LOSARTAN POTASSIUM + AMLODIPINE BESILATE

Rx

CODILAVASC

50 mg/ 5 mg Film-Coated Tablet
Angiotensin II Receptor Blocker/
Calcium Channel Blocker

FORMULATION:
Each film-coated tablet contains:
Losartan potassium .....50 mg
Amlodipine (as Besilate) .....5 mg

INDICATIONS:
Losartan potassium /Amlodipine besilate is indicated for the treatment of hypertension, angina pectoris & mild to moderate hypertension, alone or in combination with other antihypertensives.

DOSAGE AND ADMINISTRATION:
The usual starting and maintenance dose is one tablet once daily for most patients. The dose may be increase to 2 tablets once daily. A lower dose should be considered for patients with a history of hepatic impairment. Or as prescribed by the Physician.

PHARMACOLOGICAL CLASSIFICATION:
Vasodilators, hypotensive medicines.

PHARMACOKINETICS:
Absorption: Amlodipine: Plasma levels peak 6-12 hr after oral administration; absolute bioavailability is estimated to be 64- 90%. Losartan: Well absorbed; undergoes substantial 1st pass metabolism by CYP450 enzymes; systemic bioavailability is about 33%; about 14% of an oral dose is converted to active metabolites.
Distribution: Amlodipine: 93% bound to plasma proteins. Losartan and its active metabolites: Highly bound to plasma proteins, mainly albumin.
Metabolism: Amlodipine: About 90% converted to inactive metabolites hepatically. Losartan is metabolised to an active carboxylic acid metabolite E-3174 (EXP-3174), which has greater pharmacological activity than losartan; some inactive metabolites are also formed.
Excretion: Amlodipine: 10% of parent compound and 60% of the metabolites are removed in the urine; elimination from the plasma is biphasic with terminal half-life of about 30-50 hr. Losartan and its active metabolites: Biliary excretion; terminal half-life: About 2 hr (Losartan) and 6-9 hr (metabolites).

CONTRAINDICATIONS:
Losartan potassium /Amlodipine besilate during pregnancy and lactation is contraindicated Safety and efficacy has not been established in children. Hypersensitivity to any of the ingredients & dihydropyridines.

WARNINGS & PRECAUTION:
Losartan potassium /Amlodipine besilate is contraindicated in pregnancy and should be used with care, if at all, during breast-feeding. Losartan potassium /Amlodipine besilate (LOSASTAL-A) should be used with caution in patients with bilateral renal artery stenosis or stenosis of an artery to a single kidney, aortic valve stenosis, and hypertrophic obstructive cardiomyopathy. Symptomatic hypotension may occur after initiation of Losartan potassium /Amlodipine besilate (LOSASTAL-A). Reduced doses must be considered in patients with hepatic impairment.

Use in the Elderly:
Elderly patients should start Losartan potassium /Amlodipine besilate (LOSASTAL-A) therapy at a lower dose.

Use in Renal Failure:
Severe renal impairment may however require a dosage reduction. Amlodipine is not dialysable.

Use in Impaired Hepatic Function:
Losartan potassium /Amlodipine besilate (LOSASTAL-A) should be administered at lower doses in these patients.

Use in Children:
Safety and efficacy has not been established.

Use in Heart Failure:
Losartan potassium /Amlodipine besilate (LOSASTAL-A) may increase in patients with heart failure.

Porphyria:
Safety has not been established.

INTERACTIONS:
Non-steroidal anti-inflammatory drugs (NSAIDs) may antagonist the antihypertensive effect. Concurrent use with sympathomimetics may reduce the antihypertensive effect Potassium-sparing diuretics: may lead to elevation of serum potassium. Concurrent administration of sublingual nitroglycerin, long-acting nitrates, beta-blockers or other antianginal agents with amlodipine may produce additive antihypertensive and antianginal effects.

ADVERSE EFFECTS:
Most Common: edema, dizziness, flushing, and palpitation.
Common: fatigue, nausea, abdominal pain, somnolence.
Other Adverse Effects:
Cardiovascular: arrhythmia (including ventricular tachycardia and atrial fibrillation), bradycardia, chest pain, peripheral ischemia, syncope, tachycardia, vasculitis.
Central and Peripheral Nervous System: hypoesthesia, neuropathy peripheral, paresthesia, tremor vertigo.
Gastrointestinal: anorexia, constipation, dysphagia, diarrhea, flatulence, pancreatitis, vomiting, gingival hyperplasia.
General: allergic reaction, asthenia, 1 back pain, hot flushes, malaise, pain, rigors, weight decrease.
Musculoskeletal System: arthralgia, arthritis, muscle cramps, myalgia.
Psychiatric: sexual dysfunction (male and female), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization.
Respiratory System: dyspnea, epistaxis.
Skin and Appendages: angioedema, erythema multiforme, pruritus, rash, rash erythematous, rash maculopapular.
Special Senses: abnormal vision, conjunctivitis, diplopia, eye pain, tinnitus.
Urinary System: micturition frequency, micturition disorder, nocturia.
Autonomic Nervous System: dry mouth, sweating increased.
Metabolic and Nutritional: hyperglycemia, thirst.
Hematopoietic: leukopenia, purpura, thrombocytopenia.

OVERDOSAGE:
Hypotension, tachycardia, Bradycardia could occur from parasympathetic (vagal) stimulation. Neither Losartan potassium /Amlodipine besilate (LOSASTAL-A) nor the active metabolite can be removed by haemodialysis.
Gastric lavage may be of benefit. Intravenous calcium gluconate may be of benefit in reversing the effects of calcium channel blockade.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

AVAILABILITY:
Alu/ Clear PVC Blister Pack of 10's (Box of 100's)

Primera

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