoliation										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
15-Jul-2016										
12559201										
NON-EXPEDITED										
Preferred Term										
Drug effect incomplete										
Incorrect product storage										
Product physical issue										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
15-Jul-2016										
12559202										
NON-EXPEDITED										
Preferred Term										
Application site erythema										
Application site reaction										
FDA Received Date										
Case #										
Case Type										
Health Professional										
Outcomes										
Role										
Route										
Dosage Text										
Duration										
Manufacturer										
15-Jul-2016										
12559203										
NON-EXPEDITED										
Preferred Term										
Drug ineffective										
Application site erythema										
Application site pain										
Application site paraesthesia										
Application site pruritus										
Application site urticaria										



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15-Jul-2016	12559204	NON-EXPEDITED			US-TEVA-6633350USA	50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site laceration	ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559205	NON-EXPEDITED			US-TEVA-663341USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Hypersensitivity Application site erythema Application site inflammation Application site pruritus	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559206	NON-EXPEDITED			US-TEVA-665333USA	50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site dryness Application site erythema Application site inflammation Application site pruritus Product adhesion issue Product packaging issue Product physical issue	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559207	NON-EXPEDITED			US-TEVA-665381USA	27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECURITY	S	Transdermal			TEVA		



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15-Jul-2016	12559208	NON-EXPEDITED			US-TEVA-665313USA	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559209	NON-EXPEDITED			US-TEVA-665407USA	17 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chest discomfort		ZECUITY	S	Transdermal			TEVA	
Drug ineffective								
Joint stiffness								
Pain								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559210	NON-EXPEDITED			US-TEVA-665419USA	25 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECUITY	S	Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site pruritus								
Application site warmth								
Flushing								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12559211	NON-EXPEDITED			US-TEVA-663325USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECUITY	S	Transdermal			TEVA	
		SUMATRIPTAN	C	Nasal				



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15-Jul-2016	12559212	NON-EXPEDITED			S	Transdermal		US-TEVA-662928USA	19 YR	Female	USA
Preferred Term											
Application site paraesthesia											
Application site erythema											
Application site pain											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
15-Jul-2016	12559213	NON-EXPEDITED			S	Transdermal		US-TEVA-665295USA		Female	USA
Preferred Term											
Application site erythema											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
15-Jul-2016	12559216	NON-EXPEDITED			S	Transdermal		US-TEVA-668194USA	52 YR	Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Application site inflammation											
Application site pain											
Incorrect drug administration duration											
FDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
15-Jul-2016	12562444	EXPEDITED (15-DAY)			OT			US-TEVA-676990USA	42 YR	Female	USA
Preferred Term											
Application site burn											
Application site erythema											



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18-Jul-2016	11628255	EXPEDITED (15-DAY)		OT	US-TEVA-597348USA	53 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>			<u>Manufacturer</u>
Chemical Injury				S	Transdermal			TEVA
Application site pain				C				
Application site erythema								
Application site pain								
Application site warmth								
Drug ineffective								
Product adhesion issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	11656111	EXPEDITED (15-DAY)		OT	US-TEVA-602841USA		Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>			<u>Manufacturer</u>
Application site burn				S	Transdermal			TEVA
Application site discoloration								
Application site erythema								
Application site pain								
Device leakage								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	11838341	EXPEDITED (15-DAY)		OT	US-TEVA-617600USA		Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>			<u>Manufacturer</u>
Application site burn				S	Transdermal			TEVA
Application site erythema								
Application site pain								



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18-Jul-2016	11854123	EXPEDITED (15-DAY)		OT	US-TEVA-619458USA	39 YR	Female	USA
Preferred Term								
Burns second degree			Product	Role	Dosage Text	Duration	Manufacturer	
Burns second degree			ZECUITY	S	Transdermal		TEVA	
Burns second degree			LEVAQUIN	C				
Burning sensation			MORPHINE	C				
Application site pain			NALBUPHINE	C				
Application site erythema			IMITREX	C	stat dose			
Application site discoloration								
Drug ineffective								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	11877984	EXPEDITED (15-DAY)		OT	US-TEVA-621707USA	50 YR	Female	USA
Preferred Term								
Application site burn			Product	Role	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S	Transdermal		TEVA	
Application site inflammation								
Application site pain								
Application site warmth								
Drug effect delayed								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	11962827	EXPEDITED (15-DAY)		OT	US-TEVA-627740USA	26 YR	Female	USA
Preferred Term								
Application site scar			Product	Role	Dosage Text	Duration	Manufacturer	
Application site bruise			ZECUITY	S	Transdermal		TEVA	
Application site discoloration								
Application site dryness								
Application site exfoliation								
Application site pain								



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18-Jul-2016	12081496	EXPEDITED (15-DAY)		OT	US-TEVA-634000USA	32 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site oedema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site scar								
Application site vesicles								
Chemical Injury								
Drug ineffective								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	12085718	EXPEDITED (15-DAY)		OT	US-TEVA-634458USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal	6.5 mg / 4 hours		TEVA	
Application site discolouration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site vesicles								
Drug hypersensitivity								



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18-Jul-2016	12138579	EXPEDITED (15-DAY)		OT	US-TEVA-636465USA	61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECURITY	S	Transdermal			TEVA		
Application site discolouration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Device battery issue								
Drug ineffective								
Limb discomfort								
Muscle tightness								
Peripheral swelling								
Skin exfoliation								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	12249957	EXPEDITED (15-DAY)		OT	US-TEVA-649269USA	42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECURITY	S	Transdermal			TEVA		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site irritation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Application site warmth								
Product physical issue								



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18-Jul-2016	12566756	EXPEDITED (15-DAY)		OT	US-TEVA-672965USA	44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site scar	ZECUITY	S	Transdermal			TEVA		
Application site discoloration								
Application site erythema								
Application site pain								
Incorrect drug administration duration								
Wrong technique in product usage process								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12272122	EXPEDITED (15-DAY)		OT	US-TEVA-651464USA	56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site burn	ZECUITY	S	Transdermal			TEVA		
Application site discomfort								
Application site erythema								
Application site exfoliation								
Application site hypersensitivity								
Application site pain								
Application site pruritus								
Application site vesicles								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12277258	NON-EXPEDITED			US-TEVA-640149USA	54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		



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19-Jul-2016	12277315	NON-EXPEDITED			US-TEVA-637408USA	36 YR	Female	USA
Preferred Term								
Histamine abnormal				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Condition aggravated				S Transdermal			TEVA	
Application site erythema				S Transdermal			TEVA	
Application site pruritus								
Application site swelling								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12277323	NON-EXPEDITED			US-TEVA-637328USA		Female	USA
Preferred Term								
Drug ineffective				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Device battery issue				S Transdermal			TEVA	
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12281744	NON-EXPEDITED			US-TEVA-643958USA	20 YR	Female	USA
Preferred Term								
Application site erythema				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site dryness				S Transdermal			TEVA	
Application site inflammation								
Application site pain								



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12284706	NON-EXPEDITED			US-TEVA-645666USA		Female	USA
Preferred Term								
Drug ineffective								
Device leakage								
<u>Product</u> ZECUITY								
<u>Role Route</u> S Transdermal								
<u>Dosage Text</u> TEVA								
<u>Duration</u> TEVA								
<u>Manufacturer</u> TEVA								
FDA Received Date								
19-Jul-2016	12284741	NON-EXPEDITED			US-TEVA-645591USA		Female	USA
Preferred Term								
Application site erythema								
Application site pruritus								
Pain								
<u>Product</u> ZECUITY								
<u>Role Route</u> S Transdermal								
<u>Dosage Text</u> TEVA								
<u>Duration</u> TEVA								
<u>Manufacturer</u> TEVA								
FDA Received Date								
19-Jul-2016	12287682	EXPEDITED (15-DAY)		OT	US-TEVA-652702USA	60 YR	Female	USA
Preferred Term								
Sunburn								
Application site discoloration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site rash								
Chemical injury								
Dermatitis								
Device adhesion issue								
Device battery issue								
Device leakage								
Drug ineffective								



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19-Jul-2016	12318624	EXPEDITED (15-DAY)		OT	US-TEVA-656168USA		Female	USA
Preferred Term								
Application site burn								
Application site erythema								
Device battery issue								
Incorrect drug administration duration								
FDA Received Date								
19-Jul-2016	12331342	EXPEDITED (15-DAY)		OT	US-TEVA-656411USA	45 YR	Female	USA
Preferred Term								
Sunburn								
Application site dryness								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site warmth								
Injection site scar								
Product physical issue								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
45 YR								
Manufacturer								
TEVA								



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19-Jul-2016	12475513	EXPEDITED (15-DAY)		OT	US-TEVA-667943USA	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Burns first degree		ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site scar		ZECURITY	S				TEVA	
Application site vesicles		Vitamin D	C				TEVA	
Application site pain		Vitamin C	C				TEVA	
Application site paraesthesia		Multi-Vitamin	C				TEVA	
Product physical issue		Venlafaxine	C				TEVA	
Product adhesion issue		Estrogen	C				TEVA	
Application site discomfort								
Drug ineffective								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12477143	EXPEDITED (15-DAY)		OT	US-TEVA-667579USA	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site erythema		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site exfoliation								
Application site inflammation								
Application site irritation								
Application site pain								
Application site pruritus								
Application site scab								
Application site urticaria								
Drug ineffective								
Product physical issue								
Wrong technique in product usage process								



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19-Jul-2016	12489471	EXPEDITED (15-DAY)		OT	US-TEVA-668828USA	52 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site dybness		ZECURITY	S	Transdermal			TEVA	
Application site discoloration								
Application site discomfort								
Application site dybness								
Application site erythema								
Application site pain								
Application site pruritus								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12522356	EXPEDITED (15-DAY)		OT	US-TEVA-672309USA	53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site warmth								
Sunburn								



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19-Jul-2016	12538159	EXPEDITED (15-DAY)		OT	US-TEVA-673331USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECURITY	S	Transdermal		TEVA		
Application site bruise								
Application site discoloration								
Application site dryness								
Application site erythema								
Application site inflammation								
Application site irritation								
Application site paraesthesia								
Application site pruritus								
Drug ineffective								
Feeling abnormal								
Incorrect drug administration duration								
Musculoskeletal pain								
Pain in extremity								
Product adhesion issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12540551	NON-EXPEDITED			US-TEVA-650264USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECURITY	S	Transdermal		TEVA		
Paraesthesia		ZECURITY	S	Transdermal		TEVA		
Application site exfoliation								
Application site pruritus								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12540673	NON-EXPEDITED			S	Transdermal	US-TEVA-657709USA		Female	USA
Preferred Term										
Wrong technique in product usage process										
Blister										
Device battery issue										
Erythema										
Pain										
Pruritus										
<hr/>										
19-Jul-2016	12540712	NON-EXPEDITED					US-TEVA-654268USA	63 YR	Female	USA
Preferred Term										
Application site erythema										
Application site swelling										
Application site pruritus										
Device battery issue										
Migraine										
Product adhesion issue										
Product physical issue										
Product use issue										
<hr/>										
19-Jul-2016	12546875	EXPEDITED (15-DAY)			OT		US-TEVA-675481USA		Female	USA
Preferred Term										
Application site scar										
Application site pruritus										
Application site rash										
Drug ineffective										
Incorrect drug administration duration										
Product adhesion issue										



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19-Jul-2016	12550652	NON-EXPEDITED			US-TEVA-666671USA	34 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug effect incomplete		ZECUITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12551262	NON-EXPEDITED			US-TEVA-655206USA	32 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Musculoskeletal stiffness		ZECUITY	S	Transdermal			TEVA	
Head discomfort		ZECUITY	S	Transdermal			TEVA	
Application site pain		ZECUITY	S	Transdermal			TEVA	
Nausea		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site irritation								
Application site pruritus								
Application site warmth								
Device leakage								
Skin exfoliation								
Skin reaction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12551272	NON-EXPEDITED			US-TEVA-655499USA	36 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia		ZECUITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								



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19-Jul-2016	12551326	NON-EXPEDITED			US-TEVA-658352USA	35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site discoloration Drug ineffective Incorrect product storage	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12551343	NON-EXPEDITED			US-TEVA-658829USA	38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug effect incomplete Wrong technique in product usage process	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12559097	NON-EXPEDITED			US-TEVA-661520USA	31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site paraesthesia Application site discoloration Application site erythema Application site inflammation Application site vesicles Application site warmth Product physical issue	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12559122	NON-EXPEDITED			US-TEVA-665267USA	69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site pain Product physical issue	ZECUITY	S	Transdermal			TEVA		



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19-Jul-2016	12559127	NON-EXPEDITED			US-TEVA-663391USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Crying		ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Emotional disorder		ELAVIL	C					
Application site erythema		ZOLOFT	C					
Application site discoloration								
Application site pruritus								
Drug effect incomplete								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12561948	EXPEDITED (15-DAY)		OT	US-TEVA-676682USA	42 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site vesicles								
Burning sensation								
Incorrect drug administration duration								
Product adhesion issue								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570036	NON-EXPEDITED			US-TEVA-661844USA	38 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECUITY	S	Transdermal			TEVA	
Migraine		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Product physical issue								



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19-Jul-2016	12570037	NON-EXPEDITED			US-TEVA-665796USA	23 YR	Female	USA
Preferred Term								
Application site oedema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site pain								
Application site pruritus								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570038	NON-EXPEDITED			US-TEVA-665795USA	38 YR	Female	USA
Preferred Term								
Application site rash			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site pain			ZECUITY	S Transdermal			TEVA	
Incorrect drug administration duration								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570041	NON-EXPEDITED			US-TEVA-665798USA	18 YR	Female	USA
Preferred Term								
Wrong technique in product usage process			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Product physical issue								



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19-Jul-2016	12570042	NON-EXPEDITED			US-TEVA-665917USA	29 YR	Female	USA
Preferred Term								
Product physical issue			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site pain			ZECUITY	S Transdermal	6.5 mg / 4 hours		TEVA	
Drug ineffective								
Incorrect drug administration duration								
Incorrect product storage								
Product adhesion issue								
Product physical issue								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570043	NON-EXPEDITED			US-TEVA-665806USA	44 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discolouration			ZECUITY	S Transdermal			TEVA	
Application site inflammation								
Application site pruritus								
Application site swelling								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570044	NON-EXPEDITED			US-TEVA-665802USA	53 YR	Female	USA
Preferred Term								
Drug ineffective			Product	Role Route	Dosage Text	Duration	Manufacturer	
Abdominal pain			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Diarrhoea								



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19-Jul-2016	12570045	NON-EXPEDITED			US-TEVA-665972USA	61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Product physical issue Wrong technique in product usage process	ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570046	NON-EXPEDITED			US-TEVA-665935USA	48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Gastroesophageal reflux disease	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570047	NON-EXPEDITED			US-TEVA-665916USA		Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570048	NON-EXPEDITED			US-TEVA-665797USA	26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site dryness Product physical issue	ZECUITY	S	Transdermal			TEVA		



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19-Jul-2016	12570049	NON-EXPEDITED			US-TEVA-665940USA	40 YR	Female	USA
Preferred Term								
Product physical issue			Role Route		Dosage Text	Duration	Manufacturer	
			S Transdermal		6.5 mg over 4 hours		TEVA	
Application site discoloration								
Application site irritation								
Application site paraesthesia								
Application site pruritus								
Drug ineffective								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570050	NON-EXPEDITED			US-TEVA-665928USA	42 YR	Female	USA
Preferred Term								
Application site erythema			Role Route		Dosage Text	Duration	Manufacturer	
			S Transdermal				TEVA	
Application site discoloration								
Application site pain								
Application site pruritus								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570051	NON-EXPEDITED			US-TEVA-665930USA	51 YR	Female	USA
Preferred Term								
Application site rash			Role Route		Dosage Text	Duration	Manufacturer	
			S Transdermal				TEVA	
Application site erythema								
Application site pain								
Application site pruritus								
Application site swelling								



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19-Jul-2016	12570053	NON-EXPEDITED			US-TEVA-666016USA	32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site dryness Application site erythema Application site urticaria	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570054	NON-EXPEDITED			US-TEVA-665939USA	36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Product physical issue Application site erythema Application site paraesthesia	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570055	NON-EXPEDITED			US-TEVA-665929USA	59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Dermatitis contact Drug effect delayed	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570056	NON-EXPEDITED			US-TEVA-665799USA	33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Wrong technique in product usage process Drug effect incomplete Product physical issue	ZECUITY	S	Transdermal			TEVA		



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19-Jul-2016	12570062	NON-EXPEDITED			S	Transdermal	US-TEVA-666011USA	60 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUITY							TEVA
Product physical issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570063	NON-EXPEDITED			S	Transdermal	US-TEVA-666001USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUITY							TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570065	NON-EXPEDITED			S	Transdermal	US-TEVA-665936USA	39 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY							TEVA
Application site dryness										
Application site irritation										
Application site pruritus										
Product physical issue										
Wrong technique in product usage process										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570066	NON-EXPEDITED			S	Transdermal	US-TEVA-666017USA	21 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY							TEVA
Application site discomfort										
Application site pain										
Application site paraesthesia										
Product physical issue										
Wrong technique in product usage process										



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19-Jul-2016	12570067	NON-EXPEDITED			S	Transdermal	US-TEVA-666338USA		Unknown	USA
Preferred Term Dermatitis allergic Urticaria										
Product	ZECUITY									TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570068	NON-EXPEDITED					US-TEVA-666028USA		Female	USA
Preferred Term Drug ineffective										
Product	ZECUITY				S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570069	NON-EXPEDITED			S	Transdermal	US-TEVA-666325USA	43 YR	Male	USA
Preferred Term Application site paraesthesia Product physical issue Application site erythema Wrong technique in product usage process										
Product	ZECUITY				S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570070	NON-EXPEDITED			S	Transdermal	US-TEVA-666025USA	58 YR	Male	USA
Preferred Term Application site pain Application site erythema										
Product	ZECUITY				S	Transdermal				TEVA



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19-Jul-2016	12570072	NON-EXPEDITED			S	Transdermal	US-TEVA-666360USA	46 YR	Female	USA
Preferred Term										
Application site erythema										
Application site discoloration										
Application site paraesthesia										
Application site swelling										
Application site urticaria										
<hr/>										
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570073	NON-EXPEDITED			S	Transdermal	US-TEVA-666022USA		Male	USA
Preferred Term										
Drug ineffective										
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570074	NON-EXPEDITED			S	Transdermal	US-TEVA-666376USA	51 YR	Female	USA
Preferred Term										
Application site pain										
Application site rash										
Application site erythema										
Application site pain										
Application site vesicles										
Drug effect incomplete										
Product physical issue										



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19-Jul-2016	12570077	NON-EXPEDITED			S	Transdermal			Female	USA
<u>Preferred Term</u> Application site pain Application site erythema Application site irritation Application site vesicles Incorrect drug administration duration										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570078	NON-EXPEDITED			S	Transdermal			Male	USA
<u>Preferred Term</u> Application site rash										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570079	NON-EXPEDITED			S	Transdermal			Female	USA
<u>Preferred Term</u> Drug ineffective Product physical issue										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570081	NON-EXPEDITED			S	Transdermal			Female	USA
<u>Preferred Term</u> Application site erythema Application site swelling										



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19-Jul-2016	12570086	NON-EXPEDITED			US-TEVA-666415USA	55 YR	Female	USA
Preferred Term								
Application site erythema			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site pruritus			ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA
<hr/>								
19-Jul-2016	12570087	NON-EXPEDITED			US-TEVA-666670USA	61 YR	Female	USA
Preferred Term								
Application site pain			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site paraesthesia			ZECUITY	S	Transdermal			TEVA
Application site pruritus								
Product colour issue								
<hr/>								
19-Jul-2016	12570088	NON-EXPEDITED			US-TEVA-666532USA		Female	USA
Preferred Term								
Application site pain			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site pruritus			ZECUITY	S	Transdermal			TEVA
<hr/>								
19-Jul-2016	12570089	NON-EXPEDITED			US-TEVA-666669USA	35 YR	Female	USA
Preferred Term								
Application site urticaria			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECUITY	S	Transdermal			TEVA
Application site exfoliation								
Application site inflammation								
Application site pruritus								
Product physical issue								
Wrong technique in product usage process								



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19-Jul-2016	12570096	NON-EXPEDITED			US-TEVA-666467USA	33 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Drug ineffective		ZECUITY	S	Transdermal	used another patch before 12-Apr-2016 (exact date not provided)		TEVA	
Therapeutic response unexpected		ZECUITY	S	Transdermal			TEVA	
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570097	NON-EXPEDITED			US-TEVA-666448USA		Male	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Palpitations		ZECUITY	S	Transdermal			TEVA	
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570098	NON-EXPEDITED			US-TEVA-666687USA	30 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Drug ineffective								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570099	NON-EXPEDITED			US-TEVA-666672USA	57 YR	Female	USA
Preferred Term		Product	Role	Route	Dosage Text	Duration	Manufacturer	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Application site irritation								
Incorrect drug administration duration								
Product physical issue								



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19-Jul-2016	12570100	NON-EXPEDITED			US-TEVA-667280USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site pain								
Application site pain								
Incorrect drug administration duration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570102	NON-EXPEDITED			US-TEVA-667682USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site erythema				S Transdermal			TEVA	
Application site discolouration								
Application site inflammation								
Application site pruritus								
Application site rash								
Application site urticaria								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570103	NON-EXPEDITED			US-TEVA-66664USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site discolouration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570104	NON-EXPEDITED			US-TEVA-666443USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site pain								



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19-Jul-2016	12570105	NON-EXPEDITED			US-TEVA-667206USA		Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Incorrect drug administration duration								
Product adhesion issue								
Product physical issue								
<hr/>								
19-Jul-2016	12570106	NON-EXPEDITED			US-TEVA-667684USA	37 YR	Male	USA
Preferred Term								
Burning sensation								
Product physical issue								
Application site erythema								
Application site urticaria								
Incorrect drug administration duration								
<hr/>								
19-Jul-2016	12570107	NON-EXPEDITED			US-TEVA-666710USA	51 YR	Female	USA
Preferred Term								
Laceration								
Skin haemorrhage								
Application site paraesthesia								
Product odour abnormal								
Product physical issue								



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19-Jul-2016	12570108	NON-EXPEDITED			US-TEVA-667686USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECURITY	S Transdermal			TEVA	
			Maxalt	C				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570110	NON-EXPEDITED			US-TEVA-667687USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site warmth			ZECURITY	S Transdermal			TEVA	
Application site pain								
Application site paraesthesia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570111	NON-EXPEDITED			US-TEVA-667706USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570112	NON-EXPEDITED			US-TEVA-666717USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Migraine			ZECURITY	S Transdermal			TEVA	
Incorrect product storage								
Product physical issue								



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19-Jul-2016	12570113	NON-EXPEDITED			S	Transdermal		US-TEVA-667668USA	16 YR	Female	USA
Preferred Term											
Wrong technique in product usage process											
Incorrect drug administration duration											
Product physical issue											
Application site pain											
Product use issue											
Preferred Term											
ZECURITY											
ZECURITY											
ZECURITY											
EDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
19-Jul-2016	12570114	NON-EXPEDITED			S	Transdermal		US-TEVA-667554USA	36 YR	Female	USA
Preferred Term											
Application site erythema											
Incorrect drug administration duration											
Product physical issue											
EDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
19-Jul-2016	12570115	NON-EXPEDITED			S	Transdermal		US-TEVA-667679USA	47 YR	Female	USA
Preferred Term											
Intentional product misuse											
Drug ineffective											
EDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
19-Jul-2016	12570117	NON-EXPEDITED			S	Transdermal		US-TEVA-666681USA	14 YR	Male	USA
Preferred Term											
Product use issue											
Product physical issue											



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19-Jul-2016	12570118	NON-EXPEDITED			US-TEVA-666685USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site discolouration Incorrect product storage	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570119	NON-EXPEDITED			US-TEVA-667625USA	19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain Application site discolouration Application site erythema Application site pain	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570120	NON-EXPEDITED			US-TEVA-666889USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site rash	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570121	NON-EXPEDITED			US-TEVA-667661USA	45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug effect incomplete Headache Migraine	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570123	NON-EXPEDITED			US-TEVA-667525USA	48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site discolouration	ZECUITY	S	Transdermal			TEVA		



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19-Jul-2016	12570124	NON-EXPEDITED			US-TEVA-667666USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570126	NON-EXPEDITED			US-TEVA-667258USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570127	NON-EXPEDITED			US-TEVA-666379USA	43 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570128	NON-EXPEDITED			US-TEVA-667627USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570130	NON-EXPEDITED			US-TEVA-668204USA	65 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	



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19-Jul-2016	12570131	NON-EXPEDITED			US-TEVA-667887USA	65 YR	Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site irritation	ZECUITY	S	Transdermal	6.5 mg /4 hr 1 patch up to twice daily		TEVA		
	AZELASTINE	C						
	MONTHELUKAST	C						
	DULOXETINE	C						
	DIAZEPAM	C						
	PANTOPRAZOLE	C						
	PRAVASTATIN	C						
	METFORMIN	C						
	BUTORPHANOL	C						
	SUMATRIPTAN	C						
	APAP W/BUTALBITAL	C						
	METHOCARBAMOL	C						
	GEMFIBROZIL	C						
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570132	NON-EXPEDITED			US-TEVA-667634USA	50 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug effect incomplete	ZECUITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570133	NON-EXPEDITED			US-TEVA-667928USA		Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site rash	ZECUITY	S	Transdermal			TEVA		
Application site erythema								



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19-Jul-2016	12570138	NON-EXPEDITED			US-TEVA-667631USA	69 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site pruritus	ZECURITY	S	Transdermal			TEVA		
Drug effect incomplete								
Product physical issue								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570140	NON-EXPEDITED			US-TEVA-667689USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECURITY	S	Transdermal			TEVA		
Application site discomfort								
Application site erythema								
Product adhesion issue								
Product physical issue								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570141	NON-EXPEDITED			US-TEVA-666729USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug effect incomplete	ZECURITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570142	NON-EXPEDITED			US-TEVA-667870USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug hypersensitivity	ZECURITY	S	Transdermal	6.5 mg/4 hrs needed		TEVA		



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19-Jul-2016	12570143	NON-EXPEDITED			US-TEVA-66771USA	54 YR	Female	USA
Preferred Term								
Product physical issue			Product	Role Route	Dosage Text	Duration	Manufacturer	
Drug ineffective			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
<hr/>								
19-Jul-2016	12570144	NON-EXPEDITED			US-TEVA-668428USA	34 YR	Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site papules								
Application site swelling								
Incorrect drug administration duration								
<hr/>								
19-Jul-2016	12570145	NON-EXPEDITED			US-TEVA-668323USA		Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal	used 4 patches several months ago		TEVA	
<hr/>								
19-Jul-2016	12570146	NON-EXPEDITED			US-TEVA-667717USA		Female	USA
Preferred Term								
Skin discoloration			Product	Role Route	Dosage Text	Duration	Manufacturer	
Skin reaction			ZECUITY	S Transdermal			TEVA	



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19-Jul-2016	12570147	NON-EXPEDITED			US-TEVA-668004USA	40 YR	Female	USA
Preferred Term								
Application site discolouration								
Application site dryness								
Application site erythema								
Application site exfoliation								
<hr/>								
19-Jul-2016	12570148	NON-EXPEDITED			US-TEVA-667950USA	50 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site erythema								
Application site pain								
Product physical issue								
Wrong technique in product usage process								
<hr/>								
19-Jul-2016	12570149	NON-EXPEDITED			US-TEVA-667787USA		Female	USA
Preferred Term								
Application site erythema								
Product physical issue								
Wrong technique in product usage process								



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EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570152	NON-EXPEDITED			US-TEVA-668252USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECURITY	S	Transdermal			TEVA		
Application site erythema								
Application site inflammation								
Incorrect drug administration duration								
Product physical issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570153	NON-EXPEDITED			US-TEVA-667951USA	29 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site discoloration								
Application site dryness								
Application site exfoliation								
Application site inflammation								
Application site pain								
Product physical issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570155	NON-EXPEDITED			US-TEVA-667716USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECURITY	S	Transdermal			TEVA		
Product physical issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570156	NON-EXPEDITED			US-TEVA-667934USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective	ZECURITY	S	Transdermal			TEVA		



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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570157	NON-EXPEDITED			US-TEVA-667935USA	36 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain Application site erythema Application site paraesthesia	ZECUITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570158	NON-EXPEDITED			US-TEVA-667947USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain Application site dryness Application site irritation	ZECUITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570159	NON-EXPEDITED			US-TEVA-667945USA	29 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site bruise Application site erythema Application site exfoliation Application site pruritus	ZECUITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570160	NON-EXPEDITED			US-TEVA-668420USA	52 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		



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19-Jul-2016	12570161	NON-EXPEDITED			US-TEVA-668333USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Off label use			ZECUITY	S			TEVA	
Drug administered to patient of inappropriate age								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570162	NON-EXPEDITED			US-TEVA-668806USA	53 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECUITY	S			TEVA	
Application site discoloration								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570163	NON-EXPEDITED			US-TEVA-668399USA	24 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Product physical issue			ZECUITY	S			TEVA	
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570164	NON-EXPEDITED			US-TEVA-667926USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site bruise			ZECUITY	S			TEVA	
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site pain								
Application site paraesthesia								
Product quality issue								



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19-Jul-2016	12570165	NON-EXPEDITED			US-TEVA-668380USA	56 YR	Female	USA
Preferred Term								
Application site pain								
Administration site scab								
Application site erythema								
Application site pruritus								
Application site swelling								
Incorrect drug administration duration								
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570166	NON-EXPEDITED			US-TEVA-668805USA	36 YR	Female	USA
Preferred Term								
Application site erythema								
Application site bruise								
Application site discoloration								
Application site inflammation								
Drug ineffective								
Product physical issue								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570169	NON-EXPEDITED			US-TEVA-667932USA		Female	USA
Preferred Term								
Intentional product misuse								
Product quality issue								



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19-Jul-2016	12570171	NON-EXPEDITED			US-TEVA-668407USA	32 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective Product adhesion issue Product physical issue	ZECURITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570172	NON-EXPEDITED			US-TEVA-667937USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug ineffective Intentional product use issue	ZECURITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570173	NON-EXPEDITED			US-TEVA-668818USA	54 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Drug effect incomplete	ZECURITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570174	NON-EXPEDITED			US-TEVA-667788USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site rash Drug effect incomplete Product physical issue	ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA		



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19-Jul-2016	12570175	NON-EXPEDITED			S	Transdermal	US-TEVA-668265USA	70 YR	Female	USA
Preferred Term										
Application site pain										
Application site discoloration										
Application site erythema										
Wrong technique in product usage process										
<hr/>										
19-Jul-2016	12570176	NON-EXPEDITED			S	Transdermal	US-TEVA-668366USA	32 YR	Female	USA
Preferred Term										
Drug ineffective										
Application site discoloration										
Application site discomfort										
Application site erythema										
Application site pain										
Product physical issue										
<hr/>										
19-Jul-2016	12570177	NON-EXPEDITED			S	Transdermal	US-TEVA-667940USA	38 YR	Female	USA
Preferred Term										
Application site pain										
<hr/>										
19-Jul-2016	12570178	NON-EXPEDITED			S	Transdermal	US-TEVA-668827USA	35 YR	Female	USA
Preferred Term										
Application site erythema										



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19-Jul-2016	12570179	NON-EXPEDITED			US-TEVA-667954USA	46 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Paraesthesia			ZECUITY	S Transdermal			TEVA	
Application site discolouration								
Application site exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570180	NON-EXPEDITED			US-TEVA-668404USA	49 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECUITY	S Transdermal			TEVA	
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570181	NON-EXPEDITED			US-TEVA-668781USA	38 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Product physical issue			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site pain								
Wrong technique in product usage process								
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19-Jul-2016	12570182	NON-EXPEDITED			US-TEVA-668244USA	33 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site irritation			ZECUITY	S Transdermal			TEVA	
Application site inflammation								
Drug ineffective								
Migraine								



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19-Jul-2016	12570183	NON-EXPEDITED			US-TEVA-668615USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site urticaria		ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570184	NON-EXPEDITED			US-TEVA-668807USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Product difficult to remove		ZECUITY	S	Transdermal			TEVA	
Migraine								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570185	NON-EXPEDITED			US-TEVA-668826USA	58 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site swelling								
Application site warmth								
Product physical issue								
Wrong technique in product usage process								



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19-Jul-2016	12570186	NON-EXPEDITED			US-TEVA-668782USA	43 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site inflammation			ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Application site pruritus			ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Application site bruise			ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Application site pain								
Application site papules								
Rubber sensitivity								
Wrong technique in product usage process								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570187	NON-EXPEDITED			US-TEVA-668621USA		Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Product adhesion issue			ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA
Product physical issue								
Product use issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570189	NON-EXPEDITED			US-TEVA-668928USA		Female	USA
Preferred Term								
Application site urticaria			Product	Role	Route	Dosage Text	Duration	Manufacturer
			ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA



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19-Jul-2016	12570196	NON-EXPEDITED			US-TEVA-668746USA	41 YR	Female	USA
Preferred Term								
Application site rash			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal			TEVA
Application site discoloration			ZECUITY	S	Transdermal			TEVA
Application site dybness								
Application site pruritus								
Product physical issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570197	NON-EXPEDITED			US-TEVA-668760USA	41 YR	Female	USA
Preferred Term								
Application site paraesthesia			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Application site discoloration			ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Application site pain								
Skin lesion								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2016	12570198	NON-EXPEDITED			US-TEVA-668709USA	24 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA



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19-Jul-2016	12571423	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-677090USA	44 YR	Female	USA
Preferred Term										
Application site burn										
Application site dryness										
Application site erythema										
Application site paraesthesia										
Product physical issue										
<hr/>										
19-Jul-2016	12571438	EXPEDITED (15-DAY)		OT		Transdermal	US-TEVA-677092USA	44 YR	Female	USA
Preferred Term										
Application site burn										
Application site bruise										
Application site erythema										
Application site pain										
Application site warmth										
Paraesthesia										
Product physical issue										
Sunburn										
<hr/>										
20-Jul-2016	11909329	NON-EXPEDITED					US-TEVA-608207USA	44 YR	Female	USA
Preferred Term										
Somnolence										
Application site dryness										
Drug ineffective										



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20-Jul-2016	11936791	EXPEDITED (15-DAY)		OT	US-TEVA-626866USA	55 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Burns second degree		ZECUITY	S	Transdermal	sixth patch used		TEVA	
Dermatitis contact		TREXIMET	C		as needed			
Application site rash		Relpax	C		as needed			
Application site erythema								
Application site swelling								
Application site vesicles								
Application site warmth								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12215471	EXPEDITED (15-DAY)		OT	US-TEVA-645871USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site irritation								
Application site oedema								
Application site pain								
Application site paraesthesia								
Burns second degree								
Dermatitis allergic								
Dermatitis contact								
Product physical issue								



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20-Jul-2016	12215506	EXPEDITED (15-DAY)		OT	US-TEVA-645875USA	40 YR	Female	USA
Preferred Term								
Application site burn			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site paraesthesia			ZECURITY	S	Transdermal			TEVA
Application site paraesthesia			IMITREX	C	Oral			
Application site rash			SPIRONOLACTONE	C				
Application site pruritus			Tokendi XR	C				
Application site oedema			MIRENA	C				
Erythema								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
20-Jul-2016	12245060	EXPEDITED (15-DAY)		OT	US-TEVA-623421USA		Female	USA
Preferred Term								
Application site exfoliation			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA
Application site pain								
Drug ineffective								
Skin reaction								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
20-Jul-2016	12270830	NON-EXPEDITED			US-TEVA-634427USA	42 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site discolouration			ZECURITY	S	Transdermal			TEVA
Application site dryness								
Application site irritation								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Application site scab								



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20-Jul-2016	12435414	EXPEDITED (15-DAY)		OT	US-TEVA-663990USA	38 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site scar		bactroban cream	C					
Application site discolouration								
Application site erythema								
Application site inflammation								
Application site scab								
Application site swelling								
Injection site pruritus								
Wrong technique in product usage process								

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20-Jul-2016	12482149	EXPEDITED (15-DAY)		OT	US-TEVA-668929USA	29 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg over 4 hours			
Application site discolouration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site scar								
Incorrect drug administration duration								



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20-Jul-2016	12511132	EXPEDITED (15-DAY)		OT	US-TEVA-670913USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site scar	ZECURITY	S	Transdermal			TEVA		
Application site burn								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Application site rash								
Application site scab								
Application site vesicles								
Hyperkeratosis								
Product adhesion issue								
Wrong technique in product usage process								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12522466	EXPEDITED (15-DAY)		OT	US-TEVA-672176USA	48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Sunburn	ZECURITY	S	Transdermal			TEVA		
Application site pain	ZECURITY	S	Transdermal			TEVA		
Administration site erythema								
Application site exfoliation								
Dry skin								
Skin exfoliation								
Wrong technique in product usage process								



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20-Jul-2016	12524588	EXPEDITED (15-DAY)		OT	US-TEVA-672956USA	60 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal			TEVA	
Application site discolouration								
Application site discomfort								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site warmth								
Product adhesion issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12534675	EXPEDITED (15-DAY)		OT	US-TEVA-673789USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn				S Transdermal			TEVA	
Application site bruise								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12540527	NON-EXPEDITED			US-TEVA-649379USA	49 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia				S Transdermal			TEVA	
Application site erythema								
Application site reaction								



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20-Jul-2016	12570122	NON-EXPEDITED			US-TEVA-667662USA	57 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Nausea				S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site urticaria								
Incorrect drug administration duration								
Malaise								
Migraine								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12570125	NON-EXPEDITED			US-TEVA-667710USA	32 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Asthenia				S Transdermal	6.5 mg over 4 hours		TEVA	
Dizziness								
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12570129	NON-EXPEDITED			US-TEVA-667703USA	45 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pruritus				S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site pain								
Application site rash								
Application site swelling								
Application site vesicles								
Wound secretion								



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20-Jul-2016	12570139	NON-EXPEDITED					US-TEVA-668001USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>				<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Drug ineffective			ZECUITY		S	Transdermal				TEVA
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12570167	NON-EXPEDITED					US-TEVA-668395USA	43 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site pain			ZECUITY		S	Transdermal				TEVA
Application site pain										
Application site pain										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12570170	NON-EXPEDITED					US-TEVA-668402USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema			ZECUITY		S	Transdermal				TEVA
Product physical issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572773	NON-EXPEDITED					US-TEVA-669825USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site pain			ZECUITY		S	Transdermal				TEVA
Incorrect drug administration duration										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>			<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572775	NON-EXPEDITED			OT		US-TEVA-669540USA	56 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Rash			ZECUITY		S	Transdermal				TEVA



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20-Jul-2016	12572776	NON-EXPEDITED			S	Transdermal		US-TEVA-669057USA		Female	USA
<u>Preferred Term</u>											
Application site pain											
Application site bruise											
Application site paraesthesia											
Incorrect drug administration duration											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572777	NON-EXPEDITED			S	Transdermal		US-TEVA-669796USA	42 YR	Female	USA
<u>Preferred Term</u>											
Application site discoloration											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572778	NON-EXPEDITED			S	Transdermal		US-TEVA-669102USA	36 YR	Female	USA
<u>Preferred Term</u>											
Application site pain											
Application site discoloration											
Application site erythema											
Application site pain											
Application site swelling											
Incorrect drug administration duration											
Wrong technique in product usage process											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572779	NON-EXPEDITED			S	Transdermal		US-TEVA-669103USA	22 YR	Female	USA
<u>Preferred Term</u>											
Application site paraesthesia											
Incorrect drug administration duration											
Product physical issue											



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20-Jul-2016	12572780	NON-EXPEDITED			S	Transdermal		US-TEVA-669119USA	22 YR	Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Application site inflammation											
FDA Received Date											
20-Jul-2016											
Case #											
12572781											
Case Type											
NON-EXPEDITED											
Health Professional											
Outcomes											
S											
Role											
S											
Route											
Transdermal											
Dosage Text											
Manufacturer Control #											
US-TEVA-66981USA											
Age											
Sex											
Female											
Country											
USA											
Preferred Term											
Application site pain											
Application site discoloration											
Application site erythema											
Application site paraesthesia											
Application site warmth											
Product physical issue											
FDA Received Date											
20-Jul-2016											
Case #											
12572785											
Case Type											
NON-EXPEDITED											
Health Professional											
Outcomes											
S											
Role											
S											
Route											
Transdermal											
Dosage Text											
Manufacturer Control #											
US-TEVA-669148USA											
Age											
Sex											
Female											
Country											
USA											
Preferred Term											
Drug ineffective											
FDA Received Date											
20-Jul-2016											
Case #											
12572786											
Case Type											
NON-EXPEDITED											
Health Professional											
Outcomes											
S											
Role											
S											
Route											
Transdermal											
Dosage Text											
Manufacturer Control #											
US-TEVA-669031USA											
Age											
Sex											
Female											
Country											
USA											
Preferred Term											
Application site pain											
Application site paraesthesia											
Application site erythema											
Application site exfoliation											



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20-Jul-2016	12572787	NON-EXPEDITED			US-TEVA-669117USA	57 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECURITY	S Transdermal			TEVA	
Product quality issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572788	NON-EXPEDITED			US-TEVA-669056USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Application site discoloration								
Application site inflammation								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572789	NON-EXPEDITED			US-TEVA-669053USA	41 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECURITY	S Transdermal			TEVA	
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572790	NON-EXPEDITED			US-TEVA-669112USA	61 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY	S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site pruritus								



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20-Jul-2016	12572791	NON-EXPEDITED			US-TEVA-669028USA	26 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site discoloration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site scab								
<hr/>								
20-Jul-2016	12572792	NON-EXPEDITED			US-TEVA-669058USA	54 YR	Female	USA
Preferred Term								
Application site pain								
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site mass								
Wrong technique in product usage process								
<hr/>								
20-Jul-2016	12572793	NON-EXPEDITED			US-TEVA-669547USA	51 YR	Female	USA
Preferred Term								
Application site erythema								
<hr/>								



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20-Jul-2016	12572794	NON-EXPEDITED			S	Transdermal		US-TEVA-669094USA	45 YR	Female	USA
Preferred Term											
Application site discolouration											
Application site pain											
Application site pruritus											
Application site rash											
Product adhesion issue											
Product physical issue											
<hr/>											
20-Jul-2016	12572795	NON-EXPEDITED			S	Transdermal		US-TEVA-669105USA	58 YR	Female	USA
Preferred Term											
Application site pain											
Application site erythema											
Application site inflammation											
Hypersensitivity											
Incorrect drug administration duration											
<hr/>											
20-Jul-2016	12572796	NON-EXPEDITED		OT				US-TEVA-669885USA	47 YR	Female	USA
Preferred Term											
Seizure											
Product											
ZECURITY											
AMITRIPTYLINE											
XANAX											
PROZAC											
DEPAKOTE											
IRON											
NORVASC											
CAMBIA											



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20-Jul-2016	12572797	NON-EXPEDITED			US-TEVA-670425USA	33 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site pain			ZECURITY	S Transdermal			TEVA	
Application site exfoliation			ZECURITY	S Transdermal			TEVA	
Application site pruritus								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572798	NON-EXPEDITED			US-TEVA-669875USA	24 YR	Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site pruritus								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12572799	NON-EXPEDITED			US-TEVA-669060USA	31 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECURITY	S Transdermal			TEVA	
Application site dryness								
Application site exfoliation								



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20-Jul-2016	12572800	NON-EXPEDITED			US-TEVA-669550USA	49 YR	Female	USA
Preferred Term								
Application site erythema				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site irritation				S Transdermal			TEVA	
Application site papules								
Product adhesion issue								
Product physical issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12572801	NON-EXPEDITED			US-TEVA-669026USA		Female	USA
Preferred Term								
Application site paraesthesia				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discoloration				S Transdermal			TEVA	
Application site discomfort								
Application site erythema								
Application site inflammation								
Drug ineffective								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12572802	NON-EXPEDITED			US-TEVA-669543USA		Female	USA
Preferred Term								
Application site discoloration				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	



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20-Jul-2016	12572803	NON-EXPEDITED			US-TEVA-669055USA	60 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Product physical issue Application site discolouration Application site erythema Application site pruritus Application site rash	ZECUITY	S	Transdermal			TEVA		
Wrong technique in product usage process								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12572804	NON-EXPEDITED		OT	US-TEVA-669546USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECUITY	S	Transdermal	6.5 mg/4 hours		TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12572809	NON-EXPEDITED			US-TEVA-669545USA		Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Drug effect delayed	ZECUITY BUPROPION HYDROCHLORIDE XL	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574066	NON-EXPEDITED			US-TEVA-669490USA	48 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia Drug hypersensitivity	ZECUITY	S	Transdermal			TEVA		



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20-Jul-2016	12574067	NON-EXPEDITED			US-TEVA-669760USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site inflammation								
Application site pruritus								
Application site rash								
Confusion								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574068	NON-EXPEDITED			US-TEVA-669761USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECURITY	S Transdermal			TEVA	
Application site bruise								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574070	NON-EXPEDITED			US-TEVA-669486USA	52 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY	S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site pain								
Application site pruritus								
Wrong technique in product usage process								



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20-Jul-2016	12574074	NON-EXPEDITED			US-TEVA-669610USA		Unknown	USA
Preferred Term								
Application site erythema								
Administration site discoloration								
Application site bruise								
Application site pain								
Application site reaction								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574075	NON-EXPEDITED			US-TEVA-669762USA	29 YR	Female	USA
Preferred Term								
Application site erythema								
Application site inflammation								
Application site pain								
Application site warmth								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574076	NON-EXPEDITED			US-TEVA-669744USA	23 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site erythema								
Application site pain								
Application site pruritus								
Miliaria								



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20-Jul-2016	12574081	NON-EXPEDITED			S	Transdermal		US-TEVA-669770USA	36 YR	Female	USA
Preferred Term											
Application site paraesthesia											
Application site erythema											
Application site pruritus											
Product physical issue											
<hr/>											
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574083	NON-EXPEDITED			S	Transdermal		US-TEVA-669930USA	29 YR	Female	USA
Preferred Term											
Application site erythema											
Application site discolouration											
<hr/>											
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574084	NON-EXPEDITED			S	Transdermal		US-TEVA-669978USA	49 YR	Female	USA
Preferred Term											
Application site discoloration											
Application site erythema											
Application site inflammation											
Application site irritation											
Application site pain											
Application site paraesthesia											
<hr/>											
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574085	NON-EXPEDITED			S	Transdermal		US-TEVA-669805USA	34 YR	Female	USA
Preferred Term											
Application site erythema											
Application site discoloration											
Application site exfoliation											



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20-Jul-2016	12574086	NON-EXPEDITED			S	Transdermal		US-TEVA-669786USA	56 YR	Female	USA
Preferred Term											
Application site erythema											
Product ZECURITY											
Product physical issue											
EDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
20-Jul-2016	12574087	NON-EXPEDITED			S	Transdermal		US-TEVA-669807USA	32 YR	Female	USA
Preferred Term											
Application site erythema											
Product ZECURITY											
Application site rash											
Product ZECURITY											
Application site irritation											
Application site pain											
Application site pruritus											
Incorrect drug administration duration											
EDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
20-Jul-2016	12574088	NON-EXPEDITED			S	Transdermal		US-TEVA-669766USA	45 YR	Female	USA
Preferred Term											
Application site pruritus											
Product ZECURITY											
Application site erythema											
EDA Received Date											
Case #											
Case Type											
Health Professional											
Outcomes											
Role											
Route											
Dosage Text											
Manufacturer Control #											
Age											
Sex											
Country											
20-Jul-2016	12574095	NON-EXPEDITED			S	Transdermal		US-TEVA-669971USA	58 YR	Female	USA
Preferred Term											
Application site erythema											
Product ZECURITY											
Application site exfoliation											
Application site pruritus											
Application site warmth											
Drug ineffective											



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20-Jul-2016	12574096	NON-EXPEDITED			S	Transdermal	US-TEVA-669776USA	64 YR	Male	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site irritation										
Application site pruritus										
Skin lesion										
Wrong technique in product usage process										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574097	NON-EXPEDITED			S	Transdermal	US-TEVA-669933USA	40 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site irritation										
Application site pruritus										
Application site urticaria										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574098	NON-EXPEDITED			S	Transdermal	US-TEVA-669774USA	25 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site irritation										
Application site paraesthesia										
<hr/>										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574099	NON-EXPEDITED			S	Transdermal	US-TEVA-669973USA	44 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										



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20-Jul-2016	12574100	NON-EXPEDITED			S	Transdermal	US-TEVA-669887USA	19 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site warmth										
Product physical issue										
Wrong technique in product usage process										
<hr/>										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574101	NON-EXPEDITED			S	Transdermal	US-TEVA-669785USA	54 YR	Female	USA
Preferred Term										
Application site pain										
Chest discomfort										
Application site erythema										
<hr/>										
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574102	NON-EXPEDITED			S	Transdermal	US-TEVA-669927USA	52 YR	Female	USA
Preferred Term										
Application site discoloration										
Application site pruritus										
Application site rash										
Application site urticaria										
Incorrect drug administration duration										



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20-Jul-2016	12574103	NON-EXPEDITED			US-TEVA-669812USA	53 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Application site dryness Application site inflammation Application site vesicles	ZECURITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574104	NON-EXPEDITED			US-TEVA-670251USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site coldness Product physical issue	ZECURITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574105	NON-EXPEDITED			US-TEVA-669793USA	42 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia Application site dryness Application site erythema Application site exfoliation	ZECURITY	S	Transdermal			TEVA		
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574107	NON-EXPEDITED			US-TEVA-670258USA	63 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site paraesthesia Application site erythema Incorrect drug administration duration	ZECURITY	S	Transdermal			TEVA		



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20-Jul-2016	12574114	NON-EXPEDITED			US-TEVA-670283USA	36 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site exfoliation			ZECUITY	S Transdermal			TEVA	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site urticaria								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574115	NON-EXPEDITED			US-TEVA-670193USA	64 YR	Female	USA
Preferred Term								
Application site rash			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECUITY	S Transdermal			TEVA	
Application site erythema								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574116	NON-EXPEDITED			US-TEVA-670487USA	31 YR	Female	USA
Preferred Term								
Application site paraesthesia			Product	Role Route	Dosage Text	Duration	Manufacturer	
Product physical issue			ZECUITY	S Transdermal			TEVA	
Application site discoloration			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site inflammation								
Application site pain								
Product physical issue								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574117	NON-EXPEDITED			US-TEVA-670272USA		Female	USA
Preferred Term								
Application site rash			Product	Role Route	Dosage Text	Duration	Manufacturer	
			ZECUITY	S Transdermal			TEVA	



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20-Jul-2016	12574118	NON-EXPEDITED			US-TEVA-670263USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574119	NON-EXPEDITED			US-TEVA-670279USA	37 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574120	NON-EXPEDITED			US-TEVA-669889USA	50 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site erythema Application site injury Application site pain Application site rash Skin haemorrhage								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574121	NON-EXPEDITED			US-TEVA-669932USA	43 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	



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20-Jul-2016	12574122	NON-EXPEDITED			US-TEVA-670291USA	35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Application site inflammation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574124	NON-EXPEDITED			US-TEVA-670269USA	41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site discomfort								
Application site dryness								
Application site pain								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574125	NON-EXPEDITED			US-TEVA-670440USA	58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574126	NON-EXPEDITED			US-TEVA-670200USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site discoloration	ZECUITY	S	Transdermal			TEVA		
Application site erythema								



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20-Jul-2016	12574127	NON-EXPEDITED			US-TEVA-669817USA	23 YR	Female	USA
<u>Preferred Term</u>								
Application site pain								
<u>Product</u>								
ZECUITY								
<u>Role Route</u>								
S Transdermal								
<u>Dosage Text</u>								
3 patches over the last six months								
<u>Manufacturer</u>								
TEVA								
Application site erythema								
Application site irritation								
Wrong technique in product usage process								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574128	NON-EXPEDITED			US-TEVA-670334USA	46 YR	Female	USA
<u>Preferred Term</u>								
Application site discolouration								
Application site erythema								
Application site urticaria								
Incorrect drug administration duration								
Product physical issue								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574129	NON-EXPEDITED			US-TEVA-670333USA	45 YR	Female	USA
<u>Preferred Term</u>								
Application site paraesthesia								
Application site erythema								
Application site discolouration								
Application site inflammation								
Application site pain								
<u>Product</u>								
ZECUITY								
<u>Role Route</u>								
S Transdermal								
<u>Dosage Text</u>								
<u>Manufacturer</u>								
TEVA								



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20-Jul-2016	12574130	NON-EXPEDITED			US-TEVA-670599USA	44 YR	Female	USA
Preferred Term								
Application site paraesthesia			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site pain			ZECUITY	S	Transdermal			TEVA
Application site discoloration			ZECUITY	S	Transdermal			TEVA
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Application site rash								
Application site urticaria								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574131	NON-EXPEDITED			US-TEVA-669976USA		Female	USA
Preferred Term								
Application site pain			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site erythema			ZECUITY	S	Transdermal			TEVA
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574132	NON-EXPEDITED			US-TEVA-670551USA	55 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role	Route	Dosage Text	Duration	Manufacturer
Application site discoloration			ZECUITY	S	Transdermal			TEVA
Application site mass								
Application site pruritus								
Product physical issue								
Wrong technique in product usage process								



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20-Jul-2016	12574133	NON-EXPEDITED			S	Transdermal		US-TEVA-670336USA	48 YR	Female	USA
Preferred Term											
Application site paraesthesia											
Application site erythema											
Administration site discoloration											
Application site pruritus											
Application site swelling											
<hr/>											
20-Jul-2016	12574134	NON-EXPEDITED			S	Transdermal		US-TEVA-670436USA	24 YR	Female	USA
Preferred Term											
Application site erythema											
Application site discoloration											
Application site pain											
Application site vesicles											
<hr/>											
20-Jul-2016	12574135	NON-EXPEDITED			S	Transdermal		US-TEVA-670609USA		Female	USA
Preferred Term											
Application site erythema											
Application site discoloration											
Application site pain											
Application site vesicles											
Drug effect incomplete											



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20-Jul-2016	12574136	NON-EXPEDITED			S	Transdermal	US-TEVA-669818USA	33 YR	Female	USA
Preferred Term										
Application site rash										
Application site erythema										
Application site exfoliation										
Application site pain										
Application site pruritus										
Application site scab										
Product physical issue										
<hr/>										
20-Jul-2016	12574137	NON-EXPEDITED			S	Transdermal	US-TEVA-669974USA		Female	USA
Preferred Term										
Application site warmth										
Application site discoloration										
Application site erythema										
Application site exfoliation										
Application site irritation										
Application site pain										
Application site pruritus										
<hr/>										
20-Jul-2016	12574138	NON-EXPEDITED			S	Transdermal	US-TEVA-670331USA		Female	USA
Preferred Term										
Application site paraesthesia										
Application site erythema										
Application site pruritus										
Application site urticaria										



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20-Jul-2016	12574140	NON-EXPEDITED			US-TEVA-670296USA	37 YR	Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Product physical issue								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574141	NON-EXPEDITED			US-TEVA-670310USA	45 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site pruritus								
Application site urticaria								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574142	NON-EXPEDITED			US-TEVA-670497USA	25 YR	Female	USA
Preferred Term								
Application site inflammation			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site dryness			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site irritation								
Application site pain								
Application site paraesthesia								
Drug effect incomplete								



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20-Jul-2016	12574143	NON-EXPEDITED			US-TEVA-669935USA	42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site inflammation	ZECURITY	S	Transdermal			TEVA		
Application site scab	ZECURITY	S	Transdermal			TEVA		
Application site erythema								
Application site pain								
Application site pruritus								
Application site warmth								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574144	NON-EXPEDITED			US-TEVA-670330USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site dryness								
Application site vesicles								
Skin exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574145	NON-EXPEDITED			US-TEVA-669883USA	39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site dryness								
Application site irritation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574146	NON-EXPEDITED			US-TEVA-670565USA	51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site dryness	ZECURITY	S	Transdermal			TEVA		
Application site exfoliation								
Application site fissure								



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20-Jul-2016	12574147	NON-EXPEDITED			US-TEVA-670454USA	56 YR	Male	USA
Preferred Term								
Application site paraesthesia			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECURITY	S	Transdermal			TEVA
Application site discoloration			ZECURITY	S	Transdermal			TEVA
Application site pruritus								
Application site urticaria								
Migraine								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574148	NON-EXPEDITED			US-TEVA-670567USA	61 YR	Male	USA
Preferred Term								
Application site pain			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECURITY	S	Transdermal			TEVA
Application site inflammation								
Application site mass								
Application site paraesthesia								
Application site vesicles								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574149	NON-EXPEDITED			US-TEVA-670449USA	17 YR	Male	USA
Preferred Term								
Application site erythema			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site pain			ZECURITY	S	Transdermal			TEVA
Product use issue								



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20-Jul-2016	12574150	NON-EXPEDITED			US-TEVA-670442USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site vesicles		ZECUITY	S	Transdermal	used 5-6 patches in the last two months		TEVA	
Application site erythema								
Application site inflammation								
Incorrect drug administration duration								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574151	NON-EXPEDITED			US-TEVA-670498USA	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Application site dryness								
Application site inflammation								
Application site pain								
Application site rash								
Product quality issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574152	NON-EXPEDITED			US-TEVA-670460USA	43 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Application site inflammation								



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20-Jul-2016	12574157	NON-EXPEDITED			S	Transdermal		US-TEVA-670516USA	41 YR	Female	USA
Preferred Term			Product								Manufacturer
Application site erythema			ZECUITY								TEVA
Application site discoloration											
Application site exfoliation											
Application site urticaria											
Application site vesicles											
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574158	NON-EXPEDITED			S	Transdermal		US-TEVA-670262USA	48 YR	Male	USA
Preferred Term			Product								Manufacturer
Application site erythema			ZECUITY								TEVA
Application site paraesthesia											
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574160	NON-EXPEDITED			S	Transdermal		US-TEVA-670607USA	68 YR	Male	USA
Preferred Term			Product								Manufacturer
Application site pain			ZECUITY								TEVA
Application site erythema											
Application site papules											
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574161	NON-EXPEDITED			S	Transdermal		US-TEVA-670290USA	41 YR	Female	USA
Preferred Term			Product								Manufacturer
Application site paraesthesia			ZECUITY								TEVA
Application site erythema											
Application site discoloration											



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20-Jul-2016	12574162	NON-EXPEDITED			US-TEVA-670612USA	59 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Paraesthesia				S Transdermal			TEVA	
Application site discolouration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Skin exfoliation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574163	NON-EXPEDITED			US-TEVA-670559USA		Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema				S Transdermal			TEVA	
Adhesion								
Application site dryness								
Application site exfoliation								
Drug effect incomplete								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574166	NON-EXPEDITED			US-TEVA-670312USA	72 YR	Female	USA
<u>Preferred Term</u>				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema				S Transdermal			TEVA	
Application site dryness								
Application site inflammation								
Application site irritation								
Application site pruritus								
Wrong technique in product usage process								



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20-Jul-2016	12574167	NON-EXPEDITED			US-TEVA-670332USA	57 YR	Female	USA
Preferred Term								
Application site pain								
Application site discoloration								
Application site erythema								
Drug ineffective								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Manufacturer Control #								
US-TEVA-670488USA								
Age								
46 YR								
Sex								
Female								
Country								
USA								
Preferred Term								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site urticaria								
Product physical issue								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Manufacturer Control #								
US-TEVA-670561USA								
Age								
Sex								
Female								
Country								
USA								
Preferred Term								
Application site rash								
Adhesion								
Product use issue								
Product								
ZECURITY								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
TEVA								
Manufacturer								
TEVA								
Manufacturer Control #								
US-TEVA-670561USA								
Age								
Sex								
Female								
Country								
USA								



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20-Jul-2016	12574171	NON-EXPEDITED			US-TEVA-670554USA	55 YR	Female	USA
Preferred Term								
Application site erythema								
Application site pruritus								
Incorrect product storage								
Product adhesion issue								
Wrong technique in product usage process								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574172	NON-EXPEDITED			US-TEVA-670611USA	39 YR	Female	USA
Preferred Term								
Application site erythema								
Application site dryness								
Application site pruritus								
Application site scab								
Application site vesicles								
Incorrect drug administration duration								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574173	NON-EXPEDITED			US-TEVA-670602USA		Female	USA
Preferred Term								
Application site erythema								
Application site discoloration								
Application site exfoliation								
Application site inflammation								
Application site pruritus								



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20-Jul-2016	12574186	NON-EXPEDITED			US-TEVA-671611USA	27 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECUITY	S Transdermal			TEVA	
Application site pain								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
20-Jul-2016	12574188	NON-EXPEDITED			US-TEVA-671026USA		Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discharge			ZECUITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site rash								
Application site vesicles								
Application site warmth								
Product physical issue								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
20-Jul-2016	12574189	NON-EXPEDITED			US-TEVA-671656USA		Male	USA
Preferred Term								
Application site discoloration			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site inflammation			ZECUITY	S Transdermal			TEVA	
Application site pruritus								
Wrong technique in product usage process								



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20-Jul-2016	12574190	NON-EXPEDITED			US-TEVA-671027USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574191	NON-EXPEDITED			US-TEVA-671641USA	44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		
Application site inflammation								
Application site pain								
Erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574193	NON-EXPEDITED			US-TEVA-671070USA	60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site discoloration								
Application site erythema								
Application site inflammation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574194	NON-EXPEDITED			US-TEVA-671615USA	41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site erythema								



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20-Jul-2016	12574198	NON-EXPEDITED			US-TEVA-671456USA	23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574199	NON-EXPEDITED			US-TEVA-671633USA	36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site inflammation								
Application site pain								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574200	NON-EXPEDITED			US-TEVA-671608USA	44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECURITY	S	Transdermal			TEVA		
Application site erythema								
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574201	NON-EXPEDITED			US-TEVA-671038USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site discoloration								
Application site irritation								
Application site pruritus								



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20-Jul-2016	12574202	NON-EXPEDITED			S	Transdermal		US-TEVA-671637USA		Male	USA
<u>Preferred Term</u> Application site pain Application site erythema Hyperaesthesia											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574203	NON-EXPEDITED			S	Transdermal		US-TEVA-671037USA	56 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site discolouration Application site pruritus											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574204	NON-EXPEDITED			S	Transdermal		US-TEVA-671453USA	42 YR	Female	USA
<u>Preferred Term</u> Application site paraesthesia Application site erythema Application site inflammation											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574205	NON-EXPEDITED			S	Transdermal		US-TEVA-671068USA		Female	USA
<u>Preferred Term</u> Application site erythema Application site discolouration											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574206	NON-EXPEDITED			S	Transdermal		US-TEVA-671355USA		Female	USA
<u>Preferred Term</u> Application site erythema											



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20-Jul-2016	12574207	NON-EXPEDITED			US-TEVA-671078USA		Female	USA
Preferred Term								
Application site vesicles								
Application site scab								
Product physical issue								
Wound								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
Manufacturer								
TEVA								
Case #								
12574208								
Case Type								
NON-EXPEDITED								
Health Professional								
Outcomes								
OT								
Manufacturer Control #								
US-TEVA-671077USA								
Age								
Sex								
Female								
Country								
USA								
Preferred Term								
Swollen tongue								
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site scab								
Application site vesicles								
Throat tightness								
FDA Received Date								
20-Jul-2016								
Case #								
12574209								
Case Type								
NON-EXPEDITED								
Health Professional								
Outcomes								
Manufacturer Control #								
US-TEVA-671357USA								
Age								
Sex								
Female								
Country								
USA								
Preferred Term								
Application site erythema								
Application site pain								
Application site pruritus								
Incorrect drug administration duration								
Role Route								
S Transdermal								
Dosage Text								
TEVA								
Duration								
Manufacturer								
TEVA								



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20-Jul-2016	12574210	NON-EXPEDITED			US-TEVA-671073USA		Female	USA
Preferred Term								
Application site paraesthesia				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema				S Transdermal				TEVA
Application site discoloration				S Transdermal				TEVA
Application site inflammation				S Transdermal				TEVA
Application site pain								
Application site photosensitivity/reaction								
Application site pruritus								
Drug ineffective								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574211	NON-EXPEDITED			US-TEVA-671348USA	46 YR	Female	USA
Preferred Term								
Application site pain				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site urticaria				S Transdermal				TEVA
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574212	NON-EXPEDITED			US-TEVA-671035USA		Female	USA
Preferred Term								
Application site warmth				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site discoloration				S Transdermal				TEVA
Application site erythema								



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20-Jul-2016	12574213	NON-EXPEDITED			US-TEVA-671332USA	44 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site pain								
Application site discoloration								
Application site erythema								
Application site inflammation								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574214	NON-EXPEDITED			US-TEVA-671071USA	24 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site pain								
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site induration								
Application site inflammation								
Application site urticaria								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574216	NON-EXPEDITED			US-TEVA-671346USA	62 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Drug dose omission								
Product quality issue								



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20-Jul-2016	12574217	NON-EXPEDITED			S	Transdermal	US-TEVA-670648USA	42 YR	Female	USA
Preferred Term										
Application site pain										
Application site discoloration										
Application site erythema										
Hypoaesthesia										
20-Jul-2016	12574218	NON-EXPEDITED			S	Transdermal	US-TEVA-671429USA	24 YR	Female	USA
Preferred Term										
Application site erythema										
Application site exfoliation										
20-Jul-2016	12574219	NON-EXPEDITED			S	Transdermal	US-TEVA-671358USA	44 YR	Male	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site exfoliation										
Drug effect incomplete										
Wrong technique in product usage process										
20-Jul-2016	12574220	NON-EXPEDITED			S	Transdermal	US-TEVA-671079USA	45 YR	Female	USA
Preferred Term										
Product physical issue										
Incorrect drug administration duration										
Product quality issue										



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20-Jul-2016	12574221	NON-EXPEDITED			US-TEVA-671644USA	37 YR	Female	USA
Preferred Term								
Application site erythema								
Application site discoloration								
Product adhesion issue								
Product physical issue								
Wrong technique in product usage process								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574222	NON-EXPEDITED			US-TEVA-671066USA	44 YR	Female	USA
Preferred Term								
Application site pain								
Application site bruise								
Application site discoloration								
Application site erythema								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574223	NON-EXPEDITED			US-TEVA-671650USA		Female	USA
Preferred Term								
Application site erythema								
Application site dryness								
Application site pruritus								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574224	NON-EXPEDITED			US-TEVA-671425USA	35 YR	Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Application site urticaria								
Drug effect incomplete								



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20-Jul-2016	12574225	NON-EXPEDITED			S	Transdermal	US-TEVA-671359USA		Unknown	USA
<u>Preferred Term</u> Application site erythema Application site discoloration										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574226	NON-EXPEDITED			S	Transdermal	US-TEVA-671361USA	27 YR	Female	USA
<u>Preferred Term</u> Application site reaction Application site erythema Application site swelling Application site vesicles Drug administration error Incorrect drug administration duration Product quality issue										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574227	NON-EXPEDITED			S	Transdermal	US-TEVA-671701USA	33 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site discoloration Application site paraesthesia										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574228	NON-EXPEDITED			S	Transdermal	US-TEVA-671435USA	35 YR	Female	USA
<u>Preferred Term</u> Application site paraesthesia Product quality issue										



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20-Jul-2016	12574229	NON-EXPEDITED			S	Transdermal	US-TEVA-670629USA		Female	USA
Preferred Term										
Application site erythema										
Application site dryness										
Application site rash										
Dry skin										
Paraesthesia										
Wrong technique in product usage process										
<hr/>										
20-Jul-2016	12574230	NON-EXPEDITED					US-TEVA-671423USA	36 YR	Female	USA
Preferred Term										
Application site paraesthesia										
Application site erythema										
WARFARIN										
<hr/>										
20-Jul-2016	12574231	NON-EXPEDITED					US-TEVA-671434USA	39 YR	Female	USA
Preferred Term										
Application site erythema										
ZECURITY										
<hr/>										
20-Jul-2016	12574232	NON-EXPEDITED					US-TEVA-670646USA		Male	USA
Preferred Term										
Malaise										
ZECURITY										



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20-Jul-2016	12574233	NON-EXPEDITED			US-TEVA-670617USA	28 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site swelling								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574234	NON-EXPEDITED			US-TEVA-670621USA	45 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site discoloration								
Drug effect decreased								
Paraesthesia								
Skin texture abnormal								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574235	NON-EXPEDITED			US-TEVA-670651USA	30 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Burning sensation								
Application site erythema								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574236	NON-EXPEDITED			US-TEVA-671430USA	66 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECURITY	S Transdermal			TEVA	
Application site vesicles								
Application site bruise								
Drug effect incomplete								
Pruritus								



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20-Jul-2016	12574237	NON-EXPEDITED			US-TEVA-670615USA	34 YR	Female	USA
Preferred Term								
Application site discolouration			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site dryness			ZECUITY	S Transdermal			TEVA	
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574238	NON-EXPEDITED			US-TEVA-671072USA	60 YR	Male	USA
Preferred Term								
Application site rash			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discolouration			ZECUITY	S Transdermal			TEVA	
Application site erythema								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574239	NON-EXPEDITED			US-TEVA-670894USA		Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site rash								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574241	NON-EXPEDITED			US-TEVA-671783USA		Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site exfoliation			ZECUITY	S Transdermal			TEVA	
Application site rash								



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20-Jul-2016	12574242	NON-EXPEDITED			US-TEVA-670669USA	38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site discoloration Application site paraesthesia	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574243	NON-EXPEDITED			US-TEVA-671445USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574244	NON-EXPEDITED			US-TEVA-670653USA	20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site reaction Application site erythema Wrong technique in product usage process	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574245	NON-EXPEDITED			US-TEVA-671416USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site irritation Product physical issue Wrong technique in product usage process	ZECURITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574247	NON-EXPEDITED			US-TEVA-670670USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECURITY	S	Transdermal			TEVA		



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20-Jul-2016	12574248	NON-EXPEDITED			S	Transdermal			US-TEVA-670876USA	50 YR	Female	USA
Preferred Term Product physical issue												
Product ZECURITY												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574249	NON-EXPEDITED			S	Transdermal	6.5 mg / 4 hours		US-TEVA-671437USA	43 YR	Female	USA
Preferred Term Application site erythema Application site inflammation Application site pain Application site vesicles Product physical issue												
Product ZECURITY												
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574250	NON-EXPEDITED			S	Transdermal			US-TEVA-671433USA	40 YR	Female	USA
Preferred Term Application site scab Application site discoloration Application site erythema Application site exfoliation Application site irritation Application site pain												
Product ZECURITY												



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20-Jul-2016	12574251	NON-EXPEDITED			US-TEVA-671428USA	54 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site bruise								
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site mass								
Application site pruritus								
Application site reaction								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574252	NON-EXPEDITED			US-TEVA-671444USA	32 YR	Female	USA
Preferred Term								
Application site pain								
Application site dryness								
Application site erythema								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574253	NON-EXPEDITED			US-TEVA-671774USA		Female	USA
Preferred Term								
Application site pain								
Application site discoloration								
Application site vesicles								
Erythema								



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20-Jul-2016	12574254	NON-EXPEDITED			S	Transdermal		US-TEVA-671426USA	52 YR	Male	USA
<u>Preferred Term</u> Application site erythema Wrong technique in product usage process											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574255	NON-EXPEDITED			S	Transdermal		US-TEVA-670872USA	46 YR	Female	USA
<u>Preferred Term</u> Application site irritation Application site erythema Application site rash Drug ineffective Product physical issue Skin injury											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574256	NON-EXPEDITED			S	Transdermal		US-TEVA-671335USA		Female	USA
<u>Preferred Term</u> Application site erythema Application site pain											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574257	NON-EXPEDITED			S	Transdermal		US-TEVA-670912USA	46 YR	Female	USA
<u>Preferred Term</u> Burning sensation Application site discolouration Application site erythema Application site pruritus											



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20-Jul-2016	12574258	NON-EXPEDITED			US-TEVA-671674USA		Female	USA
Preferred Term								
Application site pain								
Application site erythema								
<u>Product</u> ZECURITY								
<u>Role Route</u> S Transdermal								
<u>Dosage Text</u>								
<u>Duration</u> TEVA								
EDA Received Date								
20-Jul-2016	12574259	NON-EXPEDITED			US-TEVA-670683USA		Female	USA
Preferred Term								
Incorrect drug administration duration								
Application site erythema								
Application site pain								
Application site rash								
Drug administered to patient of inappropriate age								
Dyspnoea								
Palpitations								
<u>Product</u> ZECURITY								
<u>Role Route</u> S								
<u>Dosage Text</u>								
<u>Duration</u> TEVA								
EDA Received Date								
20-Jul-2016	12574260	NON-EXPEDITED			US-TEVA-670875USA		Female	USA
Preferred Term								
Application site rash								
Application site dryness								
Application site erythema								
<u>Product</u> ZECURITY								
<u>Role Route</u> S Transdermal								
<u>Dosage Text</u>								
<u>Duration</u> TEVA								
EDA Received Date								
20-Jul-2016	12574261	NON-EXPEDITED			US-TEVA-670887USA		Female	USA
Preferred Term								
Application site erythema								
<u>Product</u> ZECURITY								
<u>Role Route</u> S Transdermal								
<u>Dosage Text</u>								
<u>Duration</u> TEVA								



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20-Jul-2016	12574262	NON-EXPEDITED			US-TEVA-670668USA	45 YR	Female	USA
Preferred Term								
Application site warmth								
Application site discoloration								
Application site erythema								
Application site irritation								
Application site swelling								
<hr/>								
20-Jul-2016	12574263	NON-EXPEDITED			US-TEVA-671704USA	47 YR	Female	USA
Preferred Term								
Application site pain								
Application site discoloration								
Application site erythema								
Product physical issue								
Product use issue								
<hr/>								
20-Jul-2016	12574264	NON-EXPEDITED			US-TEVA-670857USA	50 YR	Female	USA
Preferred Term								
Application site erythema								
Application site paraesthesia								
<hr/>								
20-Jul-2016	12574265	NON-EXPEDITED			US-TEVA-671021USA		Female	USA
Preferred Term								
Application site rash								



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20-Jul-2016	12574266	NON-EXPEDITED			US-TEVA-670882USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Feeling abnormal	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574268	NON-EXPEDITED			US-TEVA-671776USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Swelling Urticaria	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574269	NON-EXPEDITED			US-TEVA-670884USA	39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site warmth Application site discoloration Application site erythema Application site inflammation Application site paraesthesia Application site pruritus Application site rash	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574270	NON-EXPEDITED			US-TEVA-670891USA	45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site irritation	ZECUITY	S	Transdermal			TEVA		



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20-Jul-2016	12574271	NON-EXPEDITED			US-TEVA-671670USA	33 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site paraesthesia								
Application site bruise								
Application site discoloration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site irritation								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574272	NON-EXPEDITED			US-TEVA-671440USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site reaction								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574273	NON-EXPEDITED			US-TEVA-671438USA	47 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574274	NON-EXPEDITED			US-TEVA-671686USA	44 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site discoloration								
Application site dryness								
Application site pruritus								



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20-Jul-2016	12574276	NON-EXPEDITED			US-TEVA-671793USA		Female	USA
Preferred Term								
Application site inflammation								
Application site discolouration								
Application site erythema								
Application site swelling								
Wrong technique in product usage process								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574277	NON-EXPEDITED			US-TEVA-671773USA	45 YR	Female	USA
Preferred Term								
Device battery issue								
Application site discolouration								
Paraesthesia								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574278	NON-EXPEDITED			US-TEVA-671775USA	35 YR	Male	USA
Preferred Term								
Erythema								
Application site pain								
Rash								
Urticaria								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574279	NON-EXPEDITED			US-TEVA-670614USA	50 YR	Female	USA
Preferred Term								
Application site erythema								
Application site discolouration								



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20-Jul-2016	12574284	NON-EXPEDITED			S	Transdermal	US-TEVA-671677USA	35 YR	Female	USA
Preferred Term										
Application site pain										
Application site dryness										
Application site erythema										
Incorrect drug administration duration										
<hr/>										
20-Jul-2016	12574286	NON-EXPEDITED			S	Transdermal	US-TEVA-671791USA	41 YR	Female	USA
Preferred Term										
Drug effect incomplete										
Application site erythema										
<hr/>										
20-Jul-2016	12574287	NON-EXPEDITED			S	Transdermal	US-TEVA-671683USA	44 YR	Female	USA
Preferred Term										
Application site pain										
<hr/>										
20-Jul-2016	12574288	NON-EXPEDITED			S	Transdermal	US-TEVA-671778USA	42 YR	Male	USA
Preferred Term										
Pruritus										
Application site erythema										
Burning sensation										



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EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574289	NON-EXPEDITED			US-TEVA-671758USA	31 YR	Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECURITY	S	Transdermal			TEVA		
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pruritus								
Incorrect drug administration duration								
Product adhesion issue								
Product physical issue								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574290	NON-EXPEDITED			US-TEVA-671785USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Fatigue	ZECURITY	S	Transdermal			TEVA		
Application site discolouration								
Application site erythema								
Dizziness								
Malaise								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12574291	NON-EXPEDITED			US-TEVA-671800USA		Male	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Product physical issue	ZECURITY	S	Transdermal	6.5 mg over 4 hours		TEVA		
Migraine								



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20-Jul-2016	12574292	NON-EXPEDITED			US-TEVA-671798USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S	Transdermal		TEVA	
Application site erythema								
Application site irritation								
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574293	NON-EXPEDITED			US-TEVA-671797USA	42 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug hypersensitivity			ZECUITY	S	Transdermal		TEVA	
Application site dryness								
Application site erythema								
Application site inflammation								
Application site irritation								
Application site mass								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Application site scab								
Application site swelling								
Application site urticaria								
Application site warmth								
Product adhesion issue								
Somnolence								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574294	NON-EXPEDITED			US-TEVA-672467USA		Unknown	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective			ZECUITY	S	Transdermal	6:5 mg/4 hours	TEVA	



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20-Jul-2016	12574295	NON-EXPEDITED			US-TEVA-669675USA	43 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Incorrect drug administration duration			ZECURITY	S Transdermal			TEVA	
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
20-Jul-2016	12574297	NON-EXPEDITED			US-TEVA-671794USA	60 YR	Female	USA
Preferred Term								
Application site pain			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration			ZECURITY	S Transdermal			TEVA	
Application site dryness								
Application site erythema								
Application site pruritus								
Drug ineffective								
Incorrect drug administration duration								
Product adhesion issue								
Wrong technique in product usage process								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
20-Jul-2016	12574298	NON-EXPEDITED			US-TEVA-671702USA	54 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
			ZECURITY	S Transdermal			TEVA	



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574300	NON-EXPEDITED			US-TEVA-671781USA	31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site discomfort	ZECUITY	S	Transdermal	used 2 patches one month ago		TEVA		
Application site erythema								
Application site exfoliation								
Drug effect incomplete								
Product physical issue								
Skin injury								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574302	NON-EXPEDITED			US-TEVA-671705USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Drug ineffective	ZECUITY	S	Transdermal			TEVA		
Application site erythema								
Application site inflammation								
Application site pain								
Product adhesion issue								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574303	NON-EXPEDITED			US-TEVA-671706USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Skin reaction	ZECUITY	S	Transdermal			TEVA		



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12574304	NON-EXPEDITED			US-TEVA-671740USA	47 YR	Female	USA
Preferred Term								
Nasopharyngitis			Role Route		Dosage Text	Duration	Manufacturer	
Upper respiratory tract infection			S Transdermal				TEVA	
Application site irritation			S Transdermal				TEVA	
Drug ineffective								
Pyrexia								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12575619	EXPEDITED (15-DAY)		OT	US-TEVA-673679USA	34 YR	Female	USA
Preferred Term								
Application site burn			Role Route		Dosage Text	Duration	Manufacturer	
Application site erythema			S Transdermal				TEVA	
Application site pain								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jul-2016	12575989	EXPEDITED (15-DAY)		OT	US-TEVA-673594USA	49 YR	Female	USA
Preferred Term								
Application site burn			Role Route		Dosage Text	Duration	Manufacturer	
Application site erythema			S Transdermal				TEVA	
Application site pain								
Application site pruritus								
Product difficult to remove								
Product physical issue								



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20-Jul-2016	12576311	EXPEDITED (15-DAY)		OT	US-TEVA-673465USA	32 YR	Female	USA
Preferred Term								
Sunburn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site discolouration								
Application site scab								
Incorrect drug administration duration								
Wrong technique in product usage process								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12577437	EXPEDITED (15-DAY)		OT	US-TEVA-677100USA	39 YR	Female	USA
Preferred Term								
Application site burn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site exfoliation				S Transdermal			TEVA	
Application site vesicles								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12281713	NON-EXPEDITED			US-TEVA-641336USA	44 YR	Female	USA
Preferred Term								
Drug effect incomplete				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discolouration				S Transdermal			TEVA	
Application site discomfort								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site paraesthesia								
Device leakage								
Hyperaesthesia								
Wound drainage								



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21-Jul-2016	12430284	EXPEDITED (15-DAY)		OT	US-TEVA-662528USA	55 YR	Female	USA
Preferred Term								
Sunburn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site burn								
Application site erythema								
Application site warmth								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12476323	EXPEDITED (15-DAY)		OT	US-TEVA-667941USA		Male	USA
Preferred Term								
Application site burn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discoloration				S Transdermal	6.5 mg / 4 hours		TEVA	
Application site erythema								
Application site pain								
Product physical issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12534670	EXPEDITED (15-DAY)		OT	US-TEVA-673788USA		Female	USA
Preferred Term								
Application site burn				<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discoloration				S Transdermal			TEVA	
Application site erythema								
Application site inflammation								
Application site pain								
Application site pruritus								
Application site scar								
Product physical issue								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12542934	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-674471USA	53 YR	Female	USA
Preferred Term										
Sunburn										
Application site pain										
Application site erythema										
Application site pain										
Product										
ZECUITY										
ZECUITY										
ZECUITY										
EDA Received Date										
21-Jul-2016										
Case #										
12551269										
Case Type										
NON-EXPEDITED										
Health Professional										
Outcomes										
S										
Transdermal										
Role										
S										
Route										
Transdermal										
Manufacturer Control #										
US-TEVA-655172USA										
Age										
29 YR										
Sex										
Female										
Country										
USA										
Preferred Term										
Drug ineffective										
Application site discolouration										
Application site erythema										
Application site pain										
EDA Received Date										
21-Jul-2016										
Case #										
12551399										
Case Type										
NON-EXPEDITED										
Health Professional										
Outcomes										
S										
Transdermal										
Role										
S										
Route										
Transdermal										
Dosage Text										
US-TEVA-658925USA										
Age										
53 YR										
Sex										
Female										
Country										
USA										
Preferred Term										
Application site erythema										
Incorrect drug administration duration										
Application site discolouration										
Application site discomfort										
Application site pruritus										
Application site urticaria										
EDA Received Date										
21-Jul-2016										
Case #										
12551404										
Case Type										
NON-EXPEDITED										
Health Professional										
Outcomes										
S										
Transdermal										
Role										
S										
Route										
Transdermal										
Dosage Text										
US-TEVA-658925USA										
Age										
56 YR										
Sex										
Female										
Country										
USA										
Preferred Term										
Drug ineffective										
ZECUITY										
ZECUITY										



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21-Jul-2016	12570151	NON-EXPEDITED			US-TEVA-668331USA	38 YR	Female	USA
Preferred Term								
Application site reaction								
Application site erythema								
Application site pain								
Product physical issue								
21-Jul-2016	12570154	NON-EXPEDITED			US-TEVA-668260USA	77 YR	Female	USA
Preferred Term								
Migraine								
Drug effect incomplete								
Migraine								
21-Jul-2016	12575632	NON-EXPEDITED			US-TEVA-675513USA		Female	USA
Preferred Term								
Application site pain								
Application site discoloration								
Application site erythema								
Application site vesicles								
Product adhesion issue								
Product physical issue								



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21-Jul-2016	12575736	NON-EXPEDITED			US-TEVA-672376USA	19 YR	Female	USA
Preferred Term								
Application site erythema								
Application site discoloration								
Application site inflammation								
Application site pain								
Application site urticaria								
Drug ineffective								
Product physical issue								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578146	NON-EXPEDITED			US-TEVA-672170USA	62 YR	Female	USA
Preferred Term								
Application site erythema								
Application site pain								
Application site papules								
Application site pruritus								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578148	NON-EXPEDITED			US-TEVA-671795USA	45 YR	Male	USA
Preferred Term								
Application site pain								
Application site erythema								
Application site swelling								
Application site vesicles								
Drug ineffective								
Incorrect drug administration duration								
Product adhesion issue								
Product physical issue								



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21-Jul-2016	12578150	NON-EXPEDITED			US-TEVA-672203USA		Female	USA
Preferred Term								
Application site rash								
Application site erythema								
Application site inflammation								
Application site irritation								
Application site pruritus								
Application site reaction								
Dry skin								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578151	NON-EXPEDITED			US-TEVA-672205USA		Male	USA
Preferred Term								
Product adhesion issue								
Application site pain								
Product physical issue								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578152	NON-EXPEDITED			US-TEVA-672213USA	61 YR	Female	USA
Preferred Term								
Application site pain								
Incorrect drug administration duration								
Product adhesion issue								
Product difficult to remove								
Product physical issue								
Wrong technique in product usage process								



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21-Jul-2016	12578156	NON-EXPEDITED			US-TEVA-672217USA	49 YR	Female	USA
<u>Preferred Term</u>								
Application site pain								
Application site pruritus								
Application site urticaria								
Incorrect drug administration duration								
<u>EDA Received Date</u>								
21-Jul-2016	12578158	NON-EXPEDITED			US-TEVA-672174USA		Female	USA
<u>Preferred Term</u>								
Wrong technique in product usage process								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site pruritus								
Application site rash								
Application site vesicles								
Fatigue								
Paraesthesia								
<u>EDA Received Date</u>								
21-Jul-2016	12578159	NON-EXPEDITED			US-TEVA-672178USA		Female	USA
<u>Preferred Term</u>								
Drug ineffective								
Application site erythema								
Application site pain								
Application site rash								
Product physical issue								
Wrong technique in product usage process								



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21-Jul-2016	12578160	NON-EXPEDITED			S	Transdermal	US-TEVA-672171USA	43 YR	Female	USA
Preferred Term										
Application site paraesthesia										
Application site erythema										
Application site inflammation										
Application site papules										
<hr/>										
21-Jul-2016	12578161	NON-EXPEDITED			S	Transdermal	US-TEVA-672172USA		Female	USA
Preferred Term										
Application site erythema										
Application site pruritus										
<hr/>										
21-Jul-2016	12578167	NON-EXPEDITED			S	Transdermal	US-TEVA-672364USA	26 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
<hr/>										
21-Jul-2016	12578168	NON-EXPEDITED			S	Transdermal	US-TEVA-672282USA	20 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Application site exfoliation										
Application site scab										



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21-Jul-2016	12578169	NON-EXPEDITED			S	Transdermal	US-TEVA-672321USA		Female	USA
<u>Preferred Term</u> Application site discolouration										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578170	NON-EXPEDITED			S	Transdermal	US-TEVA-672257USA	39 YR	Female	USA
<u>Preferred Term</u> Application site urticaria Application site erythema Application site hypertrophy Application site irritation Application site pruritus										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578171	NON-EXPEDITED			S	Transdermal	US-TEVA-672326USA	62 YR	Female	USA
<u>Preferred Term</u> Application site erythema Application site discolouration Application site inflammation Application site pruritus Application site rash Application site urticaria										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578172	NON-EXPEDITED			S	Transdermal	US-TEVA-672303USA		Male	USA
<u>Preferred Term</u> Application site erythema										



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21-Jul-2016	12578173	NON-EXPEDITED			US-TEVA-672331USA		Female	USA
Preferred Term								
Application site erosion								
Application site erythema								
Application site irritation								
Hyperaesthesia								
Product physical issue								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578174	NON-EXPEDITED			US-TEVA-672221USA	36 YR	Female	USA
Preferred Term								
Application site discolouration								
Administration site dryness								
Application site erythema								
Application site paraesthesia								
Application site pruritus								
<hr/>								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578175	NON-EXPEDITED			US-TEVA-672308USA		Female	USA
Preferred Term								
Application site erythema								
Application site pain								



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21-Jul-2016	12578176	NON-EXPEDITED			US-TEVA-672307USA	41 YR	Male	USA
Preferred Term								
Application site warmth				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema				S Transdermal	6.5 mg over 4 hours		TEVA	
Application site inflammation								
Application site pain								
Application site pruritus								
Application site urticaria								
<hr/>								
21-Jul-2016	12578177	NON-EXPEDITED			US-TEVA-672305USA	65 YR	Female	USA
Preferred Term								
Application site paraesthesia				Role Route	Dosage Text	Duration	Manufacturer	
Application site discolouration				S Transdermal			TEVA	
Application site discomfort								
Application site pruritus								
Application site urticaria								
<hr/>								
21-Jul-2016	12578178	NON-EXPEDITED			US-TEVA-672241USA		Female	USA
Preferred Term								
Application site pain				Role Route	Dosage Text	Duration	Manufacturer	
Application site dryness				S Transdermal			TEVA	
Application site erythema								
Application site paraesthesia								



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21-Jul-2016	12578180	NON-EXPEDITED			US-TEVA-672366USA	63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site pruritus Application site rash	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578181	NON-EXPEDITED			US-TEVA-672300USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site pain Product adhesion issue Product physical issue	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578182	NON-EXPEDITED			US-TEVA-672373USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site irritation	ZECUITY	S	Transdermal			TEVA		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578183	NON-EXPEDITED			US-TEVA-672293USA	45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema Application site discoloration	ZECUITY	S	Transdermal			TEVA		



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21-Jul-2016	12578184	NON-EXPEDITED			US-TEVA-672969USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site discoloration								
Application site vesicles								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578185	NON-EXPEDITED			US-TEVA-672283USA	53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site pain	ZECUITY	S	Transdermal			TEVA		
Application site dryness								
Application site erythema								
Drug ineffective								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578186	NON-EXPEDITED			US-TEVA-672371USA	25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site inflammation	ZECUITY	S	Transdermal			TEVA		
Skin disorder								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578187	NON-EXPEDITED			US-TEVA-672367USA	42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>		
Application site erythema	ZECUITY	S	Transdermal			TEVA		
Application site discoloration								
Application site exfoliation								
Application site pain								
Product physical issue								



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21-Jul-2016	12578188	NON-EXPEDITED			US-TEVA-673456USA		Female	USA
Preferred Term								
Application site erythema			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site pain			ZECUITY	S	Transdermal			TEVA
EDA Received Date								
21-Jul-2016	12578189	NON-EXPEDITED			US-TEVA-673455USA	50 YR	Female	USA
Preferred Term								
Application site paraesthesia			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site scab			ZECUITY	S	Transdermal			TEVA
Application site vesicles								
Wrong technique in product usage process								
EDA Received Date								
21-Jul-2016	12578190	NON-EXPEDITED			US-TEVA-672915USA	36 YR	Female	USA
Preferred Term								
Application site pain			<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site erythema			ZECUITY	S	Transdermal			TEVA
Application site inflammation			ZECUITY	S	Transdermal			TEVA
Application site pruritus			ZECUITY	S	Transdermal			TEVA
Application site discoloration								
Application site paraesthesia								
Product physical issue								



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21-Jul-2016	12578191	NON-EXPEDITED			S	Transdermal		US-TEVA-672377USA	53 YR	Female	USA
Preferred Term											
Application site paraesthesia											
Application site erythema											
Application site exfoliation											
Application site laceration											
Application site vesicles											
Wound secretion											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578192	NON-EXPEDITED			S	Transdermal		US-TEVA-672566USA		Female	USA
Preferred Term											
Drug ineffective											
Application site discoloration											
Application site paraesthesia											
<hr/>											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578193	NON-EXPEDITED			S	Transdermal		US-TEVA-672599USA	38 YR	Male	USA
Preferred Term											
Incorrect drug administration duration											
Incorrect drug administration duration											
Application site discoloration											
Application site erythema											
Application site pain											
Application site pruritus											
Product adhesion issue											
Product physical issue											



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21-Jul-2016	12578194	NON-EXPEDITED			US-TEVA-672659USA	53 YR	Female	USA
Preferred Term								
Application site pain				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema				S Transdermal			TEVA	
Application site erythema				S Transdermal			TEVA	
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578195	NON-EXPEDITED			US-TEVA-672374USA	48 YR	Female	USA
Preferred Term								
Application site rash				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema				S Transdermal			TEVA	
Application site exfoliation								
Application site urticaria								
Tinea infection								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578196	NON-EXPEDITED			US-TEVA-672970USA	37 YR	Female	USA
Preferred Term								
Application site pain				Role Route	Dosage Text	Duration	Manufacturer	
Application site bruise				S Transdermal			TEVA	
Application site rash								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578197	NON-EXPEDITED			US-TEVA-672636USA	57 YR	Female	USA
Preferred Term								
Inappropriate schedule of drug administration				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema				S Transdermal			TEVA	
Application site irritation								
Application site pain								
Drug ineffective								
Wrong technique in product usage process								



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21-Jul-2016	12578198	NON-EXPEDITED			US-TEVA-672617USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Application site discolouration								
Application site dryness								
Application site pain								
Incorrect drug administration duration								
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578199	NON-EXPEDITED			US-TEVA-672664USA	40 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site paraesthesia								
Application site vesicles								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578200	NON-EXPEDITED			US-TEVA-672378USA	42 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site paraesthesia			ZECURITY	S Transdermal			TEVA	
Application site pain								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578201	NON-EXPEDITED			US-TEVA-672983USA	36 YR	Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECURITY	S Transdermal	6.5 mg over 4 hours		TEVA	
Application site erythema								
Incorrect drug administration duration								
Paraesthesia								



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21-Jul-2016	12578202	NON-EXPEDITED			US-TEVA-672661USA		Female	USA
Preferred Term								
Application site discolouration								
Application site pain								
Application site pruritus								
Incorrect drug administration duration								
<hr/>								
21-Jul-2016	12578203	NON-EXPEDITED			US-TEVA-672658USA	49 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site discolouration								
Application site dryness								
Application site erythema								
Application site inflammation								
Pain								
<hr/>								
21-Jul-2016	12578204	NON-EXPEDITED			US-TEVA-672877USA	32 YR	Female	USA
Preferred Term								
Application site paraesthesia								
Application site discolouration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pruritus								



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21-Jul-2016	12578205	NON-EXPEDITED			US-TEVA-672597USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Stress			ZECUITY	S Transdermal			TEVA	
Incorrect drug administration duration								
Wrong technique in product usage process								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578206	NON-EXPEDITED			US-TEVA-673625USA	35 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site discomfort			ZECUITY	S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pain								
Application site scab								
Application site urticaria								
Application site vesicles								
Incorrect drug administration duration								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578207	NON-EXPEDITED			US-TEVA-672890USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain			ZECUITY	S Transdermal			TEVA	
Application site erythema								
Application site pain								
Product adhesion issue								
Product physical issue								
Wrong technique in product usage process								



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21-Jul-2016	12578208	NON-EXPEDITED			US-TEVA-672909USA	22 YR	Female	USA
Preferred Term								
Application site pain								
Application site erythema								
Application site irritation								
Application site paraesthesia								
Application site warmth								
Incorrect drug administration duration								
<hr/>								
21-Jul-2016	12578209	NON-EXPEDITED			US-TEVA-672660USA		Female	USA
Preferred Term								
Application site pruritus								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site swelling								
Drug effect incomplete								
<hr/>								
21-Jul-2016	12578210	NON-EXPEDITED			US-TEVA-672641USA	50 YR	Female	USA
Preferred Term								
Application site erythema								
Application site discoloration								
<hr/>								



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21-Jul-2016	12578212	NON-EXPEDITED			S	Transdermal	US-TEVA-672938USA	44 YR	Female	USA
Preferred Term										
Application site vesicles										
Application site pruritus										
Application site urticaria										
Product adhesion issue										
Product physical issue										
<hr/>										
21-Jul-2016	12578213	NON-EXPEDITED			S	Transdermal	US-TEVA-672912USA		Female	USA
Preferred Term										
Application site pain										
Application site erythema										
<hr/>										
21-Jul-2016	12578214	NON-EXPEDITED			S	Transdermal	US-TEVA-672974USA	43 YR	Female	USA
Preferred Term										
Application site erythema										
Application site inflammation										
Application site pruritus										
Application site swelling										
<hr/>										
21-Jul-2016	12578215	NON-EXPEDITED			S	Transdermal	US-TEVA-672618USA	53 YR	Female	USA
Preferred Term										
Erythema										
Application site pain										
Dry skin										
Incorrect drug administration duration										
Product physical issue										



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21-Jul-2016	12578216	NON-EXPEDITED			S	Transdermal	US-TEVA-674491USA	60 YR	Female	USA
Preferred Term										
Application site pain										
Application site discoloration										
Application site erythema										
Application site urticaria										
<hr/>										
21-Jul-2016	12578217	NON-EXPEDITED			S	Transdermal	US-TEVA-672672USA	15 YR	Female	USA
Preferred Term										
Application site pain										
Application site erythema										
Drug administered to patient of inappropriate age										
<hr/>										
21-Jul-2016	12578218	NON-EXPEDITED			S	Transdermal	US-TEVA-672646USA		Female	USA
Preferred Term										
Application site pain										
Application site rash										
<hr/>										
21-Jul-2016	12578219	NON-EXPEDITED			S	Transdermal	US-TEVA-674731USA	54 YR	Female	USA
Preferred Term										
Paraesthesia										
Application site erythema										



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21-Jul-2016	12578220	NON-EXPEDITED			S	Transdermal		US-TEVA-672977USA	42 YR	Female	USA
Preferred Term											
Application site erythema											
Application site inflammation											
Injection site pruritus											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578221	NON-EXPEDITED			S	Transdermal		US-TEVA-673362USA	60 YR	Female	USA
Preferred Term											
Application site erythema											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578222	NON-EXPEDITED			S	Transdermal		US-TEVA-672883USA		Female	USA
Preferred Term											
Application site pruritus											
Application site erythema											
Product adhesion issue											
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Dosage Text	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578223	NON-EXPEDITED			S	Transdermal		US-TEVA-672668USA		Female	USA
Preferred Term											
Application site erythema											
Application site discoloration											
Application site inflammation											
Application site pruritus											
Application site urticaria											
Application site warmth											
Skin disorder											
Wrong technique in product usage process											



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21-Jul-2016	12578224	NON-EXPEDITED			US-TEVA-673461USA		Male	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Vomiting		ZECURITY	S	Transdermal			TEVA	
Drug ineffective								
Headache								
Incorrect drug administration duration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578225	NON-EXPEDITED			US-TEVA-672988USA	25 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Drug ineffective		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site rash								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578226	NON-EXPEDITED			US-TEVA-675901USA	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site pain		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site paraesthesia								
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578227	NON-EXPEDITED			US-TEVA-672966USA	48 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site exfoliation		ZECURITY	S	Transdermal			TEVA	
Application site dryness								
Application site erythema								



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21-Jul-2016	12578228	NON-EXPEDITED			US-TEVA-672987USA		Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
			ZECUITY	S Transdermal			TEVA	
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578229	NON-EXPEDITED			US-TEVA-673744USA	47 YR	Female	USA
Preferred Term								
Application site paraesthesia			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECUITY	S Transdermal			TEVA	
Application site pruritus								
Application site rash								
Incorrect drug administration duration								
Product physical issue								
Scratch								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578230	NON-EXPEDITED			US-TEVA-672936USA	50 YR	Female	USA
Preferred Term								
Application site erythema			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site inflammation			ZECUITY	S Transdermal			TEVA	
Application site pain								
Application site paraesthesia								
Drug effect incomplete								



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EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578231	NON-EXPEDITED			US-TEVA-673604USA	48 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECURITY	S	Transdermal			TEVA		
Application site bruise								
Application site erythema								
Application site irritation								
Application site pruritus								
Drug ineffective								
Wrong technique in product usage process								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578232	NON-EXPEDITED			US-TEVA-673656USA	47 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema	ZECURITY	S	Transdermal			TEVA		
Application site exfoliation								
Application site scab								
Application site urticaria								
Application site vesicles								
Drug ineffective								
Incorrect drug administration duration								

EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578233	NON-EXPEDITED			US-TEVA-672899USA		Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site pain	ZECURITY	S	Transdermal			TEVA		
Drug ineffective								



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21-Jul-2016	12578234	NON-EXPEDITED			US-TEVA-673709USA	19 YR	Male	USA
Preferred Term								
Application site exfoliation								
Application site erythema								
Application site pain								
Application site vesicles								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578235	NON-EXPEDITED			US-TEVA-673462USA	55 YR	Female	USA
Preferred Term								
Application site erythema								
Application site irritation								
Application site pruritus								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578236	NON-EXPEDITED			US-TEVA-672971USA		Female	USA
Preferred Term								
Application site rash								
Application site dryness								
Feeling abnormal								
Wrong technique in product usage process								



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21-Jul-2016	12578237	NON-EXPEDITED			US-TEVA-675476USA		Female	USA
Preferred Term								
Application site pain								
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site pruritus								
Wrong technique in product usage process								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578238	NON-EXPEDITED			US-TEVA-673430USA	56 YR	Female	USA
Preferred Term								
Application site hypoaesthesia								
Application site discoloration								
Application site erythema								
Application site vesicles								
Incorrect drug administration duration								
<hr/>								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578240	NON-EXPEDITED			US-TEVA-673746USA		Female	USA
Preferred Term								
Application site erythema								
Product								
ZECURITY								
Role Route								
S Transdermal								
Product								
estrogen patch								
Role Route								
C Transdermal								
Dosage Text								
TEVA								



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21-Jul-2016	12578241	NON-EXPEDITED			S	Transdermal	US-TEVA-673708USA	62 YR	Female	USA
Preferred Term							Dosage Text	Duration	Manufacturer	
Application site erythema									TEVA	
Drug ineffective										
Product adhesion issue										
Product physical issue										
Wrong technique in product usage process										
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578242	NON-EXPEDITED			S	Transdermal	US-TEVA-672997USA		Female	USA
Preferred Term							Dosage Text	Duration	Manufacturer	
Application site discolouration									TEVA	
Application site erythema										
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578243	NON-EXPEDITED			S	Transdermal	US-TEVA-673745USA	38 YR	Female	USA
Preferred Term							Dosage Text	Duration	Manufacturer	
Dizziness									TEVA	
Incorrect drug administration duration										
Nausea										
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Role	Route	Manufacturer Control #	Age	Sex	Country
21-Jul-2016	12578244	NON-EXPEDITED			S	Transdermal	US-TEVA-675893USA		Female	USA
Preferred Term							Dosage Text	Duration	Manufacturer	
Application site rash									TEVA	
Application site erythema										
Application site exfoliation										
Application site scab										
Wound										



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21-Jul-2016	12580873	EXPEDITED (15-DAY)		OT	US-TEVA-673753USA	58 YR	Female	USA
Preferred Term								
Sunburn				Role Route	Dosage Text	Duration	Manufacturer	
				S Transdermal			TEVA	
Application site erythema								
Application site joint pain								
Drug effect incomplete								
EDA Received Date Case # Case Type Health Professional Outcomes Manufacturer Control # Age Sex Country								
21-Jul-2016	12581369	EXPEDITED (15-DAY)		OT	US-TEVA-673801USA		Female	USA
Preferred Term								
Application site burn				Role Route	Dosage Text	Duration	Manufacturer	
				S Transdermal			TEVA	
Application site bruise								
Application site discoloration								
Application site erythema								
Application site pain								
Application site scab								
Application site scar								



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22-Jul-2016	12228022	EXPEDITED (15-DAY)		OT	US-TEVA-647195USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site scab								
Application site swelling								
Device battery issue								
Device leakage								
Drug ineffective								
Product adhesion issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2016	12234748	EXPEDITED (15-DAY)		OT	US-TEVA-645089USA	28 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site rash		ZECURITY	S	Transdermal			TEVA	
Application site pruritus		Topamax	C					
Migraine		Ambien	C					
Application site erythema		amitriptyline	C					
Drug ineffective		Phenergan	C					
Product physical issue		nucentra	C					
Application site pain		wellbutrin	C					
		verapamil	C					
		NORTRIPTYLINE	C					
		tylenol	C					



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22-Jul-2016	12581824	NON-EXPEDITED			US-TEVA-672918USA	39 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Application site irritation	ZECUITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jul-2016	12581825	NON-EXPEDITED			US-TEVA-673711USA	65 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site erythema Product quality issue	ZECUITY	S	Transdermal			TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jul-2016	12586638	DIRECT				53 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site urticaria Application site burn Application site pruritus	ZECUITY, 6.5 MG TEVA BENICAR	S C		24 patch(es) As needed Applied as medicated patch to skin		TEVA		
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jul-2016	11644003	EXPEDITED (15-DAY)		OT	US-TEVA-602196USA	46 YR	Female	USA
Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer		
Application site burn Application site discoloration Application site erythema Application site vesicles Device malfunction Drug effect incomplete Product physical issue	ZECUITY	S	Transdermal			TEVA		



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25-Jul-2016	12116875	EXPEDITED (15-DAY)		OT	US-TEVA-636492USA	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site erythema								
Application site paraesthesia								
Application site rash								
Drug ineffective								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2016	12140764	EXPEDITED (15-DAY)		OT	US-TEVA-638845USA	39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site pruritus		ZECURITY		S Transdermal			TEVA	
Application site bruise								
Application site erosion								
Application site erythema								
Application site pain								
Application site vesicles								
Device battery issue								
Device leakage								
Incorrect drug administration duration								
Product adhesion issue								
Scratch								



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25-Jul-2016	12154393	EXPEDITED (15-DAY)		OT	US-TEVA-637696USA	62 YR	Male	USA
Preferred Term								
Sunburn				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal	6.5 mg / 4 hours		TEVA	
Application site burn								
Application site erythema								
Device battery issue								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jul-2016	12538232	EXPEDITED (15-DAY)		OT	US-TEVA-674490USA	61 YR	Female	USA
Preferred Term								
Application site burn				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site discolouration								
Application site discomfort								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
<hr/>								
EDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jul-2016	12572774	EXPEDITED (15-DAY)		OT	US-TEVA-669052USA	36 YR	Female	USA
Preferred Term								
Sunburn				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
				S Transdermal			TEVA	
Application site discomfort								
Application site erythema								
Application site pain								
Application site vesicles								
Application site warmth								



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25-Jul-2016	12568113	EXPEDITED (15-DAY)		OT	US-TEVA-678770USA	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site erythema		ZECUITY		S Transdermal			TEVA	
Application site inflammation								
Application site pain								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2016	12590481	EXPEDITED (15-DAY)		OT	US-TEVA-674744USA	57 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site bruise								
Application site discoloration								
Application site discomfort								
Application site pain								
Drug effect decreased								
Product substitution issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	12542935	EXPEDITED (15-DAY)		OT	US-TEVA-674472USA	40 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site exfoliation								
Application site pain								



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26-Jul-2016	12550762	EXPEDITED (15-DAY)		OT	US-TEVA-675632USA	36 YR	Female	USA
Preferred Term								
Sunburn				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema				S Transdermal			TEVA	
Application site discoloration				S Transdermal			TEVA	
Application site dybness								
Application site pain								
Application site pruritus								
Application site urticaria								
Skin wrinkling								
<hr/>								
26-Jul-2016	12596189	EXPEDITED (15-DAY)		OT	US-TEVA-678793USA	41 YR	Female	USA
Preferred Term								
Application site burn				Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema				S Transdermal			TEVA	
<hr/>								
27-Jul-2016	12582706	EXPEDITED (15-DAY)		OT	US-TEVA-679055USA		Female	USA
Preferred Term								
Application site scar				Role Route	Dosage Text	Duration	Manufacturer	
Application site discoloration				S Transdermal			TEVA	
Application site pain								
Application site pruritus								
Application site reaction								
Application site scab								
Application site vesicles								
Thermal burn								
Urticaria								



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27-Jul-2016	12600621	EXPEDITED (15-DAY)		OT	US-TEVA-678216USA		Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Thermal burn			ZECUITY	S Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2016	12164746	EXPEDITED (15-DAY)		OT	US-TEVA-629494USA	54 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn			ZECUITY	S Transdermal			TEVA	
Application site discomfort								
Application site erythema								
Application site irritation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Device battery issue								
Headache								
Medication overuse headache								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2016	12453352	EXPEDITED (15-DAY)		OT	US-TEVA-664593USA	63 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn			ZECUITY	S Transdermal			TEVA	
Application site pain			PERCOCET	C	prn			
Application site inflammation			LIPITOR	C				
Application site erythema			NORTRIPTYLINE	C	20 mg at HS			
Application site urticaria			AXERT	C	12.5 mg prn			
Inappropriate schedule of drug administration			PROPRANOLOL	C	10mg BID			
			BONIVA	C	150mg 1 every month			



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28-Jul-2016	12461686	EXPEDITED (15-DAY)		OT	US-TEVA-666529USA	29 YR	Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Application site swelling								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jul-2016	12583650	EXPEDITED (15-DAY)		OT	US-TEVA-675228USA		Female	USA
Preferred Term								
Application site scar			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site discolouration			ZECURITY	S Transdermal			TEVA	
Application site erythema								
Application site paraesthesia								
Application site pruritus								
Application site vesicles								
<hr/>								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jul-2016	12603346	EXPEDITED (15-DAY)		OT	US-TEVA-678085USA		Female	USA
Preferred Term								
Application site burn			Product	Role Route	Dosage Text	Duration	Manufacturer	
Application site erythema			ZECURITY	S Transdermal			TEVA	
Application site inflammation								
Application site pain								



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<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2016	12603587	EXPEDITED (15-DAY)		OT	US-TEVA-678071USA		Female	USA
<u>Preferred Term</u>								
Application site burn								
Application site erythema								
Application site pain								
Application site scar								
Product adhesion issue								
Product physical issue								
Wrong technique in product usage process								
<u>EDA Received Date</u>								
28-Jul-2016	12603985	EXPEDITED (15-DAY)		OT	US-TEVA-678081USA	18 YR	Female	USA
<u>Preferred Term</u>								
Application site scar								
Application site bruise								
Application site erythema								
Application site inflammation								
Application site rash								
Application site scab								
Application site urticaria								



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28-Jul-2016	12606400	DIRECT				29 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Burning sensation				S	6.5mg/4hrs 1 PRN for headaches transdermal			TEVA
<u>Product</u>								
ZECUITY, SUMATRIPTAN IONTOPHORETIC TRANSDERMAL SYSTEM) TEVA								
VENLAFAXINE HCL ER				C				
TOPIRAMATE				C				
GABAPENTIN				C				
DUEXIS				C				
COQ10				C				
TUMERIC				C				
Skin discoloration								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2016	11909414	EXPEDITED (15-DAY)		OT	US-TEVA-609652USA	37 YR	Female	USA
<u>Preferred Term</u>					<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Sunburn				S				TEVA
Transdermal								
Application site dryness								
Application site erythema								
Application site urticaria								
Application site warmth								
Device adhesion issue								
Device battery issue								
Device leakage								
Drug effect decreased								
Product adhesion issue								
Product physical issue								
Underdose								



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29-Jul-2016	12338949	EXPEDITED (15-DAY)		OT	US-TEVA-656613USA	27 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal			TEVA	
Application site erythema				S Transdermal			TEVA	
Application site bruise								
Application site discoloration								
Application site inflammation								
Application site vesicles								
Device issue								
Device leakage								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2016	12459211	EXPEDITED (15-DAY)		OT	US-TEVA-666104USA		Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Chemical injury				S Transdermal			TEVA	
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2016	12461699	EXPEDITED (15-DAY)		OT	US-TEVA-666369USA	54 YR	Female	USA
<u>Preferred Term</u>				<u>Role Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn				S Transdermal	6:5 mg / 4 hours		TEVA	
Application site pain				S Transdermal	6:5 mg / 4 hours		TEVA	
Application site discoloration								
Application site erythema								
Application site paraesthesia								



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29-Jul-2016	12477293	EXPEDITED (15-DAY)		OT	US-TEVA-667956USA	30 YR	Female	USA
Preferred Term				Role Route	Dosage Text	Duration	Manufacturer	
Burns second degree				S Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site inflammation								
Application site pain								
Application site pustules								
Application site warmth								
Gait disturbance								
Myalgia								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jul-2016	12482926	EXPEDITED (15-DAY)		OT	US-TEVA-667592USA	51 YR	Female	USA
Preferred Term				Role Route	Dosage Text	Duration	Manufacturer	
Application site burn				S Transdermal			TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site pain								
Application site paraesthesia								
Drug ineffective								
Product physical issue								
FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jul-2016	12607815	EXPEDITED (15-DAY)		OT	US-TEVA-679796USA		Female	USA
Preferred Term				Role Route	Dosage Text	Duration	Manufacturer	
Application site burn				S Transdermal			TEVA	
Application site scar								



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29-Jul-2016	12608287	EXPEDITED (15-DAY)		OT	US-TEVA-680074USA	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Topical			TEVA	
Application site erythema								
Application site pain								
Application site pruritus								
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12104334	EXPEDITED (15-DAY)		OT	US-TEVA-635757USA	56 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal	6.5 mg / 4 hours		TEVA	
Application site discomfort								
Application site dryness								
Application site pain								
Application site pruritus								
Application site warmth								
Burns first degree								
Incorrect drug administration duration								



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01-Aug-2016	12147002	EXPEDITED (15-DAY)		OT	US-TEVA-639935USA	64 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Sunburn		ZECUITY		S Transdermal				TEVA
Application site erythema		ZECUITY		S Transdermal				TEVA
Application site exfoliation								
Application site inflammation								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site urticaria								
Application site warmth								
Hypersensitivity								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12171812	EXPEDITED (15-DAY)		OT	US-TEVA-627683USA	42 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Burns first degree		ZECUITY		S Transdermal				TEVA
Application site scar		ZECUITY		S				TEVA
Application site rash		Florinal		C	as needed			
Application site erythema		Losartan with HCTZ		C				
Application site discoloration								
Application site pain								
Application site swelling								



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01-Aug-2016	12177309	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-642075USA		Female	USA
Preferred Term										
Application site burn										
Application site discoloration										
Application site erythema										
Application site pain										
Application site scar										
Device battery issue										
Device leakage										
Device use error										
<hr/>										
01-Aug-2016	12316227	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-655256USA	48 YR	Female	USA
Preferred Term										
Application site burn										
Application site discoloration										
Application site dryness										
Application site erythema										
Application site pain										
Application site scar										
Electric shock										
<hr/>										
01-Aug-2016	12345857	EXPEDITED (15-DAY)		OT	S	Transdermal	US-TEVA-658026USA	56 YR	Female	USA
Preferred Term										
Application site burn										
Application site erythema										
Application site pain										
Application site pruritus										



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01-Aug-2016	12456978	EXPEDITED (15-DAY)		OT	US-TEVA-666002USA	37 YR	Female	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site burn								
Application site erythema								
Incorrect drug administration duration								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12477259	EXPEDITED (15-DAY)		OT	US-TEVA-667948USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site burn								
Application site discolouration								
Application site erythema								
Application site irritation								
Application site paraesthesia								
Application site urticaria								
Wrong technique in product usage process								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12610434	EXPEDITED (15-DAY)		OT	US-TEVA-679969USA		Male	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S Transdermal			TEVA	
Application site burn								
Application site erythema								
Application site pain								
Application site pruritus								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12613490	DIRECT					Unknown	USA
<u>Preferred Term</u>			<u>Product</u>	<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
			ZECUITY	S				
Application site pain								
Application site erythema								



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01-Aug-2016	12613621	DIRECT				45 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Burning sensation		ZECUITY, 6.5 MG		S	Transdermal	1 patch as needed applied as medicated patch to skin	3.5 HR	
Pruritus		ZECUITY		S				
Application site erythema								
Application site irritation								
Application site pruritus								
Application site scar								
Application site swelling								
Application site vesicles								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2016	11720261	EXPEDITED (15-DAY)		OT	US-TEVA-607311USA	44 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>
Application site burn		ZECUITY		S	Transdermal			TEVA
Application site erythema								
Application site pain								



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02-Aug-2016	11788660	EXPEDITED (15-DAY)		OT	US-TEVA-610374USA	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site erythema		Compounded Pain Cream		C				
Application site swelling		Escitalopram		C				
Application site pain		Midrin		C				
Application site pain		Naratriptan		C				
Headache		Omeprazole		C				
Device leakage		Ranitidine		C				
		Verapamil		C				
		Zolpidem		C				
		Maxalt		C				
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2016	12177474	EXPEDITED (15-DAY)		OT	US-TEVA-642172USA	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal	6.5 mg / 4 hours		TEVA	
Application site discolouration								
Application site dryness								
Application site erythema								
Application site infection								
Application site pruritus								
Application site scar								
Application site urticaria								
Application site vesicles								
Device use error								



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02-Aug-2016	12177500	EXPEDITED (15-DAY)		OT	US-TEVA-642198USA	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECUITY		S Transdermal	6.5 mg / 4 hours			TEVA
Application site erythema		ZECUITY		S Transdermal	6.5 mg / 4 hours			TEVA
Application site urticaria		ZECUITY		S Transdermal	6.5 mg / 4 hours			TEVA
Application site discoloration								
Application site erythema								
Application site paraesthesia								
Application site pruritus								
Application site swelling								
Product adhesion issue								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2016	12184897	EXPEDITED (15-DAY)		OT	US-TEVA-642470USA	30 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECUITY		S Transdermal				TEVA
Application site discoloration								
Application site erythema								
Application site paraesthesia								
Application site scar								
Application site vesicles								
Product adhesion issue								



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02-Aug-2016	12192549	EXPEDITED (15-DAY)		OT	US-TEVA-643591USA	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Application site pain		ZECUITY	S	Transdermal			TEVA	
Application site discoloration								
Application site irritation								
Application site paraesthesia								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2016	12518529	EXPEDITED (15-DAY)		OT	US-TEVA-671853USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2016	12522556	EXPEDITED (15-DAY)		OT	US-TEVA-672650USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	



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03-Aug-2016	12177912	EXPEDITED (15-DAY)		OT	US-TEVA-643121USA	36 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Adverse event								
Application site pain								
Application site pruritus								
Application site rash								
Application site urticaria								
Application site warmth								
Chemical Injury								
Migraine								
Nausea								
Product physical issue								
Sunburn								
Vomiting								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2016	12577411	EXPEDITED (15-DAY)		OT	US-TEVA-673739USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S Transdermal			TEVA	
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site pain								



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03-Aug-2016	12578211	EXPEDITED (15-DAY)		OT	US-TEVA-674489USA	51 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECUITY		S Transdermal	6.5mg/4 hours			TEVA
Application site discolouration								
Application site erythema								
Application site Inflammation								
Application site pain								
Application site pruritus								
Application site urticaria								
Application site warmth								
Drug ineffective								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2016	12621296	DIRECT				35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site erythema		ZECUITY, 6.5 MG		S	1 Patch every 4 hours applied as medicated patch to skin			
Application site bruise		TOPAMAX		C				
Application site discolouration		APRI		C				
Application site pain								



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04-Aug-2016	12577717	EXPEDITED (15-DAY)		OT	US-TEVA-677281USA	46 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal	6.5 mg / 4 hours		TEVA	
Application site discolouration								
Application site dryness								
Application site erythema								
Application site inflammation								
Application site irritation								
Application site pain								
Application site warmth								
Skin reaction								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2016	12540604	EXPEDITED (15-DAY)		OT	US-TEVA-650301USA	29 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal	6.5mg/4hr		TEVA	
Application site pain		ZECUITY	S	Transdermal			TEVA	
Application site erythema		FLEXERIL	C	Unknown			TEVA	
Application site haemorrhage		DICLOFENAC	C	Unknown				
Application site dermatitis								
Application site rash								
Application site vesicles								



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08-Aug-2016	12493935	EXPEDITED (15-DAY)		OT	US-TEVA-669484USA	33 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Sunbum		ZECUITY		S Transdermal				TEVA
Application site discolouration								
Application site erythema								
Application site exfoliation								
Application site irritation								
Application site pain								
Application site rash								
Migraine								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2016	12245117	EXPEDITED (15-DAY)		OT	US-TEVA-626200USA	54 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Sunbum		ZECUITY		S Transdermal				TEVA
Application site erythema								
Application site pain								



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09-Aug-2016	12345331	EXPEDITED (15-DAY)		OT	US-TEVA-654935USA	29 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY	S	Transdermal			TEVA	
Application site erythema		ZECUITY	S	Transdermal			TEVA	
Application site discoloration								
Application site exfoliation								
Application site laceration								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site rash								
Application site swelling								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2016	11686983	EXPEDITED (15-DAY)		OT	US-TEVA-604825USA		Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site scar		ZECUITY	S	Transdermal	6.5 mg/4 hrs		TEVA	
Application site discoloration								
Application site erythema								
Application site urticaria								
Drug ineffective								
Visual impairment								



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11-Aug-2016	11949997	EXPEDITED (15-DAY)		OT	US-TEVA-627630USA	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discharge								
Application site discoloration								
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site pruritus								
Application site scab								
Application site scar								
Application site vesicles								
Chemical Injury								

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12-Aug-2016	12170600	EXPEDITED (15-DAY)		OT	US-TEVA-637715USA	18 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S Transdermal			TEVA	
Application site discoloration								
Application site dryness								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Application site rash								
Drug ineffective								
Hypersensitivity								



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12-Aug-2016	12391261	EXPEDITED (15-DAY)		OT	US-TEVA-660376USA	30 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Wrong technique in product usage process		ZECUITY	S	Transdermal			TEVA	
Application site discoloration								
Application site erythema								
Application site rash								
Product physical issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12235465	EXPEDITED (15-DAY)		OT	US-TEVA-647859USA	35 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECUITY	S	Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site paraesthesia								
Application site rash								
Application site swelling								
Application site vesicles								
Product adhesion issue								



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15-Aug-2016	12263960	EXPEDITED (15-DAY)		OT	US-TEVA-650646USA	57 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Application site pain		ZECUITY		S Transdermal			TEVA	
Application site pain		IMITREX		C				
Application site discoloration		AMLODIPINE		C				
Application site erythema		HYDROCODONE W/ ACETAMINOPHEN		C				
Application site dermatitis								
Application site pruritus								
Application site vesicles								
Product adhesion issue								
Product use issue								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12306580	EXPEDITED (15-DAY)		OT	US-TEVA-654001USA	49 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Thermal burn		ZECUITY		S Transdermal			TEVA	
Application site erythema								
Application site pain								
Application site warmth								
Device battery issue								
Intentional product misuse								



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15-Aug-2016	12452731	EXPEDITED (15-DAY)		OT	US-TEVA-666020USA	63 YR	Female	USA
Preferred Term								
Sunburn								
Application site erythema				S	Transdermal			TEVA
Application site discoloration				S	Transdermal			TEVA
Application site inflammation								
Application site vesicles								
Product adhesion issue								
Product odour abnormal								
Product physical issue								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12505994	EXPEDITED (15-DAY)		OT	US-TEVA-670536USA	56 YR	Female	USA
Preferred Term								
Burns second degree				S	Transdermal			TEVA
Application site warmth				C	Unknown			
Application site discoloration								
Application site erythema								
Application site inflammation								
Application site pain								
Application site paraesthesia								
Application site vesicles								
Wrong technique in product usage process								



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16-Aug-2016	11720564	EXPEDITED (15-DAY)		OT	US-TEVA-606947USA	45 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Headache		ZECUITY		S Transdermal			TEVA	
Application site bruise		MAXALT		C			TEVA	
Application site discoloration								
Application site pain								
Application site pruritus								
Incorrect drug administration duration								
Reaction to preservatives								

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16-Aug-2016	12185596	EXPEDITED (15-DAY)		OT	US-TEVA-642848USA	51 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u> <u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECUITY		S Transdermal			TEVA	
Chemical injury		ZECUITY		S Transdermal			TEVA	
Abasia								
Application site discoloration								
Application site erythema								
Application site exfoliation								
Application site pain								
Application site paraesthesia								
Burns first degree								
Hypotonia								
Muscular weakness								
Pain in extremity								
Product physical issue								



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16-Aug-2016	12232533	EXPEDITED (15-DAY)		OT	US-TEVA-635048USA	36 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECURITY		S				TEVA
Sunburn		ZECURITY		S	Transdermal			TEVA
Application site discolouration								
Application site erythema								
Application site irritation								
Application site pain								
Application site pruritus								
Product physical issue								
Underdose								

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12281814	EXPEDITED (15-DAY)		OT	US-TEVA-643681USA	53 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Manufacturer</u>
Application site burn		ZECURITY		S				TEVA
Application site erythema		ZECURITY		S	Transdermal			TEVA
Application site warmth		ZECURITY		S	Transdermal			TEVA
Application site pain		ZECURITY		S	Transdermal			TEVA
Application site discolouration								
Application site inflammation								
Application site paraesthesia								
Application site pruritus								
Application site swelling								
Product physical issue								



FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12456942	EXPEDITED (15-DAY)		OT	US-TEVA-665422USA	53 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Sunburn		ZECURITY		S	6.5 mg / 4 hours		TEVA	
Application site paraesthesia		Augmentin		C				
Application site pain		Bactrim		C				
Application site erythema		ceftin		C				
Application site exfoliation		prednisone		C				
Application site dryness								
Application site oedema								
Application site urticaria								
Drug effect incomplete								
Product physical issue								
<u>EDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Professional</u>	<u>Outcomes</u>	<u>Manufacturer Control #</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12493401	EXPEDITED (15-DAY)		OT	US-TEVA-669087USA	45 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>		<u>Role</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Manufacturer</u>	
Application site burn		ZECURITY		S			TEVA	
Application site pruritus		METOPROLOL		C				
Application site paraesthesia		HYDROCODONE		C				
Application site pain		PRILLOSEC		C				
Application site dryness		VYTORIN		C				
Application site discoloration		ANTARA		C				
Product physical issue		WELLBUTRIN		C				
Application site inflammation		BUSPAR		C				
Application site erythema								
Application site reaction								