

ROSUCOR TABLET

Rosuvastatin Calcium (10mg)

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What Rosucor is used for

Rosucor is used to lower high cholesterol levels. As changing your diet and taking more exercise were not enough to correct your cholesterol levels.

How Rosucor works

Rosucor contains an active ingredient, rosuvastatin.

Rosuvastatin belongs to a group of medicines called statins.

It works by helping to block your body's production of 'bad' cholesterol in the liver. It also improves your body's ability to remove it from your blood.

Before you use Rosucor

- When you must not use it

Do not take Rosucor:

- If you are allergic (hypersensitive) to Rosuvastatin, or to any of the ingredients;
- 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.
- Do not take Rosucor if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Rosucor, stop taking it immediately and contact your doctor.
- If you are Breast-feeding; ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy and lactation

Do not take Rosucor if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Rosucor if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Take special care:

- If you have problems with your kidneys.
- If you have problems with your liver.
- 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.
- If you are allergic to other statins.
- If you regularly drink large amounts of alcohol.
- Talk to your doctor or pharmacist before taking Rosucor 10:
- If you have or have any 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 if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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

- Ciclosporin (used for example, after organ transplants).
- Protease inhibitors including ritonavir, atazanavir, lopinavir and/or tipranavir (antiviral medicines used to treat HIV/AIDS and hepatitis).
- Fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe and niacin).
- Indigestion remedies (used to neutralise acid in your stomach).
- Erythromycin and fusidic acid (antibiotic).

- The effects of these medicines could be changed by Rosucor or they could change the effects of Rosucor:
 - Warfarin (or any other medicine used for thinning the blood).
 - Oral contraceptive/hormone replacement therapy (HRT).

How to use Rosucor

- How much to use

The usual start dose is Rosucor 5-10 mg once daily and the majority of patients are controlled at this dose. A dose adjustment to 20 mg can be made after 4 weeks, if necessary. Your doctor will decide the dose that suits you base on your condition.

- When to use it

Rosucor may be given at any time of day, with or without food.

- How long to use it

Continue taking Rosucor for as long as your doctor recommends

- 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)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Rosuvastatin.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.
- Continue your diet control and exercise while you are taking Rosucor.

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- Things you must not do

- Do not stop taking your medicine unless your doctor tells you to.
- Do not take any new medicines without consulting your doctor.
- Do not give Rosucor to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of Driving and using machines

Rosuvastatin is not expected to affect the ability to drive or use machines. If the tablets make you feel sick, dizzy or drowsiness or tired do not drive or use machines and contact your doctor immediately.

Side effects

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

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

- Hypersensitivity reactions including angioedema (severe swelling of the mucous membrane).
- Headache, dizziness, polyneuropathy (Symptoms appear especially affected feet and hands, causing weakness, loss of sensation, pins-and-needle sensations or burning pain).
- Constipation, nausea, abdominal pain, inflammation of pancreas, diarrhoea
- Pruritus (Itching), rash, urticaria (kind of skin rash).
- Stevens-Johnson syndrome (disorder of skin and mucous membranes).
- Aching muscles, muscle tenderness or weakness not caused by exercise, particularly if you also have a fever or generally feel unwell, rhabdomyolysis (rapid destruction of skeletal muscle),

joint pain.

- Abnormal physical weakness or lack of energy, protein or blood in the urine.
- Jaundice, hepatitis (inflammation of liver), increase in liver enzymes.
- Memory loss, forgetfulness, memory impairment, confusion.
- High sugar in the blood, increased fasting blood sugar level.
- Unknown frequency:
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used in 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 period of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

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.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects (ConSERF) or Vaccine (AEFI)).

Storage and Disposal of Rosucor

- Storage

- Store below 30°C.
- Protected from moisture.

- Keep out of reach of children.

- 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

White to off white colored, round, biconvex, film coated tablets with break line on one side and plain on other side.

- Ingredients

Active ingredient:

- Rosuvastatin Calcium.

Inactive ingredients:

- Lactose Monohydrate.
- Microcrystalline cellulose.
- Crospovidone XL-10.
- Magnesium stearate.
- Hypromellose.
- Triacetin.

- MAL number:

MAL10080066AZ

Manufacturer

Torrent Pharmaceuticals Limited
Indrad 382 721, Tal: Kadi,
City: Indrad, Dist. Mehsana, India

Product Registration Holder

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Date of revision

17/06/2025

Serial Number

NPRA(R2/1)250910/1536