

ROSUVAGEN ROSUVASTATIN FILM-COATED TABLET

Rosuvastatin Calcium (10mg, 20mg)

What is in this leaflet

1. What Rosuvagen Rosuvastatin is used for
2. How Rosuvagen Rosuvastatin works
3. Before you use Rosuvagen Rosuvastatin
4. How to use Rosuvagen Rosuvastatin
5. While you are using Rosuvagen Rosuvastatin
6. Side Effects
7. Storage and disposal of Rosuvagen Rosuvastatin
8. Product description
9. Manufacturer
10. Product registration holder
11. Date of revision
12. Serial number

What Rosuvagen Rosuvastatin is used for

Rosuvagen Rosuvastatin belongs to a group of medicines called statins.

You have been prescribed Rosuvagen Rosuvastatin because:

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 Rosuvagen Rosuvastatin. Or 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 Rosuvagen Rosuvastatin works

Rosuvagen 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).

- Rosuvagen 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.

Before you use Rosuvagen Rosuvastatin

-When you must not use it

- If you have ever had an allergic reaction to Rosuvagen Rosuvastatin or similar medicines, or to any of its ingredients. Rosuvagen 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 Rosuvagen 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

Talk to your doctor or pharmacist before taking Rosuvagen Rosuvastatin.

- 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 previous
- history of muscle problems when taking other cholesterol-lowering medicines.
- If you regularly drink large amounts of alcohol.
- If you take other medicines called fibrates to lower your cholesterol.
- If you take medicines used to fight the HIV infection e.g. lopinavir/ritonavir, please see Taking other medicines.
- You are of Asian origin.
- You have severe respiratory failure.
- Your thyroid gland is not working properly.
- You take other medicines called fibrates to lower your cholesterol.
- You have diabetes.

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

-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.

Some medicines and Rosuvagen Rosuvastatin Tablet may interfere with each other. Tell your doctor if

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you are taking any of the following:

- Ciclosporin (used for example, after organ transplants).
- Lopinavir/ritonavir (used to fight the HIV infection).
- Fibrates (e.g gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (e.g ezetimibe).
- Antacids (used to neutralise acid in your stomach).
- Fusidic acid (an antibiotic).
- Erythromycin (an antibiotic).
- Warfarin (or any other drug used for thinning the blood).
- Oral contraceptive
- Hormone replacement therapy

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

If you are not sure, please talk to your doctor or pharmacist before use Rosuvagen Rosuvastatin tablet.

How to use Rosuvagen Rosuvastatin

-How much to use

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.

Starting dose:

The usual recommended starting dose of Rosuvagen Rosuvastatin 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 Rosuvagen 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 Rosuvagen 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.

-When to use it

Take as directed by your doctor or pharmacist.

-How long to use it

Continue taking Rosuvagen Rosuvastatin 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 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.

-Things you must not do

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

Do not take any new medicines without consulting your doctor.

Do not give Rosuvagen Rosuvastatin 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.

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

Side effects

Like all medicines, Rosuvagen Rosuvastatin can cause side effects, although not everybody gets them.

The below list 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

Nervous system disorders

Common: Headache, dizziness.

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Very rare: Nerve damage, memory loss.

Not known: Damage to peripheral nerves, sleep disturbances (including insomnia and nightmares).

Respiratory, thoracic and mediastinal disorders

Not known: Cough, breathing problem

Gastrointestinal disorders

Common: Constipation, nausea, abdominal pain.

Rare: Pancreatitis.

Not known: Diarrhea.

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.

Musculoskeletal and connective tissue disorders

Common: Muscle pain.

Rare: Muscle damage.

Not known: Immune-mediated necrotizing myopathy.

Renal and urinary disorders

Very rare: Traces of blood in urine.

Reproductive system and breast disorders

Very rare: Enlargement of a man's breast.

General disorders

Common: Lack of energy.

Not known: Oedema.

The following adverse events have been reported with some statins:

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

If you have muscle problems that do not get away even after your doctor

has told you to stop taking Rosuvagen Rosuvastatin, 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 taking this medicine. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

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 Rosuvagen

-Storage

Store below 30°C.

Keep this medicine out of the sight and reach of children.

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

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Product Description

-What it looks like

Rosuvagen Rosuvastatin 10 mg Film-Coated Tablet:

Pink, oblong, and convex film-coated tablets.

Rosuvagen Rosuvastatin 20 mg Film-Coated Tablet:

Pink, round and convex film-coated tablets.

-Ingredients

Active ingredient:

- Rosuvastatin Calcium

Inactive ingredients:

- Lactose Anhydrous
- Microcrystalline Cellulose
- Crospovidone
- Copovidone
- Talc
- Colloidal Anhydrous Silica
- Sodium Stearyl Fumarate
- Opadry II 30K34297 pink
- Lactose monohydrate
- Hypromellose
- Titanium dioxide Triacetin
- Red iron oxide

-MAL number:

Rosuvagen Rosuvastatin 10 mg Film-Coated Tablet:
MALXXXXXXXXXX

Rosuvagen Rosuvastatin 20 mg Film-Coated Tablet:
MALXXXXXXXXXX

Manufacturer

Atlantic Pharma – Produções Farmacêuticas, S.A.
R. da Tapada Grande, nº2, Abrunheira
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Product Registration Holder

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