

COMPOSITION

Losarva 25 Tablet: Each film coated tablet contains Losartan Potassium USP 25 mg.

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PHARMACOLOGY

Losarva (Losartan Potassium) is the first non-peptide orally active angiotensin II receptor blocker. It binds to the AT₁ receptor found in many tissues (e.g. vascular smooth muscle, adrenal gland, kidneys and the heart) and reduces several important biological actions including vasoconstriction and the release of aldosterone responsible for hypertension.

INDICATIONS

Hypertension

Losarva (Losartan Potassium) is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents (eg. thiazide diuretics).

Renal Protection in Type-2 Diabetic Patients with Proteinuria

Losarva (Losartan Potassium) is indicated to delay the progression of renal disease in hypertensive type-2 diabetes with proteinuria, defined as urinary albumin to creatinine ratio >300 mg/g.

DOSAGE AND ADMINISTRATION

The usual starting and maintenance dose is 50 mg once daily for most patients. If the antihypertensive effect using 50 mg once daily is inadequate, 25 mg twice daily is recommended prior to increasing the dose. For patients with intravascular volume-depletion (e.g., those treated with high-dose diuretics), a starting dose of 25 mg once daily should be considered. Losartan Potassium can be administered once or twice daily. The total daily dose ranges from 25 mg to 100 mg.

CONTRAINDICATIONS

Losartan Potassium is contraindicated in pregnant women and in patients who are hypersensitive to any component of this product. Losartan Potassium should not be administered with Aliskiren in patients with diabetes.

WARNING AND PRECAUTION

Use of Losartan Potassium during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. In patients who are intravascularly volume-depleted (e.g., those treated with high-dose diuretics), symptomatic hypotension may occur. Plasma concentration of Losartan Potassium is significantly increased in cirrhotic patients. Changes in renal function including renal failure have been reported in renal impaired patient.

SIDE EFFECTS

The side effects with the use of Losartan Potassium are mild and transient in nature. The most common side effects are dizziness, diarrhea, nasal congestion, cough, upper respiratory infection. Other side effects are fatigue, oedema, abdominal pain, chest pain, nausea, headache & pharyngitis.

USE IN PREGNANCY AND LACTATION

Pregnancy Category D. The risk to the fetus increases if Losartan Potassium is administered during the second or third trimesters of pregnancy. It is not known whether Losartan Potassium is excreted in human milk, as many drugs are excreted in human milk and 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.

USE IN CHILDREN AND ADOLESCENTS

Safety and effectiveness have not been established in paediatric patients under the age of 6.

DRUG INTERACTIONS

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

If symptomatic hypotension should occur because of Losartan overdose, supportive treatment should be given. Losartan or its active metabolite cannot be removed by hemodialysis.

STORAGE

Store below 30°C temperature in a cool and dry place. Protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Losarva 25 Tablet: Each box contains 50 tablets in Alu-PVDC blister pack.

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