

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S4

**ROSVATOR 5**

**ROSVATOR 10**

**ROSVATOR 20**

**ROSVATOR 40**

Rosuvastatin

This product contains sugar (lactose monohydrate)

### Read all of this leaflet carefully before you start taking ROSVATOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ROSVATOR** 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.

### What is in this leaflet

1. What **ROSVATOR** is and what it is used for.
2. What you need to know before you take **ROSVATOR**.
3. How to take **ROSVATOR**.
4. Possible side effects.
5. How to store **ROSVATOR**.
6. Contents of the pack and other information.

#### 1. What **ROSVATOR** is and what it is used for.

**ROSVATOR** tablets contain rosuvastatin. It belongs to a group of medicines called statins.

Rosuvastatin is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol. Most of the cholesterol in your blood is made in the liver.

You have been prescribed **ROSVATOR** because you have a high cholesterol level.

**ROSVATOR** tablet is used:

- to lower 'bad' cholesterol and triglycerides in the blood, and increase 'good' cholesterol when a low fat diet and other measures (such as exercise, weight loss) have failed.
- to lower the inherited high levels of cholesterol in your blood (homozygous familial hypercholesterolemia), together with dieting and other treatments (e.g. LDL-apheresis), or when such treatments are not adequate.
- to reduce risk of heart attack or stroke.

## **2. What you need to know before you take ROSVATOR**

**Do not take ROSVATOR:**

- If you are hypersensitive (allergic) to rosuvastatin or any of the other ingredients of **ROSVATOR**.
- If you have active liver disease including persistent elevation of liver enzymes in the blood
- If you have been diagnosed with muscle disease (myopathy; symptoms may include muscle aches and pains)
- If you take a medicine called ciclosporin (used for after organ transplants)
- If you are pregnant or intend to become pregnant.
- If you are breast-feeding currently.

**Do not take ROSVATOR tablets if any of the above applies to you. If you are not sure, please talk to your doctor or pharmacist before taking these tablets.**

### **Warnings and precautions**

**Take special care with ROSVATOR:**

- If you have problems with your kidneys
- If you have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever
- If you regularly consume large amounts of alcoholic beverages or have a history of liver disease
- If you have an underactive thyroid gland (hypothyroidism) which is treated inadequately

- If you are an elderly person (more than  $\geq 65$  years old)
- If you take other medicines called fibrates (such as gemfibrozil, niacin) to lower your cholesterol
- If you take medicines used to fight infections (e.g. erythromycin, azithromycin etc.)
- If you take medicines used to fight the HIV infection (e.g. protease inhibitors such as lopinavir/ritonavir)
- If you take medicines used to treat fungal infection (e.g. miconazole, ketoconazole)
- If you are of Asian origin
- If you are diabetic

Myopathy (muscle aches and pains) and muscle breakdown with severe kidney problems have been reported with agents of the same class as ROSVATOR. This can occur at any dose level, but are increased at the highest dose (40 mg). ROSVATOR can cause Myasthenia gravis (muscle weakness and fatigue) and ocular myasthenia (affects muscles that controls the eye movement).

Serious liver problems may occur. You should notify your medical practitioner right away if you have the following symptoms: unusual fatigue or weakness; loss of appetite; stomach pain; dark-coloured urine; or yellowing of the skin or the whites of the eyes.

Please consult your doctor if these statements were applicable to you any time in the past.

#### **While on treatment**

**ROSVATOR** should be discontinued if markedly elevated creatinine kinase levels occur or muscle breakdown is suspected.

**ROSVATOR** should not be used in patients developing severe blood infection (sepsis), low blood pressure, severe electrolyte imbalance (abnormalities in the blood levels of e.g. sodium, potassium, and/or calcium), trauma, uncontrolled fits or undergoing major surgery.

An increase in the amount of protein and traces of blood in the urine has been reported in patients taking **ROSVATOR** 40 mg tablet when compared to lower doses. During routine testing if this is observed, your doctor would consider a dose reduction.

In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will usually carry out blood test (liver function test) before and during treatment if necessary with **ROSVATOR** tablets.

**Other medicines and ROSVATOR:**

**Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).**

**Tell your doctor especially if you are taking any of the following:**

- ciclosporin (used for example, after organ transplants)
- fibrates such as gemfibrozil, fenofibrate (medicine used to lower cholesterol)
- other cholesterol lowering agents such as niacin, ezetimibe
- itraconazole, ketoconazole (medicines used to treat fungal infection)
- lopinavir/ritonavir (used to fight the HIV infection)
- antibiotics – macrolides such as erythromycin (used to treat infections)
- warfarin (or any other agent used for thinning the blood)
- antacid preparations containing aluminium and magnesium hydroxide used for indigestion (remedies used to neutralise acid in your stomach), cimetidine
- an oral contraceptive (the pill), hormone replacement therapy
- spironolactone (used as water pill)

The effects of these medicines could be changed by ROSVATOR tablets or they could change the effect of ROSVATOR tablets.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Pregnancy**

Do not take **ROSVATOR** tablets if you are pregnant. If you become pregnant while taking **ROSVATOR** tablets stop taking it immediately and tell your doctor.

Women should avoid becoming pregnant while taking **ROSVATOR** by using suitable contraception.

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

**Breast-feeding**

**ROSVATOR** must not be used during breast-feeding.

**Driving and using machinery:**

You should be aware of how you react to **ROSVATOR** before you drive or operate machinery. Effect on ability to drive and use machines has not been studied. Some people feel dizzy during treatment with **ROSVATOR** tablets. If you feel dizzy, consult your doctor before attempting to drive or use machines

### 3. How to take **ROSVATOR**:

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

Always take **ROSVATOR** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### Usual Dose in Adults

The usual starting dose of **ROSVATOR** is 5 mg, even if you have taken a higher dose of a different cholesterol lowering agent (statin) before.

The choice of your start dose will depend upon:

- Your cholesterol level
- The level of risk you have of experiencing a heart attack or stroke
- Whether you have a factor that may make you more sensitive to possible side effects

In children 10 years of age and above the usual dose range is 5 to 20 mg orally once daily.

Your doctor may decide to give you the lowest dose (5 mg) if you are of Asian origin, over 70 years of age, have kidney problems, or are at risk of muscle aches and pains.

It is important to go back to your doctor for regular cholesterol checks, to make sure your cholesterol has reached and is staying at the correct level.

If you take more **ROSVATOR** than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet or some tablets with you so that your doctor will know what you have taken.

If you forget to take **ROSVATOR**

If you miss a dose of **ROSVATOR**, take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for missed doses.

#### 4. Possible side effects

**ROSVATOR** can have side effects.

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

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

Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat, severe itching, difficulty in swallowing.

Rash or itching.

Yellowing of the skin and eyes, also called jaundice.

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

Also stop taking **ROSVATOR** tablets and talk to your doctor immediately

- If you have any unusual aches or pains in your muscles. These have become a potentially life threatening muscle damage known as rhabdomyolysis.
- Severe stomach pain due to inflamed pancreas (pancreatitis)

The following side-effects have been reported frequently:

- Headache
- Rash, itching
- Dizziness
- Stomach pain
- Constipation
- Feeling sick (nausea)
- Muscle pain
- Feeling weak (asthenia)
- Increased blood glucose levels (diabetes)

Less frequent side-effects:

- Rash, itching or other skin reactions
- Memory loss or impairment, forgetfulness and confusion

- A severe stomach pain (inflamed pancreas)
- Jaundice (yellowing of the skin and eyes)
- Hepatitis (an inflamed liver)
- Increased liver enzymes in the blood
- Joint pain
- Traces of blood in your urine
- Deficiency of platelets in the blood (thrombocytopaenia)
- Inflammation of the pancreas (pancreatitis)
- Swelling of boys' and men's breasts (gynecomastia)

Frequency not known side-effects:

- Depression
- Sleep disturbances, including nightmares and sleeplessness
- Weakness, numbness and pain from nerve damage (peripheral neuropathy)
- Myasthenia gravis (muscle weakness and fatigue)
- Ocular myasthenia (weakened muscles that controls the eye movement).
- Cough and laboured breathing
- Diarrhoea
- Serious disorder of the skin and mucous membranes (Stevens-Johnson syndrome)
- Swelling (oedema)

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

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform ([who-umc.org](http://who-umc.org)) found on SAHPRA website. Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email: [pharmacovigilance.africasme@sunpharma.com](mailto:pharmacovigilance.africasme@sunpharma.com) or tel: +27(0) 12 643 2000. By reporting side effects, you can help provide more information on the safety of

### **ROSVATOR**

#### **5. How to store ROSVATOR**

Store at or below 25 °C in the original pack, protected from light and moisture.

Do not remove the blisters from the carton until required for use.

Keep out of the reach and sight of children.

Do not take ROSVATOR tablets after expiry date on the labelling.

If your doctor tells you to stop taking the tablets, please take them back to the pharmacist.

## **6. Contents of the pack and other information**

### **What ROSVATOR contains**

The active substance is rosuvastatin.

The other ingredients are:

Crospovidone, lactose monohydrate, microcrystalline cellulose, magnesium stearate, opadry yellow or opadry pink and sodium citrate.

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

#### **ROSVATOR 5**

Each film-coated tablet contains Rosuvastatin calcium equivalent to Rosuvastatin 5 mg.

Contains sugar: Lactose monohydrate 42,952 mg per film-coated tablet.

#### **ROSVATOR 10**

Each film-coated tablet contains Rosuvastatin calcium equivalent to Rosuvastatin 10 mg.

Contains sugar: Lactose monohydrate 85,905 mg per film-coated tablet.

#### **ROSVATOR 20**

Each film-coated tablet contains Rosuvastatin calcium equivalent to Rosuvastatin 20 mg.

Contains sugar: Lactose monohydrate 171,810 mg per film-coated tablet.

#### **ROSVATOR 40**

Each film-coated tablet contains Rosuvastatin calcium equivalent to Rosuvastatin  
40 mg.

Contains sugar: Lactose monohydrate 343,619 mg per film-coated tablet.

Cartons contain 28 or 30 tablets packed in silver cold form blister packs or desiccant embedded silver cold form blister packs, each blister strip of silver cold form blister pack and desiccant embedded silver cold form blister pack contains 7 or 10 tablets.

Ranbaxy Pharmaceuticals (Pty) Ltd  
Rosvator 5/ 10/ 20/ 40  
Film coated tablets - Rosuvastatin calcium equivalent to Rosuvastatin 5/ 10/ 20/ 40 mg.

The carton contains 4 blister strips of 7 tablets each for the 28's pack and 3 blister strips of 10 tablets each for the 30's pack.

**Holder of Certificate of Registration**

Ranbaxy Pharmaceuticals (Pty) Ltd  
14 Lautre Road, Stormill, Ext 1  
Roodepoort, 1724

**This leaflet was last revised in**

22 Jan 2024

**Registration number**

**ROSVATOR 5:** 45/7.5/0955

**ROSVATOR 10:** 45/7.5/0956

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**Access to the corresponding Professional Information**

Can be obtained on the SAHPRA website