

ROSUVASTATIN STELLA FILM-COATED TABLET 10MG

Rosuvastatin (as rosuvastatin calcium) 10 mg

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What Rosuvastatin STELLA Film-Coated Tablet 10mg is used for

You have been prescribed Rosuvastatin STELLA Film-Coated Tablet 10mg 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 Rosuvastatin STELLA Film-Coated Tablet 10mg. Or
- 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 Rosuvastatin STELLA Film-Coated Tablet 10mg works

This medicine 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).

- This medicine 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 Rosuvastatin STELLA Film-Coated Tablet 10mg

- When you must not use it

Do not take Rosuvastatin STELLA Film-Coated Tablet 10mg:

- If you have ever had an allergic reaction to Rosuvastatin STELLA Film-Coated Tablet 10mg or similar medicines, or to any of its ingredients. This medicine 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 breastfeeding. If you become pregnant while taking Rosuvastatin STELLA Film-Coated Tablet 10mg stop taking it immediately and tell your doctor.
- If you have liver disease.
- If you have repeated or unexplained muscle aches or pains.
- If you are taking cyclosporine.

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

Before you take Rosuvastatin STELLA Film-Coated Tablet 10mg, tell your doctor or pharmacist if:

- You have problems with your kidneys.
- 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.
- You have problems with your liver.
- If you regularly drink large amounts of alcohol.
- You are of Asian origin.
- You take medicines used to fight the HIV infection (e.g lopinavir/ritonavir).
- 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 over 70 (as your doctor needs to choose the right start dose of rosuvastatin to suit you).
- 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

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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 Rosuvastatin STELLA Film-Coated Tablet 10mg.

- **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 Rosuvastatin STELLA Film-Coated Tablet 10mg may interfere with each other. Tell your doctor if you are taking any of the following:

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

The effects of these medicines could be changed by Rosuvastatin STELLA Film-Coated Tablet 10mg or they could change the effects of Rosuvastatin STELLA Film-Coated Tablet 10mg.

If you are not sure, please talk to your doctor or pharmacist before use Rosuvastatin STELLA Film-Coated Tablet 10mg.

How to use Rosuvastatin STELLA Film-Coated Tablet 10mg

** Please consider other suitable oral preparation for recommended dosages other than 10 mg.*

- **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 Rosuvastatin STELLA Film-Coated Tablet 10mg 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 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.

- **When to use it**

Take as directed by your doctor or pharmacist.

- **How long to use it**

Continue taking Rosuvastatin STELLA Film-Coated Tablet 10mg 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 Rosuvastatin STELLA Film-Coated Tablet 10mg

- **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 Rosuvastatin STELLA Film-Coated Tablet 10mg to anyone else, even if they have the same symptoms or condition as you.

- **Things to be careful of**

Pregnancy and breast-feeding:

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Do not take Rosuvastatin STELLA Film-Coated Tablet 10mg if you are pregnant, trying to become pregnant or are breast-feeding. If you become pregnant while taking Rosuvastatin STELLA Film-Coated Tablet 10mg stop taking it immediately and tell your doctor.

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

Driving and using machines:

Rosuvastatin STELLA Film-Coated Tablet 10mg is not expected to affect your ability to drive a car or to operate machinery.

Side effects

Like all medicines, Rosuvastatin STELLA Film-Coated Tablet 10mg 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.

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

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

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.

Musculoskeletal and connective tissue disorders
Common: Muscle pain.
Rare: Muscle damage.
Very rare: Joint pain.
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.
- Tendon disorders, sometimes complicated by rupture.

If you have muscle problems that do not get away even after your doctor has told you to stop taking Rosuvastatin STELLA Film-Coated Tablet 10mg, 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.

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.

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 Rosuvastatin STELLA Film-Coated Tablet 10mg

- Storage

The expiry date of this pack is printed on the box. Do not use this pack after this date. Keep all medicines out of reach of children.

Store in the original package.

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.

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Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Serial Number

NPRA(R2/2)250924/01547

Product description

- What it looks like

Light red, round-shaped, film-coated tablet, biconvex, breakable line on one side and plain on the other side.

Ingredients

Active ingredient:

Each film-coated tablet contains 10 mg of rosuvastatin (as rosuvastatin calcium).

Inactive ingredient(s):

Lactose monohydrate, microcrystalline cellulose, dicalcium phosphate anhydrous, crospovidone, magnesium stearate, hypromellose, polyethylene glycol 6000, talc, titanium dioxide, red iron oxide.

MAL No.:

MAL12095088AZ

Manufacturer:

**STELLAPHARM J.V. CO., LTD. -
BRANCH 1**

(A Joint Venture Company of Auxilto GmbH, Germany)

No. 40 Tu Do Avenue, Vietnam-Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam.

Product Registration Holder

Stadpharm Sdn. Bhd.

E-9-01, Oasis Square, Ara Damansara, No. 2, Jalan PJU 1A/7A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

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