

Antihypertensives

LOSATRUST-25 Tablets
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Composition

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Each film-coated tablet contains Losartan Potassium 25 mg.

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Description

Losartan potassium is an orally active, nonpeptide angiotensin II (A II) receptor antagonist. It is a novel antihypertensive agent which binds competitively and selectively to the AII subtype 1 (AT₁) receptor thereby blocking AII induced effects. It has an active metabolite, a carboxylic acid derivative, which contributes substantially to its antihypertensive effect and which persists for 24 hours after once-daily administration. By blocking AT₁ receptors, both losartan and its metabolite lead to vasodilatation and inhibition of aldosterone release.

Indications

LOSATRUST is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

Dosage and Administration

The usual starting dose of LOSATRUST is 50 mg once daily. A dose of 25 mg may be used in patients with possible depletion of intravascular volume (e.g. patients treated with diuretics) and patients with a history of hepatic impairment. LOSATRUST can be administered once or twice daily with total daily doses ranging from 25 mg to 100 mg.

Contraindications

Hypersensitivity to losartan or any of the components of this product.

Warnings and Precautions

Drug Interactions

No significant interactions have been observed during concomitant administration of losartan with hydrochlorothiazide, digoxin, warfarin and phenobarbital. The effect of agents such as ketoconazole on losartan has not been studied.

Pregnancy

Drugs acting on the renin- angiotensin system can cause fetal and neonatal morbidity and death when given to pregnant women. When pregnancy is detected, LOSATRUST should be discontinued.

Nursing Mothers

It is not known whether losartan is secreted in human milk, but losartan and its metabolites have been found in the rat milk. Because of the potential for adverse effects on the nursing infant, a decision must be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric Use

Safety and effectiveness of losartan in paediatric patients have not been established.

Impaired Hepatic Function

Plasma concentrations of losartan are increased in patients with cirrhosis, hence a lower dosage should be considered for patients with impaired liver function (See Dosage and Administration).

Impaired Renal Function

Effects similar to those occurring with ACE inhibitors should be anticipated since losartan also interferes with the renin-angiotensin system (RAS). In patients whose renal function may be dependent on the activity of the RAS such as those with severe congestive heart failure and unilateral or bilateral renal artery stenosis, treatment with ACE inhibitors has been associated with oliguria and increases in blood urea nitrogen have been reported. Similar effects have been reported with losartan. No dosage adjustment is necessary for patients with renal impairment unless they are volume depleted.

Adverse effects

In general, losartan is well tolerated and adverse effects are similar to placebo. The commonly observed adverse effects include headache, dizziness, abdominal pain, asthenia/fatigue, occasional increases in liver enzymes, blood urea or serum creatinine. Angioedema has been reported rarely in patients with losartan. Hyperkalemia has also been reported.

Overdosage

Limited data is available regarding overdosage in humans. Likely manifestations include hypotension and tachycardia; bradycardia could occur due to vagal stimulation. If symptomatic hypotension should occur, supportive therapy should be instituted. Neither losartan nor its active metabolite can be removed by dialysis.

Presentation

LOSATRUST-25 Strip of 10 tablets

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