

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ROSUVASTATIN VIATRIS

Rosuvastatin Film coated tablet 5 mg, 10 mg, 20 mg & 40 mg



What is in this leaflet

Please read this leaflet carefully before you start taking ROSUVASTATIN VIATRIS.

This leaflet answers some common questions about ROSUVASTATIN VIATRIS.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ROSUVASTATIN VIATRIS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ROSUVASTATIN VIATRIS is used for

ROSUVASTATIN VIATRIS is used to treat

- High levels of "bad" cholesterol

It reduces the

- risk of heart attacks
- risk of strokes
- need for a heart bypass

ROSUVASTATIN VIATRIS contains the active ingredient rosuvastatin. It belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as 'statins').

It works by lowering the "bad" cholesterol and raising the "good" cholesterol when exercise and changes to diet are not enough on their own. It also lowers the risk of heart attacks and strokes.

Everyone has cholesterol and triglycerides in their blood. They are fatty substances needed by the body for many things. Triglycerides are an energy source for the body. Cholesterol is used for such things as building cells, making bile acids (which help to digest food) and making some hormones.

There are different types of cholesterol. Too much of the "bad" cholesterol (LDL) can block the blood vessels that supply your heart and brain with blood, and can cause heart attack, angina and stroke. The "good" cholesterol (HDL) helps to remove the bad cholesterol from the blood vessels. High levels of triglycerides can be associated with a low level of "good" cholesterol and may increase the risk of heart disease.

Cholesterol is present in many foods and is also made by your body. While you are taking ROSUVASTATIN VIATRIS, you should reduce saturated fats, trans fats and cholesterol in your diet, control your weight and exercise regularly.

High cholesterol is also more likely to occur with certain diseases or if you have a family history of high cholesterol.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

Before you take ROSUVASTATIN VIATRIS

When you must not take it

Do not take ROSUVASTATIN VIATRIS if you are pregnant or intend to become pregnant. It may affect your developing baby if you take it during pregnancy. Ask your doctor about effective methods of contraception. If you become pregnant, stop taking ROSUVASTATIN VIATRIS as soon as you find out and see your doctor immediately.

Do not take ROSUVASTATIN VIATRIS if you are breastfeeding. The active ingredient in rosuvastatin may pass into breast milk and there is a possibility that your baby may be affected.

Do not take ROSUVASTATIN VIATRIS if you have active liver disease.

Do not take ROSUVASTATIN VIATRIS 40 mg if you have:

- low thyroid hormone levels (hypothyroidism)
- a personal or family history of hereditary muscular disorders
- a previous history of muscular problems from using other lipid-lowering agents
- a history of very heavy alcohol use
- Asian heritage
- been prescribed another class of lipid lowering agent called a fibrate
- severe kidney impairment

- situations that may increase ROSUVASTATIN VIATRIS blood levels

It may not be safe for you to take ROSUVASTATIN VIATRIS if you have any of these conditions. Your doctor may do a blood test to check if you have any problems and may adjust the dose of ROSUVASTATIN VIATRIS.

Do not take ROSUVASTATIN VIATRIS if you have an allergy to:

- any medicine containing rosuvastatin
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines ('statins') such as simvastatin, pravastatin, atorvastatin, fluvastatin

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

- you have high blood sugar levels or raised HbA1c

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- kidney problems
- low thyroid hormone levels (hypothyroidism)

- a personal or family history of muscle disorders
- a history of muscle problems from using other lipid lowering agents

It may not be safe for you to take ROSUVASTATIN VIATRIS if you have any of these conditions. Your doctor may do a blood test to check if you have any problems and may adjust your dosage. Tell your doctor if you have unexplained aches or pains in your muscles or have a history of muscle pain or if you have muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

Tell your doctor if you regularly drink large amounts of alcohol. Excessive alcohol consumption may not be safe in patients taking ROSUVASTATIN VIATRIS.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking ROSUVASTATIN VIATRIS.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking ROSUVASTATIN VIATRIS.

Some medicines may interfere with ROSUVASTATIN VIATRIS. These include:

- ciclosporin (used for example, after organ transplant)
- warfarin, clopidogrel (or any other medicine used to stop blood clots)
- gemfibrozil, ezetimibe, fenofibrates/fibric acid derivatives (used to lower blood lipids)

- antiviral medications such as atazanavir, glecaprevir, darunavir, lopinavir, ritonavir sofosbuvir, tipranavir, velpatasvir, voxilaprevir, grazoprevir, elbasvir, ombitasvir, paritaprevir, dasabuvir, glecaprevir, pibrentasvir, simeprevir (used to fight infections including infection with HIV or hepatitis)
- eltrombopag a medicine used to treat blood disorders
- dronedarone a medicine used to treat irregular heart beats
- regorafenib and darolutamide (used to treat cancer)
- antacids (medicines used to treat heartburn and indigestion). ROSUVASTATIN VIATRIS can be taken 2 hours before or 2 hours after taking an antacid.
- fusidic acid, itraconazole, erythromycin (medicines used to treat some infections)
- herbal products (such as baicalin)

These medicines may be affected by ROSUVASTATIN VIATRIS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ROSUVASTATIN VIATRIS

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or bottle, ask your doctor or pharmacist for help.

How much to take

The usual starting dose is one 10 mg tablet taken once daily. Depending on your condition and ethnic background, your doctor will decide the most appropriate starting dose for you.

Your doctor will monitor your cholesterol and triglyceride levels during your treatment, and, if needed, may increase your ROSUVASTATIN VIATRIS dose to 20 mg once daily. For most patients a maximum 20 mg ROSUVASTATIN VIATRIS daily dose is sufficient to treat their condition.

A small number of patients may need to further increase their ROSUVASTATIN VIATRIS dose to 40 mg once daily, for example patients whose high cholesterol is hereditary. Your doctor will advise you on the dose that is right for your condition. The daily dose of ROSUVASTATIN VIATRIS must not exceed 40 mg daily.

Do not increase or adjust your ROSUVASTATIN VIATRIS dose yourself.

How to take it

Swallow the tablets whole with a full glass of water.

Do not halve the tablet.

When to take it

Take your medicine once a day at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it. ROSUVASTATIN VIATRIS can be taken at any time of the day.

It does not matter if you take this medicine before or after food.

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of ROSUVASTATIN VIATRIS.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

ROSUVASTATIN VIATRIS helps lower your blood cholesterol and triglycerides. If you stop taking ROSUVASTATIN VIATRIS, your cholesterol and triglycerides levels may rise again. You may have to take cholesterol lowering medicines for the rest of your life.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking ROSUVASTATIN VIATRIS

Things you must do

Have your blood cholesterol and triglycerides checked when your doctor says so to make sure ROSUVASTATIN VIATRIS is working.

You also need to follow your doctor's dietary advice, control your weight and exercise regularly.

Stop taking ROSUVASTATIN VIATRIS and contact your doctor immediately if you become pregnant while you are taking ROSUVASTATIN VIATRIS.

If you become seriously ill or go into hospital, tell the doctor or nurse that you are taking ROSUVASTATIN VIATRIS.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ROSUVASTATIN VIATRIS.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take ROSUVASTATIN VIATRIS to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen, or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how ROSUVASTATIN VIATRIS affects you. This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do

anything else that could be dangerous. Children should be careful climbing trees and riding bicycles.

Be careful when drinking alcohol while you are taking this medicine.

Excessive alcohol consumption may not be safe in patients taking ROSUVASTATIN VIATRIS. If you drink alcohol, dizziness may be worse.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much ROSUVASTATIN VIATRIS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ROSUVASTATIN VIATRIS

This medicine helps most people with reducing the risk of heart attacks, strokes and the need for heart bypasses, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- weakness or tiredness
- constipation

- dizziness
- nausea (feeling sick)
- stomach pains
- memory loss
- stiff or painful joints (arthralgia)
- pins-and-needles sensation
- changes in sleep patterns (including insomnia and nightmare)
- changes in sex drive

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- increased urination and thirst
- involuntary muscle movements
- upper abdominal pain, nausea and vomiting
- low mood (depression)
- swollen breast tissue in males
- dry, hacking cough that does not produce phlegm
- unexplained weight loss
- any aches or pains in your muscles for which you do not know a reason, or which go on for longer than you might expect.

Unpleasant muscle effects have occurred in a small number of people who take ROSUVASTATIN VIATRIS. So, as a precaution, if you experience these muscle aches you should talk to your doctor as soon as possible. Your doctor may perform a blood test to check the condition of your muscles.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- If you develop difficulty in breathing with or without swelling of the face, eyelids, lips, tongue and/or throat;
- If you develop swelling of the face, lips, tongue and/or throat, which may cause

difficulty in swallowing or other body parts;

- If you develop severe itching of the skin (with raised lumps)
- chest pain
- yellowing of the skin or eyes, also called jaundice
- skin rash, itching or hives

An allergic reaction can be serious. You may need urgent medical attention or hospitalisation.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some of these side effects like test for diabetes can only be found when your doctor does tests from time to time to check your progress. Like other statins, increases in HbA1c, a measure of blood sugar, and onset of diabetes have been reported in patients taking ROSUVASTATIN VIATRIS.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking ROSUVASTATIN VIATRIS

Storage

Keep your tablets in the pack or bottle until it is time to take it. If you take the tablets out of the pack or bottle, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ROSUVASTATIN VIATRIS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ROSUVASTATIN VIATRIS 5 mg is a yellow, film-coated, round, biconvex tablet, debossed with "M" on one side and "RS" on the other side.

ROSUVASTATIN VIATRIS 10 mg is a pink, film-coated, round, biconvex tablet, debossed with "M" on one side and "RS1" on the other side.

ROSUVASTATIN VIATRIS 20 mg is a pink, film-coated, round, biconvex tablet, debossed with "M" on one side and "RS2" on the other side.

ROSUVASTATIN VIATRIS 40 mg is a pink, film-coated, oval, biconvex tablet, debossed with "M" on one side and "RS4" on the other side.

ROSUVASTATIN VIATRIS tablets are available in bottles of 30 or 500 tablets and blisters of 30 tablets.

Not all strengths, pack types or pack sizes may be marketed.

Ingredients

Active ingredient:

ROSUVASTATIN VIATRIS contains 5 mg, 10 mg, 20 mg or 40mg of rosuvastatin as the active ingredient.

Inactive ingredient(s):

ROSUVASTATIN VIATRIS also contains:

Tablet core:

- Microcrystalline cellulose
- Lactose
- Silica-colloidal anhydrous
- Crospovidone
- Magnesium oxide-light
- Magnesium stearate
- Iron oxide red CI77491

Film coating:

- Lactose
- Hypromellose
- Titanium dioxide
- Triacetin
- Iron oxide yellow
- Iron oxide red (10 mg, 20 mg and 40 mg tablet only)
- Ferrosoferric oxide (10 mg, 20 mg and 40 mg tablet only)

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

ROSUVASTATIN VIATRIS is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

23 August 2021
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