

## **PACKGE LEAFLET : INFORMATION FOR THE USER**

### **Rosal film-coated tablet 50 mg Losartan Potassium**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Rosal is and what it is used for
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#### **1. WHAT ROSAL IS AND WHAT IT IS USED FOR**

Losartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Rosal is used

- to treat patients with high blood pressure (hypertension) in adults and in children and adolescents 6-18 years of age.
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria  $\geq 0.5$  g per day ( a condition in which urine contains an abnormal amount of protein).
- to treat patients with chronic heart failure when therapy with specific medicines called angiotensin-converting-enzyme inhibitors (ACE inhibitors, medicine used to lower high blood pressure) is not considered suitable by your doctor. If your heart failure has been stabilized with an ACE inhibitor you should not be switched to lasartan.
- in patients with high blood pressure and a thickening of the left ventricle, ROSAL has been shown to decrease the risk of stroke (“LIFE indication”).

## **2. BEFORE YOU TAKE ROSAL**

### **Do not take Rosal**

- if you are allergic (hypersensitive) to losartan or to any of its other ingredients,
- if your liver function is severely impaired,
- if you are more than 3 months pregnant. (It is also better to avoid Rosal in early pregnancy- see "Pregnancy".).

### **Take special care with Rosal**

You must tell your doctor if you think you are (or might become) pregnant. Rosal is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section)

It is important to tell your doctor before taking Rosal

- if you have had a history of angiooedema (swelling of the face, lips, throat, and/or tongue) (see also section 4 'Possible side effects'),
- if you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body,
- if you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body (see section 3 'Dosage in special patient groups'),
- if you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently,
- if your liver function is impaired (see sections 2 "Do not take Rosal" and 3 "Dosage in special patient groups"),
- if you suffer from heart failure with or without renal impairment or concomitant severe life threatening cardiac arrhythmias. Special caution is necessary when you are treated with a  $\beta$ -blocker concomitantly,
- if you have problems with your heart valves or heart muscle,
- if you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain),
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines and natural products.

Take particular care if you are taking the following medicines while under treatment with Rosal:

- other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following drugs/ class of drugs: tricyclic antidepressants, antipsychotics, baclofen, amifostine,
- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamterene, spironolactone] or heparin),
- non-steroidal anti-inflammatory drugs such as indometacin, including COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of losartan.

If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function.

Lithium containing medicines should not be taken in combination with losartan without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

### **Taking Rosal with food and drink**

Rosal may be taken with or without food.

### **Pregnancy and breast feeding**

#### **Pregnancy**

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Rosal before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Rosal. Rosal is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

#### **Breast Feeding**

Tell your doctor if you are breast feeding or about to start breast feeding. Rosal is not recommended for mothers who are breast feeding, and your doctor may choose another treatment for you if you wish to breast feed. Especially if your baby is a newborn, or born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Use in children and adolescents**

Rosal has been studied in children. For more information,, talk to your doctor.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed. Rosal is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

## **Important information about some of the ingredients of Rosal**

Rosal contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. HOW TO TAKE ROSAL**

Always take Rosal exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of Rosal, depending on your condition and whether you are taking other medicines. It is important to continue taking Rosal for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

#### Adult patients with high blood pressure

Treatment usually starts with 50 mg losartan (one tablet Rosal 50 mg) once a day. The maximal blood pressure lowering effect should be reached 3-6 weeks after beginning treatment. In some patients the dose may later be increased to 100 mg losartan (two tablets Rosal 50 mg) once daily. If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

#### Use in children and adolescents (6 to 18 years old)

The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7 mg of losartan per kg of body weight administered once a day (up to 25 mg of Rosal). The doctor may increase the dose if blood pressure is not controlled.

#### Adult patients with high blood pressure and type 2 diabetes

Treatment usually starts with 50 mg losartan (one tablet Rosal 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets Rosal 50 mg) once daily depending on your blood pressure response.

Losartan tablets may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

#### Adult Patients with heart failure

Treatment usually starts with 12.5 mg losartan (one tablet Rosal 12.5 mg) once a day. Generally, the dose should be increased weekly step-by-step (i.e., 12.5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as determined by your physician. A maximum dose of 150 mg losartan (for example, three tablets of Rosal 50 mg or one tablet each of Rosal 100 mg and Rosal 50 mg) once daily may be used.

In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

## **Dosage in special patient groups**

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics in high doses, in patients with liver impairment, or in patients over the age of 75 years. The use of losartan is not recommended in patients with severe hepatic impairment (see section "Do not take Rosal").

## **Administration**

The tablets should be swallowed with a glass of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take Rosal until your doctor tells you otherwise.

## **If you take more Rosal than you should**

If you accidentally take too many tablets, contact your doctor immediately. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

## **If you forget to take Rosal**

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

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

If you experience the following, stop taking losartan tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

The side effects of medicines are classified as follows:

<b>Very common</b>	affects more than 1 user in 10
<b>Common</b>	affects 1 to 10 users in 100
<b>Uncommon</b>	affects 1 to 10 users in 1,000
<b>Rare</b>	affects 1 to 10 users in 10,000
<b>Very rare</b>	affects less than 1 user in 10,000 patients
<b>Not known</b>	frequency cannot be estimated from the available data

The following side effects have been reported with Rosal:

*Common:*

- dizziness,
- low blood pressure,
- debility,
- fatigue,
- too little sugar in the blood (hypoglycaemia),
- too much potassium in the blood (hyperkalaemia),
- changes in kidney function including kidney failure,
- reduced number of red blood cells (anaemia),
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure.

*Uncommon:*

- somnolence,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris),
- low blood pressure (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics),
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position,
- shortness of breath (dyspnoea),
- abdominal pain,
- obstipation,
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- rash,
- localised swelling (oedema),
- cough.

*Rare:*

- hypersensitivity,
- angiooedema,
- inflammation of blood vessels (vasculitis including Henoch-Schonlein purpura),
- numbness or tingling sensation (paraesthesia),
- fainting (syncope),
- very rapid and irregular heartbeat (atrial fibrillation)
- brain attack (stroke),
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

*Not known:*

- reduced number of thrombocytes,
- migraine,
- liver function abnormalities,
- muscle and joint pain,
- flu-like symptoms,
  
- back pain and urinary tract infection,
- increased sensitivity to the sun (photosensitivity),
- unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis),
- impotence,
- inflammation of the pancreas (pancreatitis),
- low levels of sodium in the blood (hyponatraemia),
- depression,
- generally feeling unwell (malaise),
- ringing, buzzing, roaring, or clicking in the ears (tinnitus).

Side effects in children are similar to those seen in adults.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE ROSAL**

Keep out of the reach of children.

Do not use Rosal after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store Rosal in the original package in order to protect from light and moisture at room temperature not exceeding 30°C. Do not open the blister pack until you are ready to take the medicine.

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.

## **6. FURTHER INFORMATION**

### **What Rosal contains**

The active substance is losartan potassium. Each tablet contains 50 mg of losartan potassium. The other ingredients are Povidone, microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, magnesium stearate, purified water, hypromellose, Polyethylen glycol 6000, Titanium dioxide, ethanol, methylene chloride.

### **What Rosal looks like and contents of the pack**

Rosal tablet 50 mg is supplied as White, oval, film-coated tablets containing 50 mg of

losartan potassium. The tablets can be divided into equal halves and debossed with 'LK 50' on one side and 'U' and 'T' separated by a score line on the other side.

Rosal tablet 50 mg is available in packs of 30 tablets. (10 Tablets/Blister × 3 Blisters/Box). As a push-through type of blister, the forming film and the covering (lid) are made of polyvinyl chloride (PVC) and aluminum.

**MAL11100012A**

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