

ROXATIN TABLET

Rosuvastatin Calcium (10mg/20mg)

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What Roxatin Tablet is used for

You have been prescribed Roxatin because:

- a) you have a high cholesterol level. This means you are at risk of getting a heart attack or stroke. You have been advised to take a statin, because changing your diet and taking more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking Roxatin.
- b) you have other factors that increase your risk of getting a heart attack, stroke or related health problems. Heart attack, stroke and other problems can be caused by a disease called atherosclerosis. Atherosclerosis is due to build-up of fatty deposits in your arteries.

How Roxatin Tablet works

Roxatin 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, including 'bad' cholesterol (LDL- C) and 'good' cholesterol (HDL- C).

- Roxatin can reduce the 'bad' cholesterol and increase the 'good' cholesterol.
- 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.

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 getting a heart attack, a stroke or related health problems.

Before you use Roxatin Tablet

- When you must not use it

Do not take Roxatin if:

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

Check with your doctor or pharmacist before taking Roxatin Tablet if you:

- have problems with your kidneys.
- 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.
- have problems with your liver.
- regularly drink large amounts of alcohol.

- are of Asian origin.
- take medicines used to fight the HIV infection (e.g lopinavir/ritonavir).
- have severe respiratory failure.
- your thyroid gland is not working properly.
- take other medicines called fibrates to lower your cholesterol.
- have diabetes.
- have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (disease causing eye muscle weakness) as statins may sometimes aggravate the condition.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Roxatin Tablet.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

- 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).
- 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).
- Antacids (used to neutralise acid in your stomach).
- Erythromycin (an antibiotic), or medications used to fight the HIV infection – please see "*Before you start use it*".

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- Fostamatinib (used to treat low platelet counts).
- Febuxostat (used to treat and prevent high blood levels of uric acid).
- Teriflunomide (used to treat multiple sclerosis).

The effects of these medicines could be changed by Roxatin or they could change the effects of Roxatin.

This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

If you are not sure, please talk to your doctor or pharmacist before using Roxatin tablet.

How to use Roxatin Tablet

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

- How much to use

Starting dose:

The usual recommended starting dose of Roxatin Tablet is 10 mg once daily. However, a starting dose of 5 mg once daily would be considered for certain groups of patients or patients requiring less aggressive cholesterol reductions.

Your doctor will choose your starting dose depending upon:

- Your cholesterol level.
- Your risk of suffering a heart attack or stroke.
- Whether you have factors that may make you 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 Roxatin that is right for you. There will be a

gap of four weeks between every dose adjustment.

In adults, the maximum daily dose of Roxatin 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.

- When to use it

Take as directed by your doctor or pharmacist.

- How long to use it

Continue taking Roxatin Tablet for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do 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 or anyone else may have used 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 Roxatin Tablet

- 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 using Roxatin Tablet.

Take Roxatin Tablet only with a doctor's prescription.

- Things you must not do

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

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

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

- Things to be careful of

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

Driving and using machines

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

Side effects

Like all medicines, Roxatin Tablet can cause side effects, although not everybody gets them.

The list below includes the side effects of your medicine.

Blood and lymphatic system disorders

Rare: Low platelet levels (Thrombocytopenia)

Immune system disorders

Rare: Hypersensitivity reactions including angioedema (severe swelling of the mucous membrane)

Endocrine disorders

Common: Diabetes mellitus

Psychiatric disorders:

Not known: Depression

Nervous system disorders

Common: Headache, dizziness

Very rare: Nerve damage, memory loss

Not known: Damage to peripheral nerves, sleep disturbances (including

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insomnia and nightmares), myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing)

Respiratory, thoracic and mediastinal disorders

Not known: Cough, breathing problem

Gastrointestinal disorders

Common: Constipation, nausea, abdominal pain

Rare: Pancreatitis

Not known: Diarrhoea

Hepatobiliary disorders

Rare: Increased liver enzymes in the blood

Very rare: Jaundice, hepatitis

Skin and subcutaneous tissue disorders

Uncommon: Itchiness, rash, hives

Not known: Stevens-Johnson syndrome, Drug reaction with eosinophilia and systemic symptoms (DRESS)

Musculoskeletal and connective tissue disorders

Common: Muscle pain

Rare: Muscle damage and injury

Very rare: Arthralgia

Not known: Immune-mediated necrotizing myopathy

Renal and urinary disorders

Very rare: Blood in urine

Reproductive system and breast disorders:

Very rare: Enlargement of a man's breast

General disorders and administration site conditions

Common: Lack of energy

Not known: Oedema

Eye disorder

Not known: Ocular myasthenia (a disease-causing eye muscle weakness).

The following adverse events have been reported with some statins:

- Sexual dysfunction.

- Exceptional cases of interstitial lung disease, especially with long-term therapy.

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

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

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

If any of the side effects get serious, or if you notice 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 website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Roxatin Tablet

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Store in the original package.

Do not take the tablets after the expiry date shown on the pack and blisters.

- 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

Roxatin Tablet 10 mg

Round (7 mm), light brick red biconvex film-coated tablet with Pharmaniaga icon on one side and plain on the other.

Roxatin Tablet 20 mg

Round (9.5 mm), light brick red, biconvex film-coated tablet with Pharmaniaga icon on one side and plain on the other.

Ingredients

Roxatin Tablet 10 mg:

- *Active ingredient:* Film-coated tablets contain rosuvastatin calcium equivalent to 10 mg of rosuvastatin.
- *Inactive ingredient(s):* Lactose Monohydrate, Microcrystalline Cellulose, Butylated Hydroxyanisole, Sodium Bicarbonate, Crospovidone, Magnesium Stearate, Opadry II Pink and Purified Water.

Roxatin Tablet 20 mg:

- *Active ingredients:* Film-coated tablets contain rosuvastatin calcium equivalent to 20 mg of rosuvastatin.
- *Inactive ingredient(s):* Lactose Monohydrate, Microcrystalline Cellulose, Butylated Hydroxyanisole, Sodium Bicarbonate, Crospovidone, Magnesium Stearate, Opadry II Pink and Purified Water.

- MAL numbers

Roxatin Tablet 10 mg:

MAL22016014AZ

Roxatin Tablet 20 mg:

MAL22016015AZ

Product Registration Holder and Manufacturer

Pharmaniaga Manufacturing Berhad (198001006232), No. 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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Date of revision

22/06/2026

Serial Number

NPRA(R2/1)260610/00076