

Package leaflet: Information for the user

Rosuvastatine/Fenofibraat Viatris 10 mg/160 mg filmomhulde tabletten Rosuvastatine/Fenofibraat Viatris 20 mg/160 mg filmomhulde tabletten

rosuvastatin and fenofibrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> contains two different active substances in one film-coated tablet: fenofibrate (belongs to the group called ‘fibrates’) and rosuvastatin (belongs to the group called ‘statins’).

<Invented name> is a medicine used in adult patients alongside a healthy diet and other lifestyle changes, like exercise and weight loss, to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol) and fatty substances called triglycerides in the blood. In addition, it also raises levels of “good” cholesterol (HDL cholesterol). This medicine works to reduce your cholesterol in two ways: it reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself.

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.

This medicine is used in patients whose cholesterol levels cannot be controlled by a cholesterol lowering diet alone. You should stay on your cholesterol lowering diet while taking this medicine. Your doctor may prescribe <Invented name> if you are already taking both rosuvastatin and fenofibrate at the same dose level.

2. What you need to know before you take <Invented name>

Do not take <Invented name> if you

- are allergic to rosuvastatin, fenofibrate or any of the other ingredients of this medicine (listed in section 6),

- are having or have had an allergic reaction or skin damage from sunlight or UV light while taking other medicines (other fibrates and an anti-inflammatory medicine called “ketoprofen”),
- have liver disease or gallbladder problems,
- have pancreatitis (inflamed pancreas which causes abdominal pain), which is not caused by high levels of fat in the blood,
- have moderate or severe kidney problems,
- have a **personal** history of muscle problems during treatment to lower the level of fats in the blood with either of the active substances in this medicine, or with other statins or fibrates,
- take a medicine called ciclosporin (used for example, after organ transplants),
- take a drug combination of sofosbuvir/velpatasvir/voxilaprevir (used for viral infection of the liver called hepatitis C),
- are pregnant or breast-feeding. If you become pregnant while taking <Invented name> stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking this medicine by using suitable contraceptive measures.

If any of the above applies to you (or you are in doubt), please contact your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking <Invented name> if you:

- have problems with your kidneys,
- have problems with your liver,
- may have an inflamed liver (hepatitis) - signs include yellowing of the skin and the whites of the eyes (jaundice) and an increase in liver enzymes (shown in blood tests),
- have had repeated or unexplained muscle aches or pains, Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever. Also tell your doctor or pharmacist if you have a muscle weakness that is constant
- have other risk factors that may increase your risk of muscle pain or weakness (myopathy/rhabdomyolysis). In particular, tell your doctor if::
 - you have kidney problems,
 - you have an underactive thyroid,
 - you have a personal or family history of muscle problems,
 - you have a previous history of muscle problems when taking other cholesterol-lowering medicines,
 - if you are over 70 years old,
 - you drink large amounts of alcohol,
 - you have low blood protein
 - an increase in blood levels of rosuvastatin or fenofibrate may occur.
- take medicines used to fight infections, including HIV or hepatitis C infection e.g. lopinavir/ritonavir and/or atazanavir, please see “Other medicines and <Invented name>”,
- have severe respiratory failure or a history of blood clot either in the lung(s) or that has travelled to the lungs,
- take anticoagulants such as warfarin (the risk of bleeding may be increased while taken together with this medicine),
- regularly drink large amounts of alcohol,
- suffer from hypothyroidism, where your thyroid gland is underactive,
- are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and <Invented name> can lead to serious muscle problems (rhabdomyolysis),
- 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 or lead to the occurrence of myasthenia (see section 4).

- have high cholesterol caused by taking other medicines,
- are of Asian origin as you may experience an increased exposure to rosuvastatin, one of the active substances of this medicine.

If any of the above applies to you (or if you are not sure); check with your doctor or pharmacist before you actually start taking any dose of this medicine.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with <Invented name> treatment. Stop using <Invented name> and seek medical attention immediately if you notice any of the symptoms described in section 4.

In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will regularly carry out this blood test (liver function test) during treatment with this medicine. It is important to go to the doctor for the prescribed laboratory checks.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Children and adolescents

The use of this medicine is not recommended in children and adolescents under the age of 18 years.

Other medicines and <Invented name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following:

- Ciclosporin (used for example, after organ transplants to prevent rejection of the transplanted organ. The effect of rosuvastatin is increased if used together with ciclosporin). **Do not take <Invented name> while taking ciclosporin,**
- Transporter protein inhibitors, Ezetimibe, Gemfibrozil and other lipid-lowering products (as they can increase the exposure to rosuvastatin).
- Protease inhibitors (for example ritonavir),
- Regorafenib, Darolutamide, Capmatinib and Mometinib (used to treat cancer),
- Fostatinib and Etravirine (used to treat low platelet counts),
- Febuxostat (used to treat and prevent high blood levels of uric acid),
- Teriflunomide (used to treat multiple sclerosis) and Leflunomide (used to treat active rheumatoid arthritis),
- Tafamidis (used to treat damage to the heart muscle)
- Anticoagulants such as warfarin (the risk of bleeding may be increased while taken together with this medicine) or blood thinners such as ticagrelor or clopidogrel,
- Other medicines to lower your cholesterol called fibrates (e.g. gemfibrozil and other fibrates) or statins,
- Any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see “Warnings and precautions”): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir, darunavir, tripanavir,
- Indigestion remedies containing aluminum and magnesium (used to neutralise acid in your stomach; they decrease the plasma level of rosuvastatin.) This effect may be mitigated with taking this type of medicine 2 hours after <Invented name>.

- Erythromycin (an antibiotic). The effect of rosuvastatin is reduced when taken together with this antibiotic,
- Dronedarone (used to treat heart rhythm problems),
- Itraconazole (used to treat fungal infections)
- Baicalin (used to treat various inflammatory diseases)
- Fusidic acid. If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart <Invented name>. Taking this medicine with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
- An oral contraceptive (the pill). The levels of sexual hormones absorbed from the pill are increased.
- Hormone replacement therapy (increased hormone levels in the blood).
- Roxadustat (used to treat anaemia in patients with chronic kidney disease)

If you go into hospital or receive treatment for another condition, tell the medical staff that you are taking <Invented name>.

Pregnancy and breast-feeding

Do not take <Invented name> if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking this medicine, stop taking it immediately and tell your doctor. Women should use contraceptive measures during the treatment with this medicine. Do not take <Invented name>, if you are breast-feeding, limited data shows that the medicine is passed into breast milk.

Driving and using machines

This medicine is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people get dizzy after taking this medicine. If you get dizzy you should not drive or use machines.

<Invented name> contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

<Invented name> contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take <Invented name>

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should keep on being on low-cholesterol diet and doing exercises while taking <Invented name>.

The recommended daily dose for adults is one film-coated tablet.

Take <Invented name> once daily.

You can take it at any time of the day, with food. Swallow each film-coated tablet with a drink of water.

Take your medicine at the same time every day.

This medicine is not suitable to start a treatment. Treatment initiation or dose adjustment, if necessary, should only be done by giving the active substances separately. After setting the appropriate doses, the switch to <Invented name> of the appropriate strength can be made.

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.

If you take more <Invented name> than you should

Contact your doctor or the emergency department of the nearest hospital because you might need medical help.

If you forget to take <Invented name>

Do not worry, skip the missed dose and take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking <Invented name>

Talk to your doctor if you want to stop taking this medicine. Your cholesterol levels might increase again if you stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be.

Stop taking <Invented name> and seek medical help immediately if you experience any of the following serious side effects:

Uncommon (may affect up to 1 in 100 people)

- inflammation of the pancreas, which causes a severe stomach pain which can extend to the back – this may be a sign that your pancreas is inflamed (pancreatitis)
- Chest pain and feeling breathless – these may be signs of a blood clot in the lung (pulmonary embolism),
- Pain, redness or swelling in the legs – these may be signs of a blood clot in the leg (deep vein thrombosis).

Rare side effects (may affect up to 1 in 1,000 people):

- Allergic reactions such as swelling of the face, lips, tongue and/or throat, which may cause difficulty in breathing and swallowing.
- Yellowing of the skin and whites of the eyes (jaundice), or an increase in liver enzymes – these may be signs of an inflamed liver (hepatitis).
- Unusual muscle aches or pains which go on for longer than you might expect. Rarely this can develop into potentially life threatening muscle damage known as rhabdomyolysis, which leads to malaise, fever and kidney impairment.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).
- Muscle rupture.

Not known (frequency cannot be estimated from the available data):

- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

- Long-term lung problems including persistent cough and/or shortness of breath or fever. If you get any unusual breathing discomfort, contact your doctor straight away.

Stop taking [Invented name] and contact a doctor straight away, if you notice any of the side effects above.

Other possible side effects with <Invented name>

Common side effects (may affect up to 1 in 10 people)

- diabetes mellitus. 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
- headache
- dizziness
- constipation
- feeling sick (nausea)
- being sick (vomiting)
- stomach ache
- diarrhoea
- flatulence (excess gas in the intestinal tract)
- muscle pain
- feeling weak
- feeling tired
- elevations in some laboratory blood tests of liver function (transaminases)
- blood homocysteine level increased (too much of this amino acid in the blood is related to a higher risk of coronary heart disease, stroke and peripheral vascular disease, although a causal link has not been established)

Uncommon side effects (may affect up to 1 in 100 people)

- rash, itching, hives
- sexual difficulties
- muscles spasms, weakness or inflammation
- gallstones
- Increase in the blood level of “creatinine” (substance excreted by the kidneys)

Rare side effects (may affect up to 1 in 1,000 people)

- reduction in blood platelets, drop in haemoglobin (that carries oxygen in blood) and white blood cells – shown in tests
- skin is more sensitive to sunlight, sun lamps and sunbeds,
- hair loss
- increase in “urea” – produced by the kidneys – shown in tests

Very rare side effects (may affect up to 1 in 10,000 people)

- traces of blood in your urine
- joint pain
- damage to the nerves of your legs and arms (such as numbness)
- memory loss
- breast enlargement in men (gynecomastia)

Not known (frequency cannot be estimated from the available data)

- depression
- muscle weakness that is constant
- sleep disturbances, including insomnia and nightmares
- cough, shortness of breath

- complications of gallbladder stones
- tendon injury
- oedema (swelling)
- Feeling exhausted (fatigue)
- 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

This medicine does not require any special storage conditions.
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 carton and the blister after “EXP”. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Rosuvastatine/Fenofibraat Viatris contains

The active substances are rosuvastatin (as rosuvastatin calcium) and fenofibrate.

10 mg/160 mg: Each film-coated tablet contains 10 mg rosuvastatin (as rosuvastatin calcium) and 160 mg fenofibrate.

20 mg/160 mg: Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium) and 160 mg fenofibrate.

The other ingredients in the tablet core are: Starch, pregelatinized, Microcrystalline Cellulose (E460), Meglumine, Calcium hydrogen phosphate dihydrate (E341), Crospovidone (E102), Silica, colloidal anhydrous (E551), Sodium stearyl fumarate, Mannitol (E421), Lactose monohydrate, Yellow iron oxide (E172), Povidone (K30), Sodium laurilsulfate (E487).

Coating: Hypromellose (E463), Titanium dioxide (E 171), Macrogol 4000 (E1521), Yellow iron oxide (E 172)

What Rosuvastatine/Fenofibraat Viatris looks like and contents of the pack

10 mg/160 mg: Yellow, oval shaped film-coated tablet, debossed with "F1" on one side and plain on other side.

20 mg/160 mg: Yellow, oval shaped film-coated tablet, debossed with "F2" on one side and plain on other side.

Rosuvastatine/Fenofibraat Viatris is available in blister packs containing 30 and 90 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Viatis Healthcare B.V.
Krijgsman 20
1186 DM Amstelveen

Manufacturer

Fundacio Privada Dau
Carrer Lletre C De La Zona Franca 12-14
08040 Barcelona
Spanje

Mylan Hungary Kft.
Mylan utca 1.
Komárom, 2900
Hongarije

In het register ingeschreven onder:

RVG 133381 - Rosuvastatine/Fenofibraat Viatis 10 mg/160 mg filmomhulde tabletten

RVG 133382 - Rosuvastatine/Fenofibraat Viatis 20 mg/160 mg filmomhulde tabletten

This medicine is authorised in the Member States of the European Economic Area under the following names:

België	Rosuvastatin/Fenofibrate Althera 10 mg/160 mg, 20 mg/160 mg filmomhulde tabletten
Nederland	Rosuvastatine/Fenofibraat Viatis 10 mg / 160 mg filmomhulde tabletten Rosuvastatine/Fenofibraat Viatis 20 mg / 160 mg filmomhulde tabletten
Luxemburg	Rosuvastatine/Fenofibrate Althera 10 mg/160 mg, 20 mg/160 mg comprimés pelliculés
Polen	Rosuvastatin + Fenofibrate Althera
Roemenië	Lipanthyl plus 10 mg/160 mg, 20 mg/160 mg comprimate filmate
Slowakije	Ixfenro 10 mg/160 mg, 20 mg/160 mg
Spanje	Ixfenro 10 mg/160 mg, 20 mg/160 mg comprimidos recubiertos con película

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2026

Meer informatie over dit medicijn kunt u vinden op de website van het College ter Beoordeling van Geneesmiddelen www.cbg-meb.nl.