Which hypertensive therapy

helped 7 out of 10 challenging patients reach goal?

See inside for the answer and more information!

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PROVEN POWER!

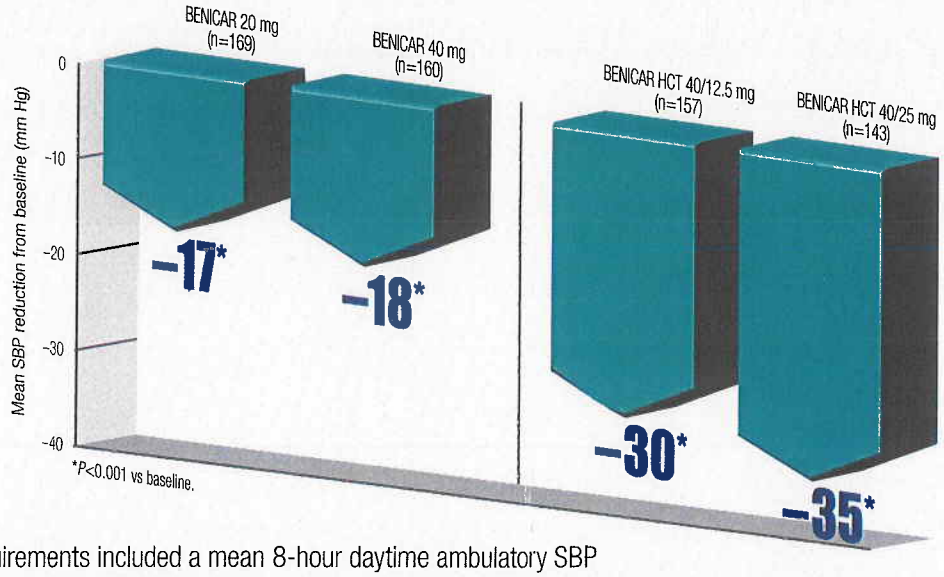
In the BeniSYS trial, 70% of patients reached a BP goal of <140/90 mm Hg by week 12 (mean baseline BP: 171/95 mm Hg).[1]

Contraindications

Do not co-administer aliskiren with BENICAR or BENCIAR HCT in patients with diabetes

In the BeniSYS trial

35 mm Hg mean SBP reduction in challenging patients titrated up to BENICAR HCT® 40/25 mg[1]



- Entry requirements included a mean 8-hour daytime ambulatory SBP >140 mm Hg and ≤180 mm Hg and a mean ambulatory DBP <110 mm Hg[1]

Mean baseline BP: 171/95 mm Hg.[1]

Mean age: 60 years.[1] A prospective, open-label, multicenter, titration trial conducted in the United States (N=170). Following a 3- to 4-week placebo run-in, patients were started on BENICAR 20 mg, and if they did not reach goal of <120/80 mm Hg, they were titrated at 3-week intervals to BENICAR 40 mg, BENICAR HCT 40 mg/12.5 mg, then 40/25 mg. The primary endpoint was the change in mean trough SBP from baseline at Week 12.[1]

The results of this open-label trial differ from those obtained in the pivotal, placebo-controlled US MATRIX trial.

In the pivotal US MATRIX trial, mean SBP reductions from baseline were: 3 mm Hg with placebo, 15 mm Hg with BENICAR 20 mg, 16 mm Hg with BENICAR 40 mg, 19 mm Hg with BENICAR HCT 40/12.5 mg, and 27 mm Hg with BENICAR HCT 40/25 mg (mean baseline BP for these treatment groups=154/103 mm Hg).

INDICATIONS:

BENICAR is indicated for the treatment of hypertension to lower blood pressure, alone or with other antihypertensive agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes including the class to which this drug principally belongs. There are no controlled trials demonstrating risk reduction with BENICAR.

Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals.

BENICAR HCT is indicated for the treatment of hypertension, alone or with other antihypertensive agents. BENICAR HCT is not indicated for initial therapy.

WARNING: FETAL TOXICITY
- **When pregnancy is detected, discontinue BENICAR or BENICAR HCT as soon as possible**
- **Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. See WARNINGS AND PRECAUTIONS: Fetal Toxicity**

Please see Important Safety Information for BENICAR® (olmesartan medoxomil) and BENICAR HCT® (olmesartan medoxomil-hydrochlorothiazide).

Please see accompanying Full Prescribing Information for BENICAR and BENICAR HCT, including Boxed **WARNING regarding Fetal Toxicity.**

Benicar® TABLETS
(olmesartan medoxomil)

BenicarHCT® TABLETS
(olmesartan medoxomil • hydrochlorothiazide)

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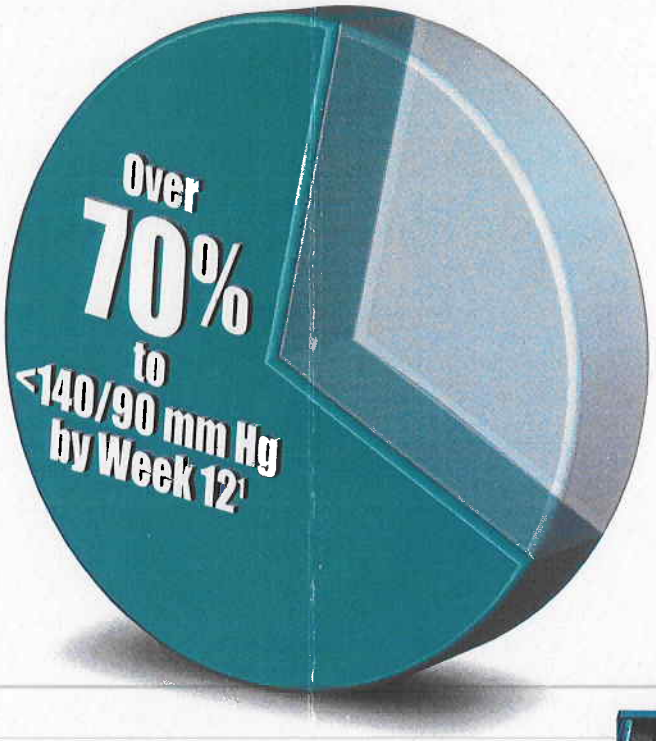
7 out of 10 challenging patients reached goal with BENICAR and BENICAR HCT



(Cumulative goal attainment: 70.4%). The cumulative goal attainment for BPs <140/90 mm Hg, <130/85 mm Hg, and <120/80 mm Hg were secondary endpoints.[1,2]

- 26 patients (15.4%) achieved BP normalization of <120/80 mm Hg and exited the study and last observation was carried forward; these patients are included in the 70% who reached goal[1]

Benicar® TABLETS
(olmesartan medoxomil)

BenicarHCT® TABLETS
(olmesartan medoxomil • hydrochlorothiazide)

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BENICAR and BENICAR HCT Important Safety Information

WARNING: FETAL TOXICITY
- **When pregnancy is detected, discontinue BENICAR or BENICAR HCT as soon as possible**
- **Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. See WARNINGS AND PRECAUTIONS: Fetal Toxicity**

Please see the following Important Safety Information for BENICAR:

Morbidity in Infants
Children <1 year of age must not receive BENICAR for hypertension. Drugs that act directly on the renin-angiotensin-aldosterone system (RAAS) can have effects on the development of immature kidneys.

Please see the following Important Safety Information for BENICAR and BENICAR HCT:

Contraindication
Do not co-administer aliskiren with BENICAR or BENICAR HCT in patients with diabetes.

Fetal Toxicity
Pregnancy Category D
Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue BENICAR or BENICAR HCT as soon as possible.

Hypotension in Volume- or Salt-Depleted Patients
In patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients (eg, those being treated with high doses of diuretics), symptomatic hypotension may occur after initiation of treatment with BENICAR or BENICAR HCT. Treatment should start under close medical supervision.

Impaired Renal Function
In studies of ACE inhibitors in patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen (BUN) have been reported. There has been no long-term use of olmesartan medoxomil in patients with unilateral or bilateral renal artery stenosis, but similar results may be expected.

Non-Steroidal Anti-Inflammatory Agents
In patients who are elderly, volume-depleted (including those on diuretics), or with compromised renal function, co-administration of olmesartan medoxomil and NSAIDs, including COX-2 inhibitors, may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically in these patients. The antihypertensive effect of olmesartan medoxomil may be attenuated by NSAIDs, including COX-2 inhibitors.

Dual Blockade of the Renin-Angiotensin System (RAS)
Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. Closely monitor blood pressure, renal function and electrolytes in patients on BENICAR or BENICAR HCT and other agents that affect the RAS.

Avoid use of aliskiren with BENICAR or BENICAR HCT in patients with renal impairment (GFR <60 mL/min).

Nursing Mothers
Avoid use while nursing; discontinue either nursing or the drug.

Due to the hydrochlorothiazide component, BENICAR HCT has the following Important Safety Information:

Contraindications
BENICAR HCT is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

Fetal/Neonatal Morbidity and Mortality
Thiazides cross the placental barrier and appear in cord blood. There is a risk of fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions that have occurred in adults.

Impaired Renal Function
BENICAR HCT is not recommended in patients with severe renal impairment.

Thiazides may precipitate azotemia in patients with renal disease. Cumulative effects of the drug may develop in patients with impaired renal function.

Hepatic Impairment
Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Electrolyte and Metabolic Imbalances
Due to the hydrochlorothiazide component, observe patients for clinical signs of fluid or electrolyte imbalance.

Hypersensitivity Reaction
Hypersensitivity reactions to hydrochlorothiazide may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such a history.

Systemic Lupus Erythematosus
Thiazide diuretics have been reported to cause exacerbation or activation of systemic lupus erythematosus.

Acute Myopia and Secondary Angle-Closure Glaucoma
Thiazides can cause an idiosyncratic reaction, resulting in acute transient myopia and acute angle-closure glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Discontinue hydrochlorothiazide as rapidly as possible in these patients. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy.

Lithium Interaction
Lithium generally should not be given with thiazides.

Adverse Reactions
- The withdrawal rates due to adverse events (AEs) were similar with BENICAR and BENICAR HCT to placebo: BENICAR (2.4% vs 2.7%); BENICAR HCT (2.0% vs 2.0%)
- The incidence of AEs with BENICAR and BENICAR HCT was similar to placebo
  - — The only AE that occurred in >1% of patients treated with BENICAR and more frequently than placebo was dizziness (3% vs 1%)
  - — AEs reported in >2% of patients taking BENICAR HCT and more frequently than placebo included nausea (3% vs 0%), hyperuricemia (4% vs 2%), dizziness (9% vs 2%), and upper respiratory tract infection (7% vs 0%)

Dosing and Administration
- No initial dosage adjustments are recommended with BENICAR in elderly or in moderate to marked renal impairment (creatinine clearance <40 mL/min)/hepatic dysfunction
  - — In patients with possible depletion of intravascular volume (eg, patients on diuretics, particularly with impaired renal function), BENICAR should be initiated under close medical supervision and consideration given to use of a lower starting dose
- BENICAR HCT is not indicated for initial therapy. Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range

Please see Full Prescribing Information for BENICAR and BENICAR HCT.

References: 1. Izzo JL Jr, Neutel JM, Silfani T, Dubiel R, Walker F. Efficacy and safety of treating stage 2 systolic hypertension with olmesartan and olmesartan/HCTZ: results of an open-label titration study. *J Clin Hypertens (Greenwich).* 2007;9:36-44. **2.** Data on file. Daiichi Sankyo, Inc., Parsippany, NJ.

Benicar® TABLETS (olmesartan medoxomil)

BenicarHCT® TABLETS (olmesartan medoxomil • hydrochlorothiazide)