

Loril[®]

Losartan Potassium USP

COMPOSITION

Loril 50 mg tablet: Each film-coated tablet contains Losartan potassium USP 50 mg.

Loril 100 mg tablet: Each film-coated tablet contains Losartan potassium USP 100 mg.

INDICATION

Loril (Losartan) is indicated in the treatment of all grades of hypertension.

DOSAGE AND ADMINISTRATION

The usual starting and maintenance dose is 50 mg tablet once daily for most patients.

The maximal antihypertensive effect is attained 3-6 weeks after initiation of therapy.

Some patients may receive an additional benefit by increasing the dose to 100 mg tablet once daily. In patients who are salt depleted corrective measures should be used before starting Loril (Losartan) and the initial dose should be reduced to 25 mg.

No dosage adjustment is necessary for patients up to 75 years of age. There is limited clinical experience in older patients and a lower starting dose of 25 mg once daily is recommended.

No initial dosage adjustment is necessary in patients with mild renal impairment (i.e. creatinine clearance 20-50 ml/min). For patients with moderate to severe renal impairment (i.e. creatinine clearance < 20 ml/min) or patients on dialysis, a lower starting dose of 25 mg is recommended.

Loril (Losartan) may be administered with other antihypertensive agents.

Loril (Losartan) may be administered with or without food.

USE IN ELDERLY

Patients up to 75 years: No initial dosage adjustment is necessary for this group of patients.

Patients over 75 years: A lower starting dose of 25 mg once daily is recommended.

CONTRAINDICATION AND PRECAUTION

It is also contraindicated to patients who are hypersensitive to any component of this product. In patients who are intravenously volume depleted (e.g. those treated with high-dose diuretics), symptomatic hypotension may occur. These conditions Losartan potassium should be corrected prior to administer Losartan or a lower starting dose (usually 25 mg) should be used.

A lower dose should be considered for patients with a history of hepatic and renal impairment. Losartan should not be used with potassium-sparing diuretics.

SIDE EFFECTS

In controlled clinical trials in patients with essential hypertension, dizziness was the only side effect reported that occurred with an incidence greater than placebo in 1% or more of patients treated with Losartan. Rarely, rash was reported although the incidence in controlled clinical trials was less than placebo. Angioedema, involving swelling of the face, lips and/or tongue has been reported rarely in patients treated with Losartan. Serious hypotension (particularly on initiating treatment in salt-depleted patients) or renal failure (mainly in patients with renal artery stenosis) may be encountered during Losartan treatment.

ACUTE OVERDOSE

Limited data are available regarding overdose in humans. The most likely manifestation of overdose would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. Supportive treatment should include repletion of the intravascular volume. Neither Losartan nor the active metabolite can be removed by hemodialysis.

DRUG INTERACTION

No drug interaction of clinical significance has been identified. Compounds which have been studied in clinical pharmacokinetic trials include hydrochlorothiazide, digoxin, warfarin, cimetidine, ketoconazole and phenobarbital.

USE IN PREGNANCY AND LACTATION

Although there is no experience with the use of Losartan in pregnant women, animal studies with Losartan potassium have demonstrated fetal and neonatal injury and death, the mechanism of which is believed to be pharmacologically mediated through effects on the renin- angiotensinaldosterone system. Losartan should not be used in pregnancy and if pregnancy is detected Losartan should be discontinued as soon as possible.

It is not known whether Losartan is excreted in human breast milk. However, significant level of Losartan found in rat milk which suggests that the drug should not be used in lactating mother.

STORAGE CONDITION

Store in a cool and dry place protected from light. Keep out of the reach of children.

HOW SUPPLIED

Loril 50 mg tablet: Box containing 3X10's tablets in blister pack.

Loril 100 mg tablet: Box containing 3X10's tablets in blister pack.

Manufactured by:

