LOSARTAN POTASSIUM

ARTOSAR 50

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50 mg Film-Coated Tablet
Angiotensin-2-Receptor Blocker

FORMULATION:
Each Film-Coated Tablet contains:
Losartan Potassium USP ..... 50 mg

PRODUCT DESCRIPTION:
Brick Red coloured, circular, biconvex, film coated, plain tablets.

PHARMACOKINETICS: Losartan increases uric acid excretion.
Pharmacokinetics: bioavailability is 25-35%: mean peak concentrations of losartan and is active metabolite are reached in 1 h and 3-4h, respectively. Losartan is metabolized into E3174 9=(an active carboxylic acid metabolite which is 10-40x more potent) by CYP2C9 and CYP3AS. Half-life of losartan is 1.52h and fat of £3174 i 4-9 h both are highly protein bound. Volume of distribution of losartan is 34L while that of E3174 5 12. Effect of food is negligible.
INDICATION: It is used in the management of hypertension, diabetic nephropathy and in myocardial infarction
DOSAGE AND ADMINISTRATION: In hypertension the usual dose of losartan potassium is 50 mg once daily. The dose may be increased, if necessary, to 100 mgdally as a single dose or in two divided doses. An initial dose of 25 mg once daily should be given to pallets with intravascular fluiddepletion. In diabetic nephropathy losartan potassium is givenin an initial dose of 50 mg daily, increased to 100 mg once dailydepending on the blood pressure. Or as prescribed by thephysician.
DRUG INTERACTION: The antihypertensive effects of losartan may be potentiated by drugs or other agents that lower blood pressure. An additive hyperkalaemia effect is possible with potassium supplements, potassium-sparing diuretics, or other drugs that can cause hyperkalaemia; losartan and potassium sparing diuretics should not generally be given together. NSAIDs should be used with caution patients taking losartan as the risk of renal impairment may be increased, particularly in those who are inadequately hydrated. Use of NSAIDs may also attenuate the hypotensive of losartan. Losartan and some other angiotensin II receptor antagonists are metabolized by cyctochrome P450 isoenzymes and interactions may occur with drugs that effect these enzymes.
ADVERSE EFFECTS: Adverse effects of losartan have been reported to be usually mild and transient, and include dizziness, headache, and dose- related orthostatic hypotension. Hypotension may occur particularly in patients with volume depletion (for example those who have received high-dose diuretic). Impaired renal function and, rarely, rash urticaria pruritus angioedema, and raised liver enzyme values, may occur. Hyperkalaemia, myalgia, and arthralgia have been reported. Losartan appears less likely than ACE inhibitors to cause cough. Other adverse effects that have been reported with angiotensin II receptor antagonists include respiratory-tract disorders, back pain, gastrointestinal disturbances, fatigue, and neutropenia. Rhabdomyolysis has been reported rarely. The following less common adverse reactions have been reported during clinical trials:
Blood and lymphatic system disorders: Anemia.
Psychiatric disorders: Depression.
Nervous system disorders: Somnolence, headache, sleep disorders, paresthesia, migraine.
Ear and labyrinth disorders: Vertigo, tinnitus.
Cardiac disorders: Palpitations, syncope, atrial fibrillation, CVA.
Respiratory, thoracic and mediastinal disorders: Dyspnea.
Gastrointestinal disorders: Abdominal pain, constipation, nausea, vomiting.
Skin and subcutaneous tissue disorders: Urticaria, pruritus, rash, photosensitivity.
Musculoskeletal and connective tissue disorders: Myalgia, arthralgia.
Reproductive system and breast disorders: Impotence.
General disorders and administration site conditions: Edema.
Cough: Persistent dry cough (with an incidence of a few percent) has been associated with ACE-inhibitor use and in practice can be a cause of discontinuation of ACE-inhibitor therapy.

The following less common adverse reactions have been reported during clinical trials:

Digestive: Hepatitis.
General Disorders and Administration Site Conditions: Malaise.
Hematologic: Thrombocytopenia.
Hypersensitivity: Angioedema, including swelling of the larynx and glottis, causing airway obstruction and/or swelling of the face, lips, pharynx, and/or tongue has been reported rarely in patients treated with losartan; some of these patients previously experienced angioedema with other drugs including ACE inhibitors. Vasculitis, including Henoch-Schönlein purpura, has been reported. Anaphylactic reactions have been reported.
Metabolic and Nutrition: Hyponatremia.
Musculoskeletal: Rhabdomyolysis.
Nervous system disorders: Dysgeusia.
Skin: Erythroderma.

REPORTING OF SUSPECTED ADVERSE REACTIONS: To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

PRECAUTIONS: Losartan is contraindicated in pregnancy. It should be used with caution in patients with renal artery stenosis. Losartan is excreted in urine and in bile hence reduced doses may therefore be required in patients with renal impairment and should be considered in patients with hepatic impairment. Patients with volume depletion (for example those who have received high-dose diuretic therapy) may experience hypotension; volume depletion should be corrected before starting therapy or a low initial dose should be used. Since hyperkalaemia may occur, serum potassium concentration should be monitored in the elderly and patients with renal impairment, and potassium-sparing diuretics should generally be avoided.

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

STORAGE CONDITION: Store at temperatures not exceeding 30°C.

AVAILABILITY: Alu-Alu Blister Pack x 10's (Box of 30's, 50's and 100's)

FDA Registration Number: DR-XY43661

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