

RASOLTAN FILM-COATED TABLET 50MG

Losartan Potassium 50mg

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1. What Rasoltan is used for

Rasoltan is used for the treatment of:

- Essential hypertension (primary high blood pressure)
- Renal disease in patients with hypertension and type 2 diabetes mellitus
- Hypertensive patients with left ventricular hypertrophy (thickening of left chamber wall in the heart)

2. How Rasoltan works

Losartan belongs to a group of medicines known as angiotensin II receptor blocker. It works by blocking a substance in the body that causes blood vessels to narrow and aldosterone to be released (a blood-pressure raising hormone), thus relaxing the blood vessels and lower your blood pressure.

3. Before you use Rasoltan

- When you must not use it

Do not take Rasoltan if you are:

- Hypersensitive to any of its ingredients
- Pregnant and lactating
- Experiencing severe liver impairment

- Before you start use it

Please tell your doctor or pharmacist if:

- You have or have had any medical problems or allergies
- You have a history of angioedema (swelling of the face, lips, throat, and/or tongue)
- You intend to become pregnant or plan to breast feed

- You have kidney and/or liver disease

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Rasoltan may interfere with each other. These include:

- Other blood pressure medicines
- Rifampicine, which is an antibiotic used to treat tuberculosis
- Fluconazole, an antibiotic to treat fungal infection
- Drugs which retain potassium eg. potassium-sparing diuretics: amiloride, triamterene, spironolactone
- Potassium supplements or salt substitutes containing potassium
- Medicines used to relieve pain, swelling, and other symptoms of inflammation
- Lithium

4. How to use Rasoltan

- How much to use

Your doctor or pharmacist will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines. Take Rasoltan only as prescribed by your doctor or pharmacist.

- When to use it

Take Rasoltan at about the same time each day, with or without food. Taking your tablet at the same time each day will have the best effect. It will also help you remember when to take the tablets.

- How long to use it

Continue taking Rasoltan for as long as your doctor or pharmacist recommends.

- If you forget to use it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, wait until then to take to dose

and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The symptom of overdosage would be hypotension (low blood tension) and tachycardia (rapid heart rate); bradycardia (slower heart rate) could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted.

5. While you are using it

- Things you must do

- Take this medicine exactly as your doctor or pharmacist has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Rasoltan.
- Tell your doctor or pharmacist immediately if you become pregnant while taking this medicine.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor or pharmacist.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Rasoltan to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Pregnancy and breast feeding

The use of Rasoltan while you are pregnant or breast feeding is not recommended. If you are pregnant or become pregnant while taking Rasoltan, stop taking Rasoltan and talk to your doctor or pharmacist as soon as possible.

Driving and using machines

Be careful driving or operating machinery until you know how Rasoltan affects you. Rasoltan may occasionally cause dizziness and drowsiness, in particularly during initiation of treatment or when the dose is increased.

6. Side effects

Like all medicines, Rasoltan can cause side effects, although not everybody gets them.

The side effects of Rasoltan used in essential hypertension are hypotension, nervous system disorders (such as dizziness and vertigo), cardiac disorders (such as feeling your heart beat and chest pain), vascular disorders (such as symptomatic low blood pressure, especially patient with severe heart failure or under high dose diuretics), gastrointestinal disorders (such as abdominal pain and severe constipation), weakness, fatigue and fluid retention.

The following adverse events occurred more often in patients receiving Rasoltan than placebo: Blood and lymphatic system disorders (such as anaemia), cardiac disorders (such as feeling of heart beat and fainting), vascular disorders (such as postural low blood pressure), gastrointestinal disorders (such as diarrhea), muscoskeletal and connective tissue disorders (such as back pain), renal and urinary disorders (such as urinary tract infection) and flu-like symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

7. Storage and Disposal of Rasoltan

- Storage

Do not store above 25°C.

Keep out reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- What it looks like

White, round, biconvex, film-coated tablet, without score (diameter 6mm)

- Ingredients

- Active ingredient:

Each tablet contains 50mg losartan potassium.

- Inactive ingredients:

Mannitol, purified water, microcrystalline cellulose, croscarmellose sodium, povidone K30, magnesium stearate, opadry white.

- MAL number

MAL09072784A

9. Manufacturer

Actavis hf.
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Product Registration Holder

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