Camlopril®

Amlodipine + Benazepril HCl

Presentation:
Camlopril® 2.5/10- Each capsule contains Amlodipine Besilate BP equivalent to Amlodipine 2.5 mg + Benazepril HCl USP 10 mg.
Camlopril® 5/10- Each capsule contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg + Benazepril HCl USP 10 mg.
Camlopril® 5/20- Each capsule contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg + Benazepril HCl USP 20 mg.
Camlopril® 10/20- Each capsule contains Amlodipine Besilate BP equivalent to Amlodipine 10 mg + Benazepril HCl USP 20 mg.

Description:
Camlopril® is a fixed combination of a Calcium Channel Blocker and an ACE inhibitor leads to additive synergy of the antihypertensive effects of the two constituents. Its pharmacological are derived from those of each of the two components taken separately.
Benazepril and benazeprilat inhibit angiotensin-converting enzyme (ACE) in human subjects and in animals. ACE is a peptidyl dipeptidase that catalyzes the conversion of angiotensin I to the vasoconstrictor substance angiotensin II. Angiotensin II also stimulates aldosterone secretion by the adrenal cortex. Inhibition of ACE results in decreased plasma angiotensin II, which leads to decreased vasopressor activity and to decreased aldosterone secretion. The latter decrease may result in a small increase of serum potassium. Amlodipine is a dihydropyridine calcium antagonist (calcium ion antagonist or slow channel blocker) that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

Indications and Uses:
Hypertension

Dosage & Administration:
Amlodipine is an effective treatment of hypertension in once-daily doses of 2.5-10 mg while benazepril is effective in doses of 10-80 mg. In clinical trials of amlodipine/benazepril combination therapy using amlodipine doses of 2.5-5 mg and benazepril doses of 10-20 mg, the antihypertensive effects increased with increasing dose of amlodipine in all patient groups, and the effects increased with increasing dose of benazepril in non black groups.

Contraindications:
This combination is contraindicated in patients who are hypersensitive to benazepril, to any other ACE inhibitor, or to amlodipine.

Side Effects:
The reported side effects were generally mild and transient, and there was no relationship between side effects and age, sex, race, or duration of therapy. Discontinuation of therapy due to side effects was required in approximately 4% of patients treated with this combination and in 3% of patients treated with placebo. The most common reasons for discontinuation of therapy with this combination were cough and edema. Body as a Whole: Asthenia and fatigue. CNS: Insomnia, nervousness, anxiety, tremor, and decreased libido. Dermatologic: Flushing, hot flashes, rash, skin nodule, and dermatitis. Digestive: Dry mouth, nausea, abdominal pain, constipation, diarrhea, dyspepsia, and esophagitis. Metabolic and Nutritional: Hypokalemia. Musculoskeletal: Back pain, musculoskeletal pain, cramps, and muscle cramps. Respiratory: Pharyngitis. Urogenital: Sexual problems such as impotence, and polyuria.

Precautions:
Impaired Renal Function: This combination should be used with caution in patients with severe renal disease. When the renin-angiotensin-aldosterone system is inhibited by benazepril, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure, whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with ACE inhibitors (including benazepril) may be associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Patients With Congestive Heart Failure: Although hemodynamic studies and a controlled trial in patients with NYHA Class II-III heart failure have shown that amlodipine did not lead to clinical deterioration as measured by exercise tolerance, left ventricular ejection fraction, and clinical symptomatology, studies have not been performed in patients with NYHA Class IV heart failure. In general, all calcium channel blockers should be used with caution in patients with heart failure.
Patients With Hepatic Failure: In patients with hepatic dysfunction due to cirrhosis, levels of benazeprilat are essentially unaltered. However, since amlodipine is extensively metabolized by the liver and the
plasma elimination half-life (t 1/2) is 56 hours in patients with impaired hepatic function, caution should be exercised when administering this combination to patients with severe hepatic impairment.

Drug Interaction:
Diuretics: Patients on diuretics, especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with this combination. The possibility of hypotensive effects with the combination can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with the combination.
Potassium Supplements and Potassium-Sparing Diuretics: Benazepril can attenuate potassium loss caused by thiazide diuretics.
Potassium-sparing diuretics (spironolactone, amiloride, triamterene, and others) or potassium supplements can increase the risk of
hyperkalemia. If concomitant use of such agents is indicated, they should be given with caution, and the patient's serum potassium should be monitored frequently.

Lithium: Increased serum lithium levels and symptoms of lithium toxicity have been reported in patients receiving ACE inhibitors during therapy with lithium. Amlodipine/Benazepril combination and lithium should be coadministered with caution, and frequent monitoring of serum lithium levels is recommended.
Other: Benazepril has been used concomitantly with oral anticoagulants, beta-adrenergic-blocking agents, calcium-blocking agents, cimetidine, diuretics, digoxin, hydralazine, and naproxen without evidence of clinically important adverse interactions.

Use in Pregnancy and Lactation:
Pregnancy Categories C (first trimester) and D (second and third trimesters).

Nursing Mothers:
Minimal amounts of unchanged benazepril and of benazeprilat are excreted into the breast milk of lactating women treated with benazepril, so that a newborn child ingesting nothing but breast milk would receive less than 0.1% of the maternal doses of benazepril and benazeprilat. It is not known whether amlodipine is excreted in human milk. In the absence of this information, it is recommended that nursing be discontinued while this combination is administered.

Use in Pediatric patients:
The safety and effectiveness in pediatric patients have not been established.

Storage Condition:
Store in a cool and dry place, protected from light and moisture.

Package Quantities:
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