

ROSART TABLETS

Losartan Potassium (50mg/100mg)

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What **ROSART TABLETS** is used for

ROSART TABLETS is used to treat high blood pressure. If you have high blood pressure and a thickening of the left ventricle, the heart's main pumping chamber, your doctor has prescribed **ROSART TABLETS** to help lower the risk of cardiovascular events, such as stroke.

ROSART TABLETS also provide kidney protection by delaying the worsening of kidney disease in type 2 diabetic patients with protein in their urine (proteinuria). Kidney disease can be measured by testing the urine for protein.

How **ROSART TABLETS** works

ROSART TABLETS contain an active substance called losartan which 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.

Your doctor however, may have prescribed this medicine for another

purpose. Ask your doctor if you have any questions why it has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use **ROSART TABLETS**

- When you must not use it

Do not take **ROSART TABLETS** if:

- you have an allergy to losartan or any of the ingredients of **ROSART TABLETS** (see **Product Description**) (An allergic reaction may include skin rash, itching or hives, swelling of the face, lips, tongue and throat or difficulty in breathing)
- You have diabetes and are taking a medicine called aliskiren to reduce blood pressure.
- You have severe liver impairment
- You are more than 3 months pregnant.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- have problems with your liver or kidney(s) or have received a kidney transplant recently
- have had a history of angioedema (swelling of the face, lips, throat, and/or tongue)
- suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body
- suffer from heart problems
- are pregnant or are planning to become pregnant
- 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)

- are taking any of the following medicines used to treat high blood pressure:
 - An ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - Aliskiren
- have problems with your heart valves or heart muscle

Losartan is not recommended in children with renal impairment

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Pregnancy and Lactation

Tell your doctor if you are pregnant or are planning to become pregnant. Your doctor will normally advise you to stop taking **ROSART TABLETS** before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of **ROSART TABLETS**. **ROSART TABLETS** are not recommended in pregnancy as it may cause serious harm to your baby.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Your doctor will decide whether you should stop nursing or you should stop taking **ROSART TABLETS** after considering the risk and benefit.

ROSART TABLETS contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **ROSART TABLETS**.

- Taking other medicines

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

Some medicines and **ROSART TABLETS** may interfere with each other. These include:

- potassium supplements, or salt substitutes containing potassium.
- water pills including potassium-sparing agents (e.g. spironolactone, triamterene, amiloride)
- drugs that may increase serum potassium (e.g., trimethoprim-containing products)
- non-steroidal anti-inflammatory drugs including COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain)
- lithium (used to treat mood swings or some types of depression)
- other blood pressure lowering medicines (ACE-inhibitors, eg. enalapril, lisinopril, ramipril)
- blood pressure may also be lowered by one of the following drugs/ class of drugs: tricyclic antidepressants, antipsychotics, baclofen, amifostine

These medicines may have an additive effect with **ROSART TABLETS** in lowering your blood pressure, or may affect how well it works, or may lead to increases in potassium in your blood. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **ROSART TABLETS**

How to use ROSART TABLETS

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the pack ask your doctor or pharmacist for help.

- How much to use

Your doctor 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 **ROSART TABLETS** only when prescribed by your doctor

Adults

The usual starting dose is 50 mg once daily. The dose may be increased to 100 mg once a day depending on your blood pressure.

Children and adolescents (6 years and above)

Your doctor will decide the right dose for your child depending on the body weight.

- When to use it

Swallow your tablets with a glass of water. **ROSART TABLETS** can be taken with or without food.

Take your **ROSART TABLETS** at about the same time each day. Taking your tablet(s) 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

Losartan helps control your high blood pressure, but does not cure it. Therefore **ROSART TABLETS** must be taken every day. Continue taking **ROSART TABLETS** for as long as your doctor prescribes.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally. **Do not take a double dose to make up for the dose you missed.**

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and emergency at the nearest hospital, if you think that you or anyone else may have taken too much of **ROSART TABLETS**. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take this leaflet or some

tablets with you so your doctor will know what you have taken.

While you are using ROSART TABLETS

- Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking **ROSART TABLETS**.

Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding. **ROSART TABLETS** is not recommended during pregnancy.

Have your blood pressure checked when your doctor says, to make sure **ROSART TABLETS** is working.

You may feel light-headed or dizzy while taking **ROSART TABLETS**, especially if you are also taking a diuretic (water pill). This may become worse if you stand up quickly as your blood pressure may fall. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. This problem is not common. If it occurs and gets worse or continues, talk to your doctor.

Make sure you drink enough water during exercise and hot weather when you are taking **ROSART TABLETS**, especially if you sweat a lot.

If you do not drink enough water while taking **ROSART TABLETS**, you may faint or feel light-headed or sick. This is because your body doesn't have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

Go to your doctor regularly for a check-up.

- Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take any new medicines without consulting your doctor.

Do not stop taking your medicine or change the dosage without checking with your doctor.

- Things to be careful of

Be careful while driving or operating machinery until you know how **ROSART TABLETS** affects you.

As with many other medicines used to treat high blood pressure, **ROSART TABLETS** may cause dizziness or light-headedness in some people. Make sure you know how you react to **ROSART TABLETS** before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If you drink alcohol, dizziness or lightheadedness may be worse.

Side effects

Like all medicines, **ROSART TABLETS** can cause side effects, but not everyone gets them. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

Very serious side effects

If any of the following happens, Stop taking ROSART TABLETS and tell your doctor immediately or go to casualty/ emergency department at your nearest hospital:

- rashes, hives, itching, chest constriction, shortness of breath or swelling of face, lips, hands / feet.

Serious side effects

Tell your doctor as soon as possible if you notice any of the following:

- low blood pressure
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position
- tiredness, headaches, shortness of breath, dizziness and looking pale; bleeding or bruising more easily than normal
- inflammation of the liver (hepatitis)
- renal impairment

- a feeling of tightness, pressure or heaviness in the chest (angina pectoris)
- An irregular, often rapid heart rate that commonly causes poor blood flow (atrial fibrillation)
- Damage to the brain from interruption of its blood supply (cerebrovascular accident)

The above list includes serious side effects that may require medical attention.

Other side effects

Tell your doctor if you notice any of the following:

- dizziness,
- 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,
- 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
- somnolence,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris),
- shortness of breath (dyspnoea),
- abdominal pain,
- obstipation,
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- rash,
- localised swelling (oedema),

- Cough.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ROSART TABLETS

- **Storage**

Store below 30°C, protected from moisture

- **Disposal**

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product Description

- **What ROSART TABLETS looks like**

ROSART TABLETS 50 mg
White to off white, circular, biconvex, film-coated tablets with score line on one side and plain on the other side. Diameter 7.6 mm

ROSART TABLETS 100 mg
White to off white, circular, biconvex, film-coated tablets with score line on one side and plain on the other side. Diameter 9.6 mm

- **Ingredients**

- **Active ingredient:**
Each Tablet Contains:
Losartan potassium...50/100 mg
- **Inactive ingredients:**
ROSART TABLETS contains:
Microcrystalline cellulose, lactose anhydrous, pregelatinized starch, magnesium stearate, colloidal silicon dioxide, purified talc, opadry 20H58983 (white), purified water

- **MAL Number**

ROSART TABLETS 50 mg:
MAL08120868AZ

ROSART TABLETS 100 mg:
MAL08120869AZ

**Manufacturer and Product
Registration Holder**

**RANBAXY (MALAYSIA) SDN.
BHD.**
Lot 23, Bakar Arang Industrial Estate,
08000 Sungai Petani, Kedah,
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