LOSARTAN POTASSIUM

MYSARTAN

Rx 50 mg Film-Coated Tablet
Angiotensin-II-Receptor
Blocker (ARB)

FORMULATION:
Each film-coated tablet contains:
Losartan Potassium USP.....50 mg

PRODUCT DESCRIPTION:
Pink-coloured heart-shaped, biconvex film-coated tablets.

PHARMACODYNAMIC PROPERTIES:
Losartan is a synthetic oral angiotensin-II receptor (type AT1) antagonist. Angiotensin II, a potent vasoconstrictor, is the primary active hormone of the renin/angiotensin system and an important determinant of the pathophysiology of hypertension. Angiotensin II binds to the AT1 receptor found in many tissues (e.g. vascular smooth muscle, adrenal gland, kidneys and the heart) and elicits several important biological actions, including vasoconstriction and the release of aldosterone. Angiotensin II also stimulates smooth muscle cell proliferation.

PHARMACOKINETICS:
Losartan is readily absorbed from the gastrointestinal tract after oral doses, but undergoes substantial first pass metabolism resulting in a systematic bioavailability of about 33%. It is metabolized to an active carboxylic acid metabolite E-3174 (EXP-3174), which has greater pharmacological activity than Losartan; some inactive metabolites are also formed. Metabolism is primarily by cytochrome P450 isoenzymes CYP2C9 and CYP3A4. Peak plasma concentrations of Losartan and E-3174 occur about 1 hour and 3 to 4 hours, respectively, after morning oral dose. Both Losartan and E-3174 are more than 98% bound to plasma proteins. Losartan is excreted in the urine, and in the faeces via bile, as unchanged drug metabolites. About 4% of an oral dose is excreted unchanged in the urine and about 6% is excreted as active metabolite. The terminal elimination half-lives of Losartan and E-3174 are about 1.5 to 2.5 hours and 3 to 9 hours, respectively.

INDICATIONS:
Management of hypertension and treatment of diabetic nephropathy.

DOSAGE AND ADMINISTRATION:
Adult Hypertension: The usual dose is 50 mg once daily. The dose may be increased if necessary to 100 mg daily as a single dose or in two divided doses. An initial dose of 25 mg once daily should be given to patients with intravascular fluid depletion.

Heart Failure: The initial dose for patients with heart failure is 2.5 mg once a day. The dose may be increased by 1.25 mg at week's interval to the usual maintenance dose of 50 mg once a day or as the patient can tolerate. Or as prescribed by the physician.

CONTRAINDICATIONS:
Losartan is contraindicated in patients with known hypersensitivity to it or any of its excipients.

WARNINGS AND PRECAUTIONS:
Losartan is contraindicated in pregnancy. It should be discontinued when pregnancy is diagnosed. It should be used with caution in patients with renal artery stenosis. Losartan is excreted in urine and in bile and reduced doses may therefore be required in patients with renal impairment and should be considered in patients with hepatic impairment. Patients with volume depletion (e.g. 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 hyperkalemia may occur, serum potassium concentrations should be monitored, especially in the elderly patients with renal impairment, and the concomitant use of potassium sparing diuretics should generally be avoided. Losartan should be used with caution in diabetic with reduced awareness of hypoglycemia.

PREGNANCY AND LACTATION:
Pregnancy
The use of losartan is not recommended during the first trimester of pregnancy. The use of losartan is contraindicated during the 2nd and 3rd trimester of pregnancy.
When pregnancy is diagnosed, treatment with losartan should be stopped immediately and, if appropriate, alternative therapy should be started.
Breastfeeding
Because no information is available regarding the use of losartan during breastfeeding, losartan is not recommended and alternative treatments with better established safety profiles during breastfeeding are preferable, especially while nursing a new-born or preterm infant.

ADVERSE DRUG REACTIONS:
Post-Marketing Experience
The following additional adverse reactions have been reported in post-marketing experience:

Digestive: Hepatitis (reported rarely)

General Disorders and Administration Site Conditions: Malaise

Hemic: Thrombocytopenia (reported rarely)

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: Hyperkalemia, hyponatremia have been reported with losartan. *Musculoskeletal:* Rare cases of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers.

Nervous system disorders: Dysgeusia

Respiratory: Dry cough

Skin: Erythroderma

DRUG INTERACTIONS:
Other antihypertensive agents may increase the hypotensive action of losartan. Concomitant use with other substances which may induce hypotension as an adverse reaction (like tricyclic antidepressants, antipsychotics, baclofen and amifostine) may increase the risk of hypotension.

OVERDOSE AND TREATMENT:
Limited data are available with regards to overdose in humans. The most likely manifestation of overdose would be hypotension and tachycardia. Bradycardia could occur from parasympathetic (vagal) stimulation.
Treatment of Intoxication
If symptomatic hypotension should occur, supportive treatment should be instituted.
After oral intake, the administration of a sufficient dose of activated charcoal is indicated. Afterwards, close monitoring of the vital parameters should be performed. Vital parameters should be corrected if necessary.
Neither losartan nor the active metabolite can be removed by hemodialysis

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

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

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

KEEP OUT OF REACH OF CHILDREN.

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

DRP-2591-03

Date of First Authorization: July 26, 2011
Date of Revision of Package Insert: November 09, 2021

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