LOSIUM

LOSARTAN POTASSIUM USP

Compositions:
Losium 25 Tablet: Each tablet contains Losartan Potassium USP 25 mg. Losium 50 Tablet: Each tablet contains Losartan Potassium USP 50 mg.

Pharmacology:
Losartan Potassium is an angiotensin II receptor (type AT1) antagonist. Angiotensin II is a potent vasoconstrictor, the primary vasoactive hormone of therein-angiotensin system. Losartan potassium and its principal active metabolite block the vasoconstriction and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT receptor found in many tissues. Losartan Potassium is now regarded as the first-line therapy option for treating high blood pressure.

Dosage And Administration:
The usual starting dose of Losium is 50 mg once daily, with 25 mg used in patients with possible depletion of intravascular volume (e.g. patients treated with diuretics), and patients with a history of hepatic impairment. Losium can be administered once or twice daily with total daily doses ranging from 25 to 100 mg. If the antihypertensive effect measured using once-a-day dosing is inadequate, a twice-a-day regimen at the same total daily dose or an increase in dose may give a more satisfactory response. If blood pressure is not controlled by Losium alone, a low dose of a diuretic may be added. No initial dosage adjustment is necessary for elderly patients or for patients with renal impairment, including patients on dialysis. Losium may be administered with or without food.

Contraindications:
Losartan potassium is contraindicated in patients who are hypersensitive to the active ingredient or any component of the drug.

Warning And Precaution:
Losium should be used with caution in patients with known hypersensitivity to drugs that act through renin-angiotensin system. A lower dose should be considered when it is administered to the patients with hepatic impairment. Safety and effectiveness of Losium in paediatric patients have not been established.

Side Effects:
In general, treatment with Losium was well tolerated. The overall incidence of adverse effects reported with Losartan potassium was similar to placebo. The most common adverse events occurring with Losartan potassium were respiratory infection, dizziness and leg pain.

Use in Pregnancy and Lactation:
Losium is contraindicated in pregnancy. It should not be prescribed during lactation, as there is no information on excretion through breast milk.

Drug Interaction:
Rifampicin and fluconazole reduce levels of active metabolite of Losartan Potassium. Concomitant use of Losartan Potassium and hydrochlorothiazide may lead to potentiation of the antihypertensive effects. Concomitant use of potassium-sparing diuretics (eg, spironolactone, triamterene, amiloride), potassium supplements or salt substitutes containing potassium may lead to increases in serum potassium. The antihypertensive effect of losartan may be attenuated by the non-steroidal anti-inflammatory drug indomethacin. The use of ACE-inhibitor, angiotensin receptor antagonist, an anti-inflammatory drug and a thiazide

diuretic at the same time increases the risk of renal impairment.

Overdosage:
Limited data are available in regard to overdosage in humans. The most likely manifestation of overdosage would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted. Neither losartan nor its active metabolite can be removed by hemodialysis.

Storage:
Store in a cool (15° - 30° C) and dry place protected from light and moisture. Keep out of the reach of children.

Packing:
Losium 25: Each box contains 3x10's Tablet in Blister Pack. Losium 50: Each box contains 3x10's Tablet in Blister Pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.