

VASTINOR TABLET

Rosuvastatin (5mg, 10mg, 20mg)

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What Vastinor Tablet is used for

You have been prescribed Vastinor because:

- You have a high cholesterol level. This means you are at risk from 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 Vastinor, OR
- You have other factors that increase your risk of having 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 Vastinor Tablet works

Rosuvastatin is the drug classified as statins. It works by blocking HMG-CoA enzyme that involves in cholesterol production. Therefore, less cholesterol is made and reduces cholesterol levels in the blood.

Before you use Vastinor Tablet

- When you must not use it

Do not take this medicine if you:

- are allergic to Rosuvastatin or any other ingredients of this medicine
- taking cyclosporine
- have active liver disease.
- have severe renal impairment
- have repeated or unexplained muscle aches or pains.
- pregnant or plan to become pregnant.
- are breast-feeding or plan to start breast-feeding.

- Before you start to use it

Tell your doctor or pharmacist:

- If you are pregnant or plan to become pregnant.
- If you are breast-feeding or plan to start breast-feeding.
- 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 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.
- If you have high blood sugar or raised HbA1c.
- 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 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 or pharmacist if you are taking any of the following:

Ciclosporin (used for example, after organ transplants), warfarin (or any other drug used for thinning the blood), fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe), indigestion remedies (used to neutralise acid in your stomach), erythromycin (an antibiotic), or medications used to fight the HIV infection – please see *Take special care with Vastinor*. The effects of these medicines could be changed by

Vastinor or they could change the effects of Vastinor.

How to use Vastinor 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

In adults' treatment with Vastinor 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.
- 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 Vastinor that is right for you. There will be a gap of four weeks between every dose adjustment.
- In adults the maximum daily dose of Vastinor 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. Vastinor should not be given to children younger than 10 years.

- When to use it

Use as directed by your doctor or pharmacist.

Taking your tablets

- Swallow each tablet whole with a drink of water.
- Take Vastinor once daily. You can take it at any time of the day with or without food.
- 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 Vastinor that is right for you.

- How long to use it

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

- 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 Vastinor Tablet- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Vastinor Tablet.

Tell your doctor immediately if you become pregnant while using this medication.

Take Vastinor Tablet only with a doctor's prescription.

- Things you must not do

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

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

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

- Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how Vastinor Tablet affects you.

Side effects

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

Possible side effects are:

- Headache
- Muscle pain
- Stomach pain
- General feeling of weakness
- Constipation
- Dizziness
- Myasthenia gravis (a disease-causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease-causing eye muscle weakness).

If you have muscle problems that do not go away even after your doctor has told you to stop taking Vastinor, 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.

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 Vastinor Tablet- Storage

Store below 30°C.

Keep out of the reach of the children.

Do not use this medicine after expiry date.

- 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

Vastinor Tablet 5mg:

Pink, round, normal convex film-coated tablet, with 'XS' marking on one side and plain on reverse, 6mm in diameter.

Vastinor Tablet 10mg:

Pink, round, normal convex film-coated tablet, with 'XS' marking on one side and plain on reverse, 7mm in diameter.

Vastinor Tablet 20mg:

Pink, round, normal convex film-coated tablet, with XSP logo on one side and plain on reverse, 9mm in diameter.

- Ingredients

- Active ingredient(s)
Rosuvastatin (As Rosuvastatin Calcium)

- Inactive ingredients

- Magnesium Oxide
- Lactose
- Microcrystalline Cellulose
- Colloidal Silicon Dioxide
- Croscopovidone
- Colour Lakes Ponceau 4R
- Magnesium Sterate
- Hydroxypropyl Methylcellulose (HPMC) Compound Mix
- Purified Water

- MAL number(s):

Vastinor Tablet 5mg:
MAL19036024AZ

Vastinor Tablet 10mg:
MAL19036025AZ

Vastinor Tablet 20mg:
MAL19036026AZ

Manufacturer and Product

Registration Holder

Xepa-Soul Pattinson (Malaysia) Sdn Bhd
1-5 Cheng Industrial Estate,
75250 Melaka, Malaysia.

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