

Package leaflet: Information for the user

Rosuvastatine/Ezetimibe Althera 5 mg/10 mg filmomhulde tabletten
Rosuvastatine/Ezetimibe Althera 10 mg/10 mg filmomhulde tabletten
Rosuvastatine/Ezetimibe Althera 20 mg/10 mg filmomhulde tabletten
Rosuvastatine/Ezetimibe Althera 40 mg/10 mg filmomhulde tabletten

rosuvastatin and ezetimibe

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. One of the active substances is rosuvastatin, belonging to the group of so called statins, the other active substance is ezetimibe.

<Invented name> is a medicine used in adult patients 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 ezetimibe at the same dose level.

This medicine does not help you lose weight.

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

Do not take <Invented name> if you

- are allergic to rosuvastatin, ezetimibe or any of the other ingredients of this medicine (listed in section 6).
- have liver disease.
- have severe kidney impairment.
- have repeated, unexplained muscle aches or pains (myopathy).
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking <Invented name> or other medicines containing rosuvastatin.
- 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.

In addition, do not take <Invented name> 40 mg/10 mg (the highest dose)

- if you have moderate kidney problems (if in doubt, please ask your doctor).
- if your thyroid gland is not working properly.
- if you have had any repeated or unexplained muscle aches or pains, or a personal or family history of muscle problems.
- if you have had a previous history of muscle problems when taking other cholesterol-lowering medicines.
- if you regularly drink large amounts of alcohol.
- if you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- if you take other medicines called fibrates to lower your cholesterol.

If any of the above applies to you (or you are in doubt), please go back and see 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.
- have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. 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.
- are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian). Your doctor needs to choose the right dose to suit you.
- take medicines used to fight infections, including HIV or hepatitis C infection e.g. lopinavir/ritonavir and/or atazanavir or simeprevir, please see “Other medicines and <Invented name>”.
- have severe respiratory failure.
- take other medicines called fibrates to lower your cholesterol. Please see “Other medicines and <Invented name>”.
- regularly drink large amounts of alcohol.
- suffer from hypothyroidism, where your thyroid gland is underactive.
- are over 70 (as your doctor needs to choose the right dose of <Invented name> to suit you).

- 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).

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.**
- Regorafenib (used to treat cancer)
- Darolutamide (used to treat cancer).
- Blood thinners e.g. warfarin, acenocoumarol or fluindione (their blood thinning effect and the risk of bleeding may be increased while taken together with this medicine), ticagrelor or clopidogrel.
- Other medicines to lower your cholesterol called fibrates, which correct also blood triglyceride levels (e.g. gemfibrozil and other fibrates). When gemfibrozil is taken together with this medicine, the effect of rosuvastatin is increased.
- Colestyramine (a medicine for lowering cholesterol), because it affects the way ezetimibe works.
- 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, simeprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.
- Indigestion remedies containing aluminium 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 rosuvastatin.

- Erythromycin (an antibiotic). The effect of rosuvastatin is reduced when taken together with this antibiotic.
- 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).

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, because it is not known if 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'.

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 or without food. Swallow each film-coated tablet whole with a drink of water.

Take your medicine at the same time every day.

If your doctor has prescribed <Invented name> along with another medicine for lowering cholesterol containing the active ingredient colestyramine or any other medicine containing bile acid sequestrant, you should take <Invented name> at least 2 hours before or 4 hours after taking the bile acid sequestrant.

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 and after setting the appropriate doses the switch to <Invented name> of the appropriate strength is possible.

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:

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.
- 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).

Other side effects

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

- headache
- constipation
- feeling sick
- muscle pain
- feeling weak
- dizziness
- 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.
- stomach ache

- diarrhoea
- flatulence (excess gas in the intestinal tract)
- feeling tired
- elevations in some laboratory blood tests of liver function (transaminases)

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

- rash, itching, hives
- elevations in some laboratory blood tests of muscle function (Creatine Kinase test)
- cough
- indigestion
- heartburn
- joint pain
- muscle spasms
- neck pain
- decreased appetite
- pain
- chest pain
- hot flush
- high blood pressure
- tingling sensation
- dry mouth
- inflammation of the stomach
- back pain
- muscle weakness
- pain in arms and legs
- swelling, especially in the hands and feet

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

- inflammation of the pancreas, which causes a severe stomach pain which can extend to the back
- reduction in blood platelets

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

- jaundice (yellowing of the skin and eyes)
- inflammation of the liver (hepatitis)
- traces of blood in your urine
- 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)

- 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
- tendon injury
- muscle weakness that is constant
- gallstones or inflammation of the gallbladder (which may cause stomach ache, nausea, vomiting)
- 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>

Store in the original package in order to protect from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date “EXP” which is stated on the carton box and the blister. 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 <Invented name> contains

- The active substances are rosuvastatin (as rosuvastatin calcium) and ezetimibe.
- Each film-coated tablet contains rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg or 40 mg rosuvastatin and 10 mg ezetimibe.

The other ingredients are:

Rosuvastatin - Core

Starch, pregelatinised (maize); Microcrystalline Cellulose (E460); Meglumine; Calcium hydrogen phosphate dihydrate (E341); Crospovidone (E1202); Colloidal anhydrous silica (E551); Sodium stearyl fumarate

Ezetimibe - Core

Mannitol (E421); Butylhydroxyanisole (E320); Sodium laurilsulfate (E487); Croscarmellose sodium (E468); Povidone (K-30) (E1201); Iron oxide red (E172); Magnesium stearate (E470 b); Sodium stearyl fumarate

Tablet coating

Hypromellose (E464); Titanium dioxide (E171); Macrogol 4000; Iron oxide red (E172)

What <Invented name> looks like and contents of the pack

<Invented name> 5 mg/10 mg are pink coloured, oblong shaped, film-coated tablets, approximately 13 mm x 8 mm, debossed with “LL” on one side.

<Invented name> 10 mg/10 mg film-coated tablets are pink coloured, round shaped, film-coated tablets with a diameter of 10.1 mm embossed with “AL” on one side.

<Invented name> 20 mg/10 mg film-coated tablets are pink coloured round shaped film-coated tablets with a diameter of 10.6 mm and plain on both sides.

<Invented name> 40 mg/10 mg are pink coloured, oval shaped film-coated tablets, approximately 13 mm x 11 mm, debossed with “L7” on one side.

OPA/Al/PVC-Al blister packs

Packs of 10, 30, 60, 90, 100 film-coated tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Althera Laboratories Ltd.
Unit 2,
Holywell Commercial Centre,
Swords,
Dublin,
Ierland
K67 E7W6

Manufacturer

Pharmadox Healthcare, Ltd.
KW20A Kordin Industrial Park,
Paola PLA3000,
Malta

Or

Aristo Pharma GmbH
Wallenroder Straße 8-10
13435 Berlin
Duitsland

In het register ingeschreven onder:

Rosuvastatine/Ezetimibe Althera 5 mg/10 mg filmomhulde tabletten	RVG 130998
Rosuvastatine/Ezetimibe Althera 10 mg/10 mg filmomhulde tabletten	RVG 118790
Rosuvastatine/Ezetimibe Althera 20 mg/10 mg filmomhulde tabletten	RVG 123044
Rosuvastatine/Ezetimibe Althera 40 mg/10 mg filmomhulde tabletten	RVG 131000

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

The Netherlands: Rosuvastatine/Ezetimibe Althera
Germany: ROSUZET

Deze bijsluiter is voor het laatst goedgekeurd in maart 2025.