SPMC
LOSARTAN POTASSIUM TABLETS BP 50 mg

PRESENTATION:

Losartan potassium Tablets BP 50 mg

Packs: 500 tablets Bulk & 10X20 tablets Blister

Orange colored 8.0 mm tablets with "SPMC" letters on one side & score mark on other side. Each Losartan potassium 50 mg Tablet contains 50 mg of losartan (as potassium salt).

INDICATIONS AND DOSE:

Diabetic nephropathy in type 2 diabetes mellitus

Adult 18–75 years: Initially 50 mg once daily for several weeks, then increased if necessary, to 100 mg once daily
Adult 76 years and over: Initially 25 mg once daily for several weeks, then increased if necessary, to 100 mg once daily.

Chronic heart failure when ACE inhibitors are unsuitable or contra-indicated

Adult: Initially 12.5 mg once daily, increased if tolerated to up to 150 mg once daily, doses to be increased at weekly intervals.

Hypertension (including reduction of stroke risk in hypertension with left ventricular hypertrophy)

Adult 18–75 years: Initially 50 mg once daily for several weeks, then increased if necessary, to 100 mg once daily
Adult 76 years and over: Initially 25 mg once daily for several weeks, then increased if necessary, to 100 mg once daily.

Hypertension with intravascular volume depletion

Adult 18–75 years: Initially 25 mg once daily for several weeks, then increased if necessary, up to 100 mg once daily

SIDE EFFECT:

Common or very common Anaemia. hypoglycaemia
Uncommon Angina pectoris. constipation. drowsiness. dyspnoea. oedema. palpitations. sleep disorder
Rare or very rare Angioedema. atrial fibrillation. hepatitis hypersensitivity. paranesthesia. stroke. syncope. vasculitis
Frequency not known Depression. erectile dysfunction. hyponatremia. increased risk of infection. influenza like illness. malaise. migraine. pancreatitis. photosensitivity reaction. rhabdomyolysis. taste altered. Tinnitus.

CAUTION:

Severe heart failure

SPECIAL PRECAUTION:

Patient with history of angioedema, volume- and/or Na-depletion, heart failure, unstented unilateral/bilateral renal artery stenosis, aortic or mitral stenosis, cirrhosis. Black race. Renal impairment and mild to moderate hepatic impairment. Children and elderly. Lactation.

INTERACTIONS:

May potentiate hypotensive effect with other antihypertensive agents. May increase risk of hypotension as an adverse reaction of antipsychotics and amifostine. Decreased plasma concentration with rifampicin and fluconazole. Increased serum K levels and enhance hyperkalaemic effect with K-sparing diuretics (e.g. amiloride, spironolactone), K supplements or K-containing salt substitutes (e.g. heparin). May increase serum lithium concentrations and toxicity. May increase risk of renal impairment and may decrease hypotensive effect with NSAIDs. **Potentially Fatal:** Increased risk of hypotension, hyperkalaemia, and nephrotoxicity with ACE-inhibitors or aliskiren.

PREGNANCY:

Angiotensin-II receptor antagonists should be avoided in pregnancy unless essential. They may adversely affect fetal and neonatal blood pressure control and renal function; neonatal skull defects and oligohydramnios has also been reported.
Pregnancy Category (US FDA)- PO: D

BREAST FEEDING:

Information on the use of angiotensin-II receptor antagonists in breast-feeding is limited. They are not recommended in breast-feeding and alternative treatment options, with better established safety information during breast-feeding, are available.

HEPATIC IMPAIRMENT:

Advises avoid in severe impairment—no information available. Dose adjustments Consider dose reduction in mild to moderate impairment. Mild to moderate: Initially, 25 mg daily. Severe: Contraindicated.

CONTRA INDICATION:

Patients with hypersensitivity to any component of Losartan potassium. Concomitant use with aliskiren-containing products in patients with diabetes mellitus or renal impairment (GFR <60 mL/min). Severe hepatic impairment. Pregnancy (2nd-3rd trimester).

PATIENT COUNSELING INFORMATION:

This drug may occasionally cause dizziness or drowsiness, if affected, do not drive or operate machinery.

OVERDOSAGE:

Symptoms: Hypotension, tachycardia, bradycardia (may occur from parasympathetic stimulation).
Management: Supportive and symptomatic treatment. Prioritise stabilisation of CVS. Administration of activated charcoal and close monitoring of vital parameters may be performed. Correct vital parameters, as necessary.

STORAGE:

Bulk

Keep tightly closed in a cool dry place. Protect from light. Store below 30^0 C

Blister.

Keep the product in the outer package, in order to protect from light. Store below 30^0C

Keep all medicines away from children

Manufactured by
State Pharmaceuticals Manufacturing Corporation
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Ratmalana, Sri Lanka.