

# ROSUVOR FILM COATED TABLET

Rosuvastatin Calcium (10mg, 20mg)

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## What Rosuvor is used for

Rosuvor belongs to a group of medicines called statins. You have been prescribed Rosuvor because you have a high cholesterol level. This means you are at risk from a heart attack or stroke.

## How Rosuvor works

Rosuvor is used to lower the levels of lipids known as cholesterol. There are different types of cholesterol found in the blood – ‘bad’ cholesterol (LDL-C) and ‘good’ cholesterol (HDL-C).

- Rosuvor can reduce the ‘bad’ cholesterol and increase the ‘good’ cholesterol
- It works by helping to block your body’s production of ‘bad’ cholesterol. It also improves your body’s ability to remove it from your blood

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke.

By lowering your cholesterol level, you can reduce your risk of having a heart attack, a stroke or related health problems.

You need to keep taking Rosuvor, even if it has got your cholesterol to the right level, because it prevents your cholesterol level from creeping up again and causing build-up of fatty deposits.

## Before you use Rosuvor

### - When you must not use it

Do not take Rosuvor:

- If you have ever had an allergic reaction to Rosuvor or similar medicines, or to any of its ingredients
- If you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking Rosuvor stop taking it immediately and tell your doctor.
- If you have liver disease
- If you have severe kidney problems
- If you have repeated or unexplained muscle aches or pains
- If you take a medicine called ciclosporin (used for example, after organ transplants)
- If you take medicines used to fight the HIV infection e.g. lopinavir/ritonavir and/or atazanavir or simeprevir (used to treat infections including HIV or hepatitis C infections) please see “Taking other medicines”

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

### - Before you start to use it

Take special care with Rosuvor and tell your doctor or pharmacist:

- If you have ever been told that you have problems with your kidneys
- If you have ever been told that you have problems with your liver
- If you have had unexplained muscle aches or pains, a history of muscle pains, or a previous history of muscle problems when

taking other cholesterol-lowering medicines

- If you regularly drink large amounts of alcohol
- If your thyroid gland is not working properly
- If you take other medicines called fibrates to lower your cholesterol
- If you have high blood sugar or raised HbA1c
- If you are over 70 years old (as your doctor needs to choose the right start dose of Rosuvor to suit you)
- If you have severe respiratory failure
- If you have intolerance to some sugars (lactose or milk sugar)
- If you have interstitial lung disease
- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition.

### - Taking other medicines

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including any you bought without a prescription.

Tell your doctor or pharmacist if you are taking any of the following:

- ciclosporin (used for example, after organ transplants)
- warfarin (or any other medicine used for thinning the blood)
- fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe)
- antacid (used to neutralise acid in your stomach)
- erythromycin (an antibiotic)

- protease inhibitors (medications used to fight the HIV infection such as atazanavir and ritonavir)
- oral contraceptive/ hormone replacement therapy

The effects of these medicines could be changed by Rosuvor or they could change the effects of Rosuvor. This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

### How to use Rosuvor

#### - How much to use

Always take Rosuvor as your doctor has told you. You should check with your doctor or pharmacist if you are not sure what to do.

#### *Starting dose:*

In adults treatment with Rosuvor is usually started with the 10 mg dose taken once daily, even if you have taken a higher dose of a different statin before. Some people may be asked to start treatment with one 5 mg tablet taken once a day. 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 may be more sensitive to possible side effects

#### *Increasing the dose and maximum daily dose:*

After checking the amount of lipids in your blood, your doctor may decide to increase your dose until you are taking the amount of Rosuvor that is right for you. There will be a gap of four weeks between every dose adjustment.

In adults the maximum daily dose of Rosuvor is 40 mg. It is only for patients with high cholesterol levels and at high risk of heart attacks or stroke whose cholesterol levels are

not lowered enough with 20 mg. A dosage of 40 mg once daily should only be initiated under specialist supervision.

#### - When to use it

Take Rosuvor once daily. You can take it in the morning or evening. Try to take your tablet at the same time every day to help you to remember to take it.

#### *Regular cholesterol checks:*

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. Your doctor may decide to increase your dose so that you are taking the amount of Rosuvor that is right for you.

#### - How long to use it

Do not stop taking your Rosuvor, even if you are feeling well, unless your doctor tells you to or unless you become pregnant.

Talk to your doctor if you want to stop taking Rosuvor. Your cholesterol levels might increase again if you stop taking Rosuvor.

#### - If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

#### - If you use too much (overdose)

If you take more Rosuvor than prescribed by your doctor, talk to your doctor or pharmacist straight away.

### While you are using Rosuvor

#### - Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Rosuvor.

Tell your doctor immediately if you become pregnant while using this medication.

#### - Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Rosuvor to anyone else, even if they have the same symptoms or condition as you.

#### - Things to be careful of

##### *Pregnancy and breastfeeding:*

Do not take Rosuvor if you are pregnant, trying to become pregnant or are breastfeeding. If you become pregnant while taking Rosuvor, stop taking it immediately and tell your doctor.

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

##### *Driving and using machines:*

Rosuvor is not expected to affect your ability to drive a car or to operate machinery.

### Side effects

Like all medicines, Rosuvor can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be.

Stop taking Rosuvor and seek medical help immediately if you have any of the following allergic reactions:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing

- Severe itching of the skin (with raised lumps)

Also, stop taking Rosuvor and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than you might expect. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as rhabdomyolysis.

If you have muscle problems that do not go away even after your doctor has told you to stop taking Rosuvor, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Common side effects:

- Headache
- Muscle pain
- Stomach pain
- General feeling of weakness
- Constipation
- Dizziness
- Feeling sick

Side effects of unknown frequency:

- Sleep disturbances, including insomnia (difficulty in sleeping) and nightmares.
- Depression
- Increases in HbA1c (a measure of the average amount of sugar in your blood over time).
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Visit your doctor or pharmacist immediately if you experience any side effects after using medicine.

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

### Storage and Disposal of Rosuvor

#### - Storage

Keep out of the reach and sight of children.

Do not use Rosuvor after the expiry date which is stated on the box/blisters after EXP. The expiry date refers to the last day of the month.

Store your tablets below 30°C.

#### - 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.

### Product Description

#### - What it looks like

Rosuvor comes in two tablet strengths:

- ROSUVOR FILM COATED TABLET 10MG

A pink colour film coated round tablet, one side impressed with 'Y'. The other side is plain. The tablet is not intended to be cut into half.

- ROSUVOR FILM COATED TABLET 20MG

A pink colour film coated round tablet, one side impressed with 'YSP' and the other side impressed with a score. The tablet is intended to be cut into half.

Rosuvor 10 mg and 20 mg tablets come in blister packs containing 30 tablets, 100 tablets and 500 tablets.

### - Ingredients

#### - Active ingredient(s)

- The active substance in Rosuvor is *rosuvastatin*. Rosuvor film-coated tablets contain *rosuvastatin* calcium equivalent to 10 mg and 20 mg of *rosuvastatin*.

#### - Inactive ingredients

- Sodium citrate,
- Lactose,
- Microcrystalline cellulose,
- Crospovidone,
- Magnesium stearate,
- Purified water,
- Opadry pink

#### - MAL number:

10 mg: MAL20096011AZ

20 mg: MAL20096012AZ

### Manufacturer and Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd.  
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03/07/2025

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