گولیاں

لوٹینس-ایچ®

لوزارٹن پوٹاشیم یو.ایس.پی ۵۰ ملی گرام
ہائیڈروکلوروتھائیازائیڈ یو.ایس.پی ۱۲.۵ ملی گرام

دافع بلند فشارِ خون

خوراک:

لوٹینس-ایچ کی عمومی ابتدائی خوراک ایک گولی دن میں ایک مرتبہ اور بالائی خوراک دو گولیاں دن میں ایک مرتبہ جو کہ کھانے کے ساتھ یا کھانے کے بغیر بھی دی جاسکتی ہے۔

ہدایات:

- دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
- دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
- یہ دوا صرف ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
- تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیشکش:

لوٹینس-ایچ فلم کوٹڈ گولیاں (۲×۱۰) ایلو-ایلو پیک میں دستیاب ہیں۔

Manufactured by:
Schazoo Zaka (Pvt) Ltd.
Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

Tablets

Lotense-H®

Losartan Potassium U.S.P. **50 mg**
Hydrochlorothiazide U.S.P. **12.5 mg**

COMPOSITION:
Each film coated tablet contains:
Losartan Potassium U.S.P. ..... 50 mg
Hydrochlorothiazide U.S.P. ..... 12.5 mg

CLINICAL PHARMACOLOGY:
Lotense-H (Losartan potassium and Hydrochlorothiazide) is the first combination of an angiotensin II receptor (typeAT1) antagonist & a diuretic. 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 adrenal cortex. Losartan is a reversible competitive inhibitor of the AT1 receptor. Losartan and its principle active metabolite block the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor found in many tissues. There is also an AT_2 receptor found in many tissues but it is not known to be associated with cardiovascular homeostasis. Both Losartan and its principle active metabolite do not exhibit any partial agonist activity at the AT_1 receptor and have much greater affinity for the AT_1 receptor than for the AT_2 receptor. Hydrochlorothiazide is a thiazide diuretic. It decreases the plasma volume, with consequent increase in plasma renin activity, aldosterone secretion, urinary potassium loss and decrease in serum potassium. The renin-aldosterone link is mediated by angiotensin II receptor antagonist tends to reverse the potassium loss associated with these diuretics.

INDICATIONS:
Lotense-H is indicated for the treatment of hypertension in those patients to whom combination therapy is appropriate.

DOSAGE & ADMINISTRATION:
The usual starting and maintenance dose is one tablet once daily. The maximum dose is two tablets once daily. In general, the antihypertensive effect is attained within three weeks after initiation of therapy. Lotense-H should not be initiated in patients who are intravascularly volume- depleted (e.g, those treated with high-dose diuretics). **Lotense-H** is not recommended to patients with severe renal impairment (creatinine clearance ≤ 30ml / min) or to patients with hepatic impairment. No initial dosage adjustment is necessary for elderly patients. **Lotense-H** may be administered with other antihypertensive agents. **Lotense-H** may be administered with or without food.

CONTRA-INDICATIONS:
Lotense-H is contra-indicated in Patients
- With anuria.
- Hypersensitive to any component of this product.
- Hypersensitive to other sulfonamide-derived drugs.

PRECAUTIONS:
LOSARTAN POTASSIUM:
Hypersensitivity: Angioedema
Renal function impairment:
Changes in renal function including renal failure have been reported. In susceptible individuals; these changes in renal function may be reversible upon discontinuation of therapy.

Liver Function Impairment:
Based on pharmacokinetic data which demonstrate significantly increased plasma concentrations of Losartan in cirrhotic patients, a lower dose should be considered for patients with a history of hepatic impairment.

HYDROCHLOROTHIAZIDE:
Hypotension and electrolyte / fluid imbalance:
Patients should be observed for clinical signs of fluid or electrolyte imbalance, e.g. volume depletion, hyponatremia, hypochloremic alkalosis, hypomagnesemia or hypokalemia which may occur during intercurrent diarrhoea or vomiting. Periodic determination of serum electrolytes should be performed at appropriate intervals in such patients.

Metabolic and endocrine effects:
Thiazides may decrease urinary calcium excretion and may cause intermittent and slight elevation of serum calcium. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazide should be discontinued before carrying out tests for parathyroid function.
Increase in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.
Losartan in combination with hydrochlorothiazide attenuates the diuretic-induced hyperuricemia.

PREGNANCY:
When used during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death in the developing fetus. Hence when pregnancy is detected, **Lotense-H** should be discontinued as soon as possible.

NURSING MOTHERS:
Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug , taking into account the importance of the drug to the mother.

PEDIATRIC USE:
Safety and effectiveness in children have not been established.

USE IN ELDERLY PATIENTS:
There is no clinically significant differences in the efficacy and safety profiles of Losartan and Hydrochlorothiazide in older (=65years) and younger patients (< 65years).

DRUG INTERACTIONS:

LOSARTAN POTASSIUM:
No drug interactions of clinical significance with hydrochlorothiazide, digoxin, warfarin, cimetidine, phenobarbital, ketoconazole and erythromycin have been identified. Rifampin and fluconazole have been reported to reduce levels of active metabolite. The clinical consequences of these interactions have not been evaluated.
As with other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics [e.g., spironolactone, triamterene, amiloride], potassium supplements, or salt substitutes containing potassium may lead to increase in serum potassium concentration.
As with other antihypertensive agents, the antihypertensive effect of Losartan may be attenuated by the non-steroidal anti-inflammatory drug indomethacin.

HYDROCHLOROTHIAZIDE:
When given concurrently, the following drugs may interact with thiazide diuretics.
Alcohol, barbiturates, or narcotics-potentiated Drugs: Orthostatic hypotension may occur.
Antidiabetic drugs (oral agents and insulin): Dosage adjustment of the antidiabetic drugs may be required.
Corticosteroids, ACTH: Intensified electrolyte depletion, particularly hypokalemia.
Skeletal muscle relaxants, nondepolarizing(e.g., tubocurarine): Possible increased responsiveness to the muscle relaxant.
NSAIDS: In some patients, the administration of NSAIDS can reduce the diuretic, natriuretic and antihypertensive effects of diuretics.

SIDE EFFECTS:
Losartan has been found to be well tolerated. Side effects are usually mild and transient in nature which do not require discontinuation of therapy. Additional side effects are;

Hypersensitivity: Anaphylactic reactions, 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 patient treated with Losartan .
Gastrointestinal: Hepatitis (reported rarely), diarrhoea.
Hematologic: Anemia.
Musculoskeletal: Myalgia.
Nervous System / Psychiatric: Migraine.
Respiratory: Cough.
Skin: Urticaria, Pruritus.

OVERDOSAGE:
Limited data is available in regard to over dosage in humans. The most likely manifestation of over dosage would be hypotension and tachycardia: bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension occurs, supportive treatment should be instituted.
Neither Losartan nor the active metabolite can be removed by hemodialysis.

STORAGE CONDITIONS:
* Store in a cool and dry place.
* Protect from heat, light and moisture.
* Keep all medicines out of the reach of children.

PACKING:
Lotense-H film coated tablets are available in (2x10) Alu-Alu pack.