

Losartan Potassium USP & Hydrochlorothiazide BP

Composition

Losart[®] Plus 50/12.5 : Each film-coated tablet contains Losartan Potassium USP 50 mg and Hydrochlorothiazide BP 12.5 mg.

Losart[®] Plus 100/12.5 : Each film-coated tablet contains Losartan Potassium USP 100 mg and Hydrochlorothiazide BP 12.5 mg.

Pharmacology

Losart[®] Plus is a fixed-dose combination containing Losartan Potassium and Hydrochlorothiazide. Losartan and its principal active metabolite blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT₁ receptor found in many tissues (e.g. vascular smooth muscle, adrenal gland). Hydrochlorothiazide is a thiazide diuretic. Thiazides affect the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. Indirectly, the diuretic action of Hydrochlorothiazide 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 an angiotensin II receptor antagonist tends to reverse the potassium loss associated with these diuretics.

Indication

Losart[®] Plus is indicated for the treatment of hypertension & reduction of the risk of stroke in patients with hypertension and left ventricular hypertrophy.

Dosage and Administration

Route of administration : Oral.

Hypertension:

The usual starting dose is **Losart[®] Plus (50/12.5)** one tablet once daily. More than two tablets of **Losart[®] Plus (50/12.5)** or one tablet of **Losart[®] Plus (100/25)** once daily is not recommended. Maximum Antihypertensive effect is attained about three weeks after initiation of therapy. Patients whose blood pressure is not adequately controlled with losartan or hydrochlorothiazide monotherapy, may be switched to **Losart[®] Plus (50/12.5)** once daily. If blood pressure remains uncontrolled after about three weeks of therapy, the dose may be increased to one tablet of **Losart[®] Plus (100/12.5)** or two tablets of **Losart[®] Plus (50/12.5)** or one **Losart[®] Plus (100/25)** once daily. Patients whose blood pressure is not adequately controlled with losartan 100 mg monotherapy, may be switched to **Losart[®] Plus (100/12.5)** once daily. If blood pressure remains uncontrolled after about three weeks of therapy the dose may be increased to two tablets of **Losart[®] Plus (50/12.5)** or one **Losart[®] Plus (100/25)** once daily.

Hypertensive Patients with Left Ventricular Hypertrophy:

In patients whose blood pressure is not adequately controlled on 50 mg losartan potassium, initiate treatment with **Losart[®] Plus 50/12.5**. If additional blood pressure reduction is needed, increase the dose to **Losart[®] Plus 100/12.5**, followed by **Losart[®] Plus 100/25**. For further blood pressure reduction add other antihypertensives.

OR AS DIRECTED BY THE PHYSICIAN.

Geriatric Patients

No overall differences in effectiveness were observed between geriatric patients and younger patients

Hepatic Impairment

Initiation of **Losart[®] Plus** is not recommended for patients with hepatic impairment because the appropriate starting dose of Losartan, 25 mg, is not available

Renal Impairment

Safety and effectiveness of **Losart[®] Plus** in patients with severe renal impairment (creatinine clearance <30 mL/min) have not been established.

Contraindications

This combination is contraindicated in patients who are hypersensitive to any component of this product. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

Precaution

- Hypersensitivity: Angioedema.
- Hydrochlorothiazide therapy is associated with electrolyte imbalance: namely, hyponatremia, hypochloremic alkalosis, and hypokalemia. Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.
- Hyperglycemia may occur with thiazide diuretics. In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required
- Impaired renal function
- Symptomatic hypotension

Side effects

Common side effects : The combination of Losartan Potassium and Hydrochlorothiazide is generally well tolerated. However few side effects including abdominal pain, edema/swelling, palpitation, back pain, dizziness, cough, sinusitis, upper respiratory tract infection, rash.

Rare side effects : Black, tarry stools, blood in the urine or stools, pinpoint red spots on the skin, severe stomach pain, nausea and vomiting, skin rash.

Use in Pregnancy and Lactation

Pregnancy: Not recommended

Nursing mother: Not recommended

Use in Children and Adolescents

Safety and effectiveness of **Losart[®] Plus** in pediatric patients have not been established.

Drug interactions

With medicine:

Losartan Potassium: No significant drug-drug pharmacokinetic interactions have been found in interaction studies with Hydrochlorothiazide, Digoxin, Warfarin, Cimetidine and Phenobarbital. 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. As with other antihypertensive agents, the antihypertensive effect of Losartan may be blunted by the non-steroidal anti-inflammatory drug Indomethacin.

Hydrochlorothiazide: When administered concurrently, the following drugs may interact with thiazide diuretics:- Alcohol, barbiturates, or narcotics: potentiation of orthostatic hypotension may occur. Antidiabetic drugs (oral agents and insulin): dosage adjustment of the antidiabetic drug may be required. Other antihypertensive drugs: additive effect or potentiation. Skeletal muscle relaxants: possible increased responsiveness to the muscle relaxant. NSAIDs: In some patients the administration of a non-steroidal anti-inflammatory agent can reduce the antihypertensive effects of thiazide diuretics.

With food & others: There is no established drug-food interaction.

Overdose

Losartan Potassium : 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 occurs, supportive treatment should be instituted.

Hydrochlorothiazide :The most common signs and symptoms observed are those caused by electrolyte depletion (hypokalemia, hypochloremia) and dehydration resulting from excessive diuresis. If digitalis has also been administered, hypokalemia may accentuate cardiac arrhythmias.

Storage

Store below 30°C temperature and dry place, protected from light.

Keep all medicines out of reach of children.

Packing

Losart[®] Plus 50/12.5 : Each box contains 5x10 tablets in blister strip.

Losart[®] Plus 100/12.5 : Each box contains 3x10 tablets in blister strip.

* Further information is available on request.



Manufactured by:
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For Health, Vigour and Happiness