

ROVASTIN FILM COATED TABLET

Rosuvastatin 5mg and 10mg

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What Rovastin is used for

Rovastin belongs to a group of medicines called statins. You have been prescribed Rovastin 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 Rovastin.

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 it works

Most of the cholesterol in your blood is made in the liver. Rovastin works by reducing cholesterol in 2 ways:

- Rovastin blocks an enzyme in the liver causing the liver to make less cholesterol
- Rovastin increases the uptake and breakdown by the liver of cholesterol already in the blood.

Along with diet, Rovastin lowers bad (LDL) cholesterol and slows plaque buildup in arteries as part of a treatment plan to lower cholesterol to goal.

You may see results for lowering your bad cholesterol as soon as 2-4 weeks after starting Rovastin. People can have different responses to the same medicine, so your results may vary.

Before you use Rovastin

- When you must not use it
Do not take Rovastin:

- If you have ever had an allergic reaction to Rovastin or similar medicines, or to any of its ingredients. Rovastin 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 Rovastin stop taking it immediately and tell your doctor.
- 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 drug called ciclosporin (used, for example, after organ transplants)
- 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

Take special care with Rovastin and tell your doctor or pharmacist:

- 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 a 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
- 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 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. The effects of these medicines could be changed by Rovastin or they could change the effects of Rovastin.

How to use Rovastin

- 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

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

- When to use it

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Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Rovastin 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 Rovastin

- 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 Rovastin.

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

- 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 Rovastin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Pregnancy and breastfeeding

Do not take Rovastin if you are pregnant, trying to become pregnant or are breastfeeding. If you become pregnant while taking Rovastin stop taking it immediately and tell your doctor.

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

Driving and using machines

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

Side effects

Like all medicines, Rovastin 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.

Stop taking Rovastin and seek medical help immediately if you have any of the following allergic reactions:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- Severe itching of the skin (with raised lumps).

Also, stop taking Rovastin and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than you might expect. Muscle symptoms are more common in children and adolescents than in adults. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as *rhabdomyolysis*.

Common possible side effects (these may affect between 1 in 10 and 1 in 100 patients):

- Headache
- Stomach pain
- Constipation
- Feeling sick
- Muscle pain
- Feeling weak
- Dizziness
- An increase in the amount of protein in the urine -this usually returns to normal on its own without having to stop taking your Rovastin tablets (only Rovastin 40 mg)
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

Uncommon possible side effects (these may affect between 1 in 100 and 1 in 1,000 patients):

- Rash, itching or other skin reactions
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rovastin tablets (only Rovastin 5 mg, 10 mg and 20mg).

Rare possible side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, then stop taking Rovastin and seek medical help immediately
- Muscle damage in adults – as a precaution, stop taking Rovastin and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected
- A severe stomach pain (inflamed pancreas)
- Increase in liver enzymes in the blood

Very rare possible side effects (these may affect less than 1 in 10,000 patients):

- Jaundice (yellowing of the skin and eyes)
- Hepatitis (an inflamed liver)
- Traces of blood in your urine
- Damage to the nerves of your legs and arms (such as numbness)
- Joint pain
- Memory loss
- Breast enlargement in men (gynaecomastia)

Side effects of unknown frequency may include:

- Diarrhoea (loose stools)
- Stevens-Johnson syndrome (serious blistering condition of the skin, mouth, eyes and genitals)
- Cough
- Shortness of breath
- Oedema (swelling)
- Sleep disturbances, including insomnia and nightmares
- Sexual difficulties
- Depression
- Breathing problems, including persistent cough and/or shortness of breath or fever

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- Tendon injury
- Muscle weakness that is Constant
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when 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 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 calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Rovastin

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- 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

Rovastin 5mg Film Coated Tablet:
Round, yellow film coated tablets,
engraved with $\frac{CCP}{231}$ on one side and plain on the reverse.

Rovastin 10mg Film Coated Tablet:
Round, pink filmcoated tablets,
engraved with $\frac{CCP}{173}$ on one side and plain on the reverse.

- Ingredients

- Active Ingredient
 - Rosuvastatin
- Inactive Ingredients
 - Lactose monohydrate, Sodium bicarbonate, Crospovidone, Colloidal Silicon Dioxide, Microcrystalline Cellulose,

Polyvinyl pyrrolidone K30,
Magnesium Stearate,
Hydroxypropyl methylcellulose
E6, P.E.G. 6000, Titanium Dioxide,
Yellow Ferric Acid, Red Iron
Oxide.

- MAL numbers:

Rovastin 5mg Film Coated Tablet:

MAL19016039ACZ

Rovastin 10mg Film Coated Tablet

MAL18126103ACZ

Manufacturer

China Chemical & Pharmaceutical Co.,
Ltd.

182-1, Keng Tze Kou, Hsinfong,
Hsinchu, Taiwan R.O.C.

Product Registration Holder

Abio Marketing Sdn Bhd
No. 2, Jalan SS 13/5, 47500
Subang Jaya, Selangor,
Malaysia.

Date of Revision

11/6/2025

Serial Number

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