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LOSARTAN POTASSIUM

50 mg Film-Coated Tablet
ANGIOTENSIN II RECEPTOR BLOCKER

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FORMULATION:
Each film-coated tablet contains:
Losartan Potassium ..... 50 mg
Excipients.....q.s.

PRODUCT DESCRIPTION:
A green colour round shaped biconvex film-coated tablet plain on both sides.

PHARMACOLOGICAL CLASSIFICATION:
Losartan is a non-peptide angiotensin II receptor antagonist with high affinity and selectivity for the At1 receptor, without binding to or blocking other hormone receptors or ion channels important in cardiovascular regulation. Angiotensin II is a potent vasoconstrictor, a primary active hormone of the renin-angiotensin system and a major determinant of the pathophysiology of hypertension. Losartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by inhibiting the binding of angiotensin II to the At1 receptor.

PHARMACODYNAMICS:
Losartan inhibits the pressor effect of angiotensin II (as well as angiotensin I) infusions. A dose of 100 mg inhibits the pressor effect by about 85% at peak with 25-40% inhibition persisting for 24 hours. Removal of the negative feedback of angiotensin II causes a doubling to tripling in plasma renin activity and consequent rise in angiotensin II plasma concentration in hypertensive patients. Losartan does not affect the response to bradykinin, whereas ACE inhibitors increase the response to bradykinin. Aldosterone plasma concentrations fall following Losartan administration. In spite of the effect of Losartan on aldosterone secretion, very little effect on serum potassium was observed.

The effect of Losartan is substantially present within one week but in some studies the maximal effect occurred in 3-6 weeks. In long-term follow-up studies (without placebo control) the effect of Losartan appeared to be maintained for up to a year. There is no apparent rebound effect after abrupt withdrawal of Losartan. There was essentially no change in average heart rate in Losartan-treated patients in controlled trials.

PHARMACOKINETICS:
Losartan is readily absorbed from the gastrointestinal tract after oral dose, but undergoes substantial first-pass metabolism resulting in a systemic bioavailability of about 33%. It is metabolised to an active carboxylic acid metabolite E-3174 (EXP-3174), which has greater pharmacological activity than Losartan; some inactive metabolized 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 an 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 and metabolites. About 4% of an oral dose is excreted unchanged in urine and about 6% is excreted in urine as the 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:
Used in the management of hypertension particularly in patients who develop cough with ACE inhibitors, for the treatment of diabetic nephropathy.

DOSAGE AND ADMINISTRATION:
The usual starting and maintenance dose is 50 mg once daily for most patients.
The maximum anti-hypertensive effect is achieved 3-6 weeks after initiation of therapy. The dose may be increased to 100 mg once daily. For patients with intravascular volume-depletion (e.g., those treated with high-dose diuretics), a starting dose of 25 mg once daily should be considered. No initial dosage adjustment is necessary for the elderly patients or for patients with renal impairment, including patients on dialysis. A lower dose should be considered for patients with a history of hepatic impairment.
Losartan potassium may be administered with other anti-hypertensive agents of a different class. Losartan potassium may be administered with or without food. Or as prescribed by the physician.

CONTRAINDICATIONS:
Patients who are hypersensitive to any component of this product. The use of Losartan potassium during pregnancy and lactation is contraindicated. Losartan potassium should be discontinued as soon as possible when pregnancy is suspected. Safety and efficacy has not been established in children.

DRUG INTERACTIONS:
Non-steroidal anti-inflammatory drugs (NSAIDs) may antagonise the anti-hypertensive effect of Losartan potassium.
Concurrent use with sympathomimetics may reduce the anti-hypertensive effects of Losartan potassium.
Potassium-sparing diuretics, potassium containing medication or potassium supplements used concurrently with Losartan potassium may result in hyperkalemia since reduction of aldosterone production induced by Losartan potassium may lead to elevation of serum potassium.

WARNINGS:
Women of childbearing age should ensure adequate contraception. Losartan 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. Reduced doses must be considered in patients with hepatic impairment.

SPECIAL PRECAUTIONS:
Patients with volume-depletion (e.g., those treated with high-dose diuretics) may experience hypotension, which may be minimized by initiating treatment with a low dose of Losartan potassium. Having of the dose should be considered for patients with a history of hepatic impairment.
Since hyperkalemia may occur, serum-potassium concentrations should be monitored, especially in the elderly and patients with renal impairment and the concomitant use of potassium-sparing diuretics should generally be avoided.

Back

When impaired renal function is present, changes in renal function as a consequence of inhibiting the renin-angiotensin system including renal failure have been reported in susceptible individuals. These changes in renal function may be reversible upon discontinuation of Losartan potassium therapy, in some patients.
In patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system (e.g., patients with severe congestive heart failure), treatment with angiotensin converting enzyme inhibitors has been associated with oliguria and/or progressive azothemia and (less frequently) with acute renal failure and/or death. Similar outcomes are likely with Losartan potassium therapy.
Agents affecting the renin-angiotensin system may increase blood urea and serum creatinine in patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney. These changes in renal function may be reversible upon discontinuation of Losartan potassium therapy.

ADVERSE DRUG REACTIONS:
Hypersensitivity: Angioedema (involving swelling of the face, lips, and/or tongue)
Gastrointestinal: Diarrhea, dyspepsia, nausea
Buccal: Taste disturbances, complete taste loss
Skin: Urticaria, rash, atypical cutaneous lymphoid infiltrates
Cardiovascular: Palpitation, tachycardia
The following side effects have been reported and frequencies are unknown:
Hypotension, Myalgia, Cholestasis, Neutropenia, Impaired renal function
Musculoskeletal: Back pain, muscle cramps, leg pain
Nervous/Psychiatric: Headache, dizziness, insomnia, migraine
Respiratory: Cough, nasal congestion, pharyngitis, sinus disorder, upper respiratory infection
Hepatic: Raised liver enzymes values, severe acute hepatotoxicity
Haematological: Symptomatic anaemia, decreased haemoglobin concentrations
Pancreatic: Acute pancreatitis
Body as a Whole: Abdominal pain, asthenia/fatigue, chest pain, fatigue and edema/swelling

PREGNANCY AND LACTATION:
Pregnancy: Losartan potassium should be discontinued as soon as possible, when pregnancy is suspected. Losartan potassium should not be used in pregnancy as teratogenicity has been shown in experimental animals.
Lactation: Safety has not been established.

OVERDOSE AND TREATMENT:
The symptoms of an overdosage of Losartan potassium would be hypotension and tachycardia. Bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted.
Neither Losartan potassium nor the active metabolite can be removed by haemodialysis.

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.

Keep all medicines out of reach of children.

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

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Manufactured by:
STALLION LABORATORIES PVT. LTD.
C-1B, 305/2, 3, 4, & 5, G.I.D.C., Kerala,
Bavla-382 220, Dist. Ahmedabad, Gujarat, India

Imported by:
AMBICA INTERNATIONAL CORPORATION
No.9 Amsterdam Extension, Merville Park Subd.,
Parañaque, Metro Manila

Distributed by:
DIAFARM INC.
3270-C Armstrong Rd., Kalayaan,
Brgy. 201, Pasay, Metro Manila