

Only for the use of Medical Professionals

# Rosatan®

Losartan Potassium

## Presentation

Rosatan® 50 mg tablet: Round biconvex shaped, light green colored tablet with break line; each film-coated tablet contains 50 mg losartan potassium INN

Rosatan® 25 mg tablet: Round biconvex shaped, light purple colored tablet with break line; each film-coated tablet contains 25 mg losartan potassium INN

## Uses

Hypertension

Rosatan® is indicated in the treatment of all grades of hypertension

Heart Failure

Rosatan® is indicated for the treatment of heart failure in patients who cannot tolerate an ACE inhibitor.

Renal Protection in Type 2 Diabetic Patients with Proteinuria

Rosatan® is indicated to delay the progression of renal disease as measured by a reduction in the combined incidence of doubling of serum creatinine, end stage renal disease (need for dialysis or renal transplantation) or death; and to reduce proteinuria.

## Dosage and administration

Hypertension

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 used before starting Rosatan® and the initial dose should be reduced to 25 mg.

Rosatan® may be administered with other antihypertensive agents.

Heart Failure

The initial dose of Rosatan® in patients with heart failure is 12.5mg once daily. The dose should generally be titrated at weekly intervals (i.e., 12.5mg daily, 25mg daily, 50mg daily) to the usual maintenance dose of 50 mg once daily, as tolerated by the patient.

Rosatan® is usually given in combination with diuretics and digitalis.

Renal Protection in Type 2 Diabetic Patients with Proteinuria

The usual starting dose is 50 mg once daily. The dose may be increased to 100 mg once daily based on blood pressure response. Rosatan® may be administered with other antihypertensive agents (e.g., diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used hypoglycaemic agents (e.g., sulfonylureas, glitazones and glucosidase inhibitors). 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.

Rosatan® may be administered with or without food.

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.

### **Contraindications, warnings, etc.**

#### ***Contraindications***

Losartan is contraindicated in pregnancy and lactation. It is also contraindicated to patients who are hypersensitive to any components 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 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.

#### ***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 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.

#### ***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 rennin-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 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.

#### ***Drug interactions***

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.

#### **Pharmaceutical precautions**

Store in a cool dry place protected from light

#### **Package quantities**

Rosatan<sup>®</sup> 25 mg tablet: Cartons containing 30 tablets in blister strip

Rosatan<sup>®</sup> 50 mg tablet: Cartons containing 30 tablets in blister strip

® Registered Trade Mark



ACI Limited  
Narayanganj, Bangladesh.