LOSANIL 50

Losartan Potassium

COMPOSITION:

LOSANIL 50: Each film coated tablet contains Losartan Potassium USP 50 mg.

DESCRIPTION:

Losartan, the first of a new class of antihypertensives, is a specific and selective antagonist of angiotensin II at the AT1 sites. Angitensin II is a potent vasoconstrictor, the primary vasoactive hormone of the renin-angiotensin system and an important component in the pathophysiology of hypertension. Losartan and its principal active metabolite block the vasoconstriction and aldosterone secreting effects of angiotensin II to the AT1 receptor found in many tissues. Losartan is now regarded as the first-line therapy option for treating high bloodpressure.

INDICATIONS:

Hypertension: Losartan Potassium (LOSANIL) is indicated for the treatment of all grades of hypertension. It may be used alone or in combination with other antihypertensive agents, including diuretics. Hypertensive patients with left ventricular hypertrophy: Losartan Potassium (LOSANIL**)** is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy. Nephropathy in type-II diabetic patients: Losartan Potassium (LOSANIL) is indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type-II diabetes and a history of hypertension. In this population, Losartan Potassium (LOSANIL) reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end stage renal disease.

DOSAGE AND ADMINISTRATION:

Adult hypertensive patients: The usual starting and maintenance dose is 50 mg 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 once daily. In patients who are salt depleted, corrective measures should be taken before starting Losartan Potassium **(**LOSANIL) 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. Hypertensive patients >6 years of age: The usual recommended starting dose is 0.7 mg/kg once daily (up to 50 mg total) administered as a tablet. Dosage should be adjusted according to blood pressure response. Losartan Potassium (LOSANIL) is not recommended in pediatric patients <6 years of age or in pediatric patients with glomerular filtration rate <30 ml/min/1.73 m2.

SIDE EFFECTS:

Adverse effects of Losartan have been reported to be usually mild and transient, and include dizziness and dose-related orthostatic hypotension. Hypotension may occur particularly in patients with volume depletion. Impaired renal function and, rarely, rash, angio edema, and raised liver enzyme values may occur. Hyperkalemia and myalgia have been reported. Losartan appears less likely than ACE inhibitors to cause cough. Others include respiratory tract disorders, back pain, gastrointestinal disturbances, fatigue and neutropenia.

CONTRAINDICATIONS:

Pregnancy & patients who are hypersensitive to the active ingredient or any components of the product.

DRUG INTERACTIONS:

No drug interactions of clinical significance have been identified. Compounds that have been studies in clinical pharmacokinetic trials include- Hydrochlorothiazide, Digoxin, Warfarin, Cimetidine, Phenobarbital and Ketoconazole.

PRECAUTIONS:

Use in elderly: In elderly patients up to 75 years of age, no dosage adjustment is necessary. Caution is advised when this drug is used in patient over 75 years.

Use in pregnancy: This medication is not recommended for use during pregnancy. Losartan Potassium (LOSANIL**)** must be discontinued as soon as possible when pregnancy is detected.

Use in lactation: It should not be prescribed during lactation, as there is no information in human on the passage of Losartan into breast milk.

OVERDOSAGE:

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 stimulation. Supportive treatment should include repletion of the intravascular volume. Neither Losartan nor the active metabolite can be removed by hemodialysis.

STORAGE INSTRUCTION:

Store in a cool and dry place, keep away from light & moisture; should be stored at room temperature below at 30ºC. All medicines keep out of the reach of children.

HOW SUPPLIED:

LOSANIL 50 tablet: Each box containing 3 x 10’s tablets in PVC blister pack.

Manufactured by:

MEDICON

MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh