

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking RASOL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- RASOL has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

RASOL 25, losartan potassium 25 mg per tablet.

RASOL 50, losartan potassium 50 mg per tablet.

RASOL 100, losartan potassium 100 mg per tablet.

1. WHAT RASOL TABLETS CONTAINS

The active substance is losartan potassium 25 mg, 50 mg or 100 mg per film-coated tablet, respectively.

The other ingredients are microcrystalline cellulose, lactose monohydrate, pregelatinised starch, low substituted hydroxypropyl cellulose, magnesium stearate and opadry white powder. The coating agent, opadry, contains hydroxypropyl cellulose, hypromellose and titanium dioxide (C.I. No: 77891).

Contains sugar (lactose monohydrate).

2. WHAT RASOL IS USED FOR

Losartan is used to treat high blood pressure (hypertension). Losartan works by blocking the action of a substance in the body that causes blood vessels to tighten. As a result, losartan relaxes blood vessels. This lowers blood pressure.

3. BEFORE YOU TAKE RASOL

Do not take RASOL:

- If you have ever had an unusual or allergic reaction to losartan or to any of the ingredients of RASOL.

- If you have or have ever had angioedema (a condition that causes difficulty swallowing or breathing and painful swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs) whilst taking previous angiotensin-converting enzyme (ACE) inhibitor medication or angiotensin receptor blockers (ARBs). You must never again take these medicines.
- If you have abnormal thickening of the heart muscle.
- If you have moderate to severe kidney disease.
- If you have narrowing of the renal arteries to both kidneys.
- If you have narrowing of the renal artery with a single kidney.
- If you have abnormal narrowing of the aortic valve.
- If you are currently taking diuretics (water tablets) that increase potassium in the blood such as triamterene, amiloride or spironolactone.
- If you have porphyria (an inherited disorder of blood pigment metabolism).
- In combination with thiazide diuretics (water tablets that cause the body to lose potassium as well as water) such as hydrochlorothiazide, if you have Addison's disease. Addison's disease is a condition that results when your body produces insufficient amounts of certain hormones produced by your adrenal gland.
This combination therapy must also not be used if you have severe kidney disease, are unable to urinate, or are allergic to any medicine that contains sulphur.
- If you are taking lithium, a medicine used to treat mental illness. RASOL may increase the lithium level in your blood.
- If you are pregnant.
- If you are breastfeeding.
- For use in children. The safety and effectiveness of RASOL in children have not been established.

Take special care with RASOL:

- If your blood vessels are volume-depleted (e.g. if you are being treated with high-dose diuretics (water pills), since a low blood pressure may occur. Your doctor may decide to correct your condition before giving you RASOL, or start you on a lower dose.
- Make sure you tell your doctor if you have cirrhosis (scarred liver) or liver disease – Your doctor may need to halve your dose.
- Make sure you tell your doctor if you have kidney disease.

- Make sure you tell your doctor if you have severe congestive heart failure.

Taking RASOL with food and drink:

RASOL may be taken with or without food.

Pregnancy and Breastfeeding:

- Check with your doctor immediately if you think that you are pregnant.
- RASOL must not be used in pregnancy, as birth defects in the baby may occur if RASOL are taken during pregnancy.
- To avoid pregnancy, adequate contraceptive measures should be used while being treated with RASOL.
- RASOL must not be used if you are breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

RASOL will not affect your ability to drive and use machines.

Important information about some of the ingredients of RASOL:

RASOL contains lactose. RASOL should not be taken by patients who have inherited problems such as an intolerance to some sugars, Lapp lactase deficiency (this is when the body is unable to digest milk or milk products due to lack of an enzyme) or glucose-galactose malabsorption (this is when the small intestine is unable to absorb and transport the sugars glucose and galactose).

Taking other medicines with RASOL:

- Tell your doctor if you are taking other medicines to lower blood pressure – the blood pressure lowering effects of losartan may be increased by other medicines that lower blood pressure.
- Tell your doctor if you are taking potassium supplements, potassium-sparing water pills or other medicines that can cause too much potassium in the blood.
- Tell your doctor if you are taking non-steroidal anti-inflammatory medicines.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

4. HOW TO TAKE RASOL TABLETS

Do not share medicines prescribed for you with any other person.

- Take RASOL only as directed by your doctor.
- RASOL may be taken with or without food.
- RASOL may be taken with other medicines which reduce high blood pressure.

Dose

- For high blood pressure:

Adults - The usual starting and maintenance dose is 50 mg once a day for most patients.

The dose may be increased to 100 mg once a day.

Patients with blood vessels that are volume-depleted (e.g. those treated with high-dose water pills) –

A starting dose of 25 mg once daily should be considered.

Elderly patients and patients with kidney disease – No initial dosage adjustment is necessary.

Patients with liver disease – A lower dose should be considered.

Always take RASOL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of RASOL is too strong or too weak, tell your doctor or pharmacist.

If you take more RASOL than you should:

Taking an overdose of RASOL may lead to low blood pressure and an increased heart rate. An abnormally slow pulse rate could occur.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS

RASOL can have side effects.

If any of the following happens, stop taking RASOL and tell your doctor immediately or go to the casualty department at your nearest hospital:

Swelling of face, mouth, hands, or feet, trouble in swallowing or breathing (sudden).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RASOL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Lack of energy/fatigue, abdominal pain, chest pain, swelling, rapid irregular action of heart, increased rate of heart beat, diarrhoea, indigestion, nausea, back pain, muscle cramps, headache, migraine, hives, dizziness, inability to sleep, cough, nasal congestion, inflammation of mouth and throat, sinus problems, upper respiratory infection.

Not all side effects reported for RASOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RASOL, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF RASOL

Store at or below 25 °C.

Do not store in the bathroom, near the kitchen sink, or in other damp places. Moisture may cause the medicine to break down.

Keep blisters in the original carton until required for use.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF RASOL

RASOL 25, RASOL 50, RASOL 100:

Blister Packs:

Tablets are packed in blister packs composed of white opaque PVC / PE / PVdC film and printed silver-coloured aluminium foil. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

7. IDENTIFICATION OF RASOL

RASOL 25: White to off-white, oval shaped, biconvex, film-coated tablets, debossed with “E” on one side and “45” on the other side.

RASOL 50: White to off-white, oval shaped, biconvex, film-coated tablets, debossed with “E” on one side and “46” on the other side.

RASOL 100: White to off-white, oval shaped, biconvex, film-coated tablets, debossed with “E” on one side and “47” on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

RASOL 25: 43/7.1.3/0496

RASOL 50: 43/7.1.3/0497

RASOL 100: 43/7.1.3/0498

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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