LOSIUM PLUS

LOSARTAN POTASSIUM USP + HYDROCHLOROTHIAZIDE BP

Compositions:
Losium Plus 50 Tablet: Each tablet contains Losartan Potassium USP 50 mg and Hydroclorothiazide 12.50 mg.

Pharmacology:
Losium Plus 50 is a preparation of Losartan potassium USP & Hydrochlorothiazide BP. Angiotensin II is a potent vasoconstrictor, the primary vasoactive hormone of the renin-angiotensin system and an important component in the pathophysiology of hypertension. It also stimulates aldosterone secretion by the adrenal cortex. Losartan and its principal active metabolite block the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to AT1 receptor found in many tissues (e.g. vascular smooth muscle, adrenal gland). The other component, hydrochlorothiazide, is a diuretic that reduces plasma volume, with consequent increases in plasma renin activity, increases in aldosterone secretion, increases in urinary potassium loss and decreases in serum potassium. The renin-aldosterone link is mediated by angiotensin II, so co-administration of angiotensin II receptor antagonists tends to reverse the potassium loss associated with these diuretics.

Dosage And Administration:
Adult: The usual starting dose is one tablet (50-12.5mg) per day. 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 daily dose may give a more satisfactory response. The maximum dose is two tablets per day. In general, the antihypertensive effect is attained within three weeks after initiation of therapy. To minimize side effects, it is usually appropriate to begin combination therapy only after a patient has failed to achieve the desired effect with monotherapy. It may be taken with/without food. Children: Not recommended Renal impairment: The usual regimens of therapy with Losium Plus 50 may be followed as long as the patient`s creatinine clearance is > 30 mL/min. In patients with more severe renal impairment, loop diuretics are preferred to thiazides, so Losium® Plus 50 is not recommended. Hepatic impairment: Not recommended.

Contraindications:
Hypersensitivity to Losartan potassium, Hydrochlorothiazide, anuria, pregnancy and lactation.

Warning And Precaution:
It can cause low blood pressure, especially if the patient is also taking another diuretic. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance - hyponatraemia, hypochloraemic alkalosis, hypomagnesaemia and hypokalaemia. Increase in cholesterol and triglyceride levels, decreased urinary calcium excretion may be associated with thiazide diuretic therapy. The antihypertensive effects of the drug may be enhanced in the post-sympathectomy patient. If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy. The patient may feel lightheaded or faint, especially during the first few days of therapy. If these symptoms occur, dosage may need to be adjusted or discontinued. It should be used with caution in liver or kidney disease, diabetes, asthma, gout.

Side Effects:
Generally this product is well tolerated. More common side effects include : Dizziness, upper respiratory infection. Less common side effects include : Abdominal pain, back pain, cough,

fluid retention and swelling, palpitations, sinus inflammation, skin rash.

Use in Pregnancy and Lactation:
Use in pregnancy & lactationPregnancy & Lactation: Not recommended. Renal impairment: The usual regimens of therapy with Losium Plus 50 may be followed as long as the patient`s creatinine clearance is > 30 mL/min. In patients with more severe renal impairment, loop diuretics are preferred to thiazides, so Losium® Plus 50 is not recommended. Hepatic impairment: Not recommended.

Drug Interaction:
Precaution should be taken while co-administration with the following drugs: Potassium sparing diuretics, potassium supplements, indomethacin, lithium, alcohol, barbiturates, narcotics, antidiabetic agents (oral agents and insulin), other antihypertensive drugs, cholestyramine and colestipol resins.

Overdosage:
Losartan potassium: Incidence of over dosage is rare. The possible symptoms include hypotension, tachycardia, bradycardia. Supportive treatment should be instituted. Neither Losartan nor its metabolite can be removed by hemodialysis. Hydrochlorothiazide: The most common signs and symptoms are those caused by electrolyte depletion and dehydration resulting from excessive diuresis.

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 Plus 50: Each Box contains 3 x 10`s tablet in Alu-PVC Blister strip.

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