

Losartan Potassium USP

PRESENTATION

Angilock® 25: Each film coated tablet contains Losartan Potassium USP 25 mg.

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

Angilock® 100: Each film coated tablet contains Losartan Potassium USP 100 mg.

INDICATION AND USES

Angilock® is indicated in the treatment of all grades of hypertension and heart failure. Moreover it is indicated in hypertensive patients with type II diabetes and will delay the progression of renal diseases.

DOSAGE & ADMINISTRATION

The usual starting and maintenance dose of **Angilock**® 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 **Angilock**® 100 mg once daily. In patients who are salt depleted corrective measures should be used before starting **Angilock**® 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 **Angilock**® 25 mg is recommended. **Angilock**® may be administered with other antihypertensive agents. **Angilock**® may be administered with or without food. Use in elderly patients: 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 **Angilock**® 25 mg once daily is recommended.

CONTRAINDICATION

Losartan is contraindicated in pregnancy and lactationlt is also contraindicated to patients who are hypersensitive to any component of this product.

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 overdosage in humans. The most likely manifestation of overdosage 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.

PRECAUTION

In patients who are intravenously volume depleted (e.g. those treated with high-dose diuretics), symptomatic hypotension may occur. These conditions should be corrected prior to the administration of losartan or a lower starting dose should be used. A lower dose should be considered for patients with a history of hepatic impairment. Losartan should not be used with potassium-sparing diuretics.

USE IN PREGNANCY & 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-angiotensin-aldosterone 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 if losartan is excreted in human breast milk It is found in rat milk The drug should not therefore be used in this age group.

DRUG INTERACTIONS

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

STORAGE CONDITION

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

HOW SUPPLIED

Angilock® 25: Box containing 50 tablets in blister pack.
Angilock® 50: Box containing 50 tablets in blister pack.
Angilock® 100: Box containing 30 tablets in blister pack.

Manufactured by

