

Rosmi 10 & Rosmi 20

Rosuvastatin Film Coated Tablets 10 mg

Rosuvastatin Film Coated Tablets 20 mg

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1. What Rosuvastatin is used for

You have been prescribed Rosuvastatin because you have a high cholesterol level. This means you are at risk from a heart attack or stroke.

2. How Rosuvastatin works

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

There are different types of cholesterol found in the blood – ‘bad’ cholesterol (LDL-C) and ‘good’ cholesterol (HDL-C).

- Rosuvastatin 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 levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

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

3. Before you use Rosuvastatin

- When you must not use it

Do not take Rosuvastatin:

- If you have ever had an allergic reaction to Rosuvastatin or similar medicines, or to any of its ingredients. Rosuvastatin contains lactose, which may cause a problem in a small number of patients who are allergic to lactose.
- If you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking Rosuvastatin stop taking it immediately and tell your doctor.
- If you have liver disease.
- If you have repeated or unexplained muscle aches or pains.

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 Rosuvastatin 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 take medicines used to fight the HIV infection alone or in combination e.g. lopinavir, ritonavir, atazanavir, simeprevir, sofosbuvir, velpatasvir, voxilaprevir, grazoprevir, elbasvir, ombitasvir, paritaprevir, dasabuvir, glecaprevir, pibrentasvir (used to treat infections including HIV or hepatitis C infections), regorafenib and darolutamide (used to treat cancer). Please see “*Taking other medicines*”.
- If you have high blood sugar or raised HbA1c.

- If you are over 70 (as your doctor needs to choose the right start dose of Rosuvastatin to suit you).

- If you have severe respiratory failure.

- 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 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), or medications used to fight the HIV infection – please see “*Before you start to use it*”.

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

4. How to use Rosuvastatin

- How much to use

Always take Rosuvastatin 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 Rosuvastatin 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.

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- 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 Rosuvastatin that is right for you. There will be a gap of four weeks between every dose adjustment.

In adults the maximum daily dose of Rosuvastatin 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.

In children 10-17 years of age the maximum daily dose is 20 mg. Rosuvastatin should not be given to children younger than 10 years.

- When to use it

Take Rosuvastatin 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 Rosuvastatin that is right for you.

- How long to use it

Do not stop taking your Rosuvastatin, 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 Rosuvastatin. Your cholesterol levels might increase again if you stop taking Rosuvastatin.

- If you forget to use it

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

- If you use too much (overdose)

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

5. While you are using it

- Things you must do

Take your medication daily as prescribed.

- Things you must not do

Do not take other medications together with Rosuvastatin without speaking to your doctor or pharmacist first.

- Things to be careful of

Pregnancy and breast-feeding:

Do not take Rosuvastatin if you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking Rosuvastatin stop taking it immediately and tell your doctor.

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

Driving and using machines:

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

6. Side effects

Like all medicines, Rosuvastatin 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 Rosuvastatin 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 Rosuvastatin 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 Rosuvastatin, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Common side effects (these may affect between 1 in 10 and 1 in 100 patients):

- Headache
- Muscle pain
- General feeling of weakness
- Constipation
- Dizziness
- Feeling sick
- An increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your Rosuvastatin tablets (only Rosuvastatin 40 mg)

Uncommon side effects (these may affect between 1 in 100 and 1 in 1,000 patients):

- Skin rash
- Itching
- Hives
- An increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your Rosuvastatin tablets (only Rosuvastatin 5 mg, 10 mg and 20 mg).

Rare side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, stop taking Rosuvastatin and seek medical help immediately.
- Muscle damage in adults – as a precaution, stop taking Rosuvastatin and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected.

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- A severe stomach pain (inflamed pancreas).
- Increase in liver enzymes in the blood.

Very rare side effects (these may affect less than 1 in 10,000 patients):

- Jaundice (yellowing of the skin and eyes).
- Hepatitis (an inflamed liver).
- Joint pain.
- Memory loss.

Side effects of unknown frequency and reported less frequently than 1% may include:

- Sleep disturbances, including insomnia (difficulty in sleeping) and nightmares.
- Depression.

Traces of blood in your urine (generally temporary and not associated with worsening kidney function). Increases in HbA1c (a measure of the average amount of sugar in your blood over time).

If any of the side effects become troublesome, or if you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the websitenpra.gov.my

[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and disposal of Rosuvastatin

- Storage

Keep out of the reach and sight of children.

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

Do not store above 30°C.

- Disposal

Remember to return any unused medicine to your pharmacist (chemist).

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.

8. Product description

- What it looks like

Rosuvastatin comes in two tablet strengths:

- Rosuvastatin film-coated tablets 10 mg are Pink, round, biconvex, film coated tablets, debossed with "C10" on one side and plain on other side.
- Rosuvastatin film-coated tablets 20 mg are Pink, round, biconvex, film coated tablets, debossed with "C20" on one side and plain on other side.

Rosuvastatin 10 mg and 20 mg tablets come in Blister pack (Alu/Alu) of 10 tablets. Such 3 blister pack placed in a carton with leaflet.

- Ingredients

Active ingredient:

The active substance in Rosmi is rosuvastatin. Rosuvastatin film-coated tablets contain rosuvastatin calcium equivalent to 10 mg, or 20 mg of rosuvastatin.

Inactive ingredients:

The other ingredients are: Lactose Monohydrate (Super Tab 11SD), Microcrystalline Cellulose (Avicel PH200), Sodium Hydrogen Carbonate, Crospovidone (Kollidon CL), Magnesium Stearate, Opadry II Pink 33K540006.

9. Manufacturer

Cadila Pharmaceuticals Ltd.
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Dholka- 382 225,
Dist: Ahmedabad,
Gujarat State,
India.

10. Product Registration Holder

Pahang Pharmacy Sdn. Bhd. Lot
5979, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia.

11. Date of revision

August 2023

12. Serial number:

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