Package leaflet: Information for the patient

Rozesta 5 mg/10 mg filmomhulde tabletten
Rozesta 10 mg/10 mg filmomhulde tabletten
Rozesta 20 mg/10 mg filmomhulde tabletten
Rozesta 40 mg/10 mg filmomhulde tabletten
rosuvastatin/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 Rozesta is and what it is used for

Rozesta contains 2 different active substances in 1 tablet. One of the active substances is rosuvastatin, belonging to the group of so called statins, the other active substance is ezetimibe.

Rozesta is a medicine used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, Rozesta raises levels of "good" cholesterol (HDL cholesterol).

Rozesta works to reduce your cholesterol in 2 ways. It reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself.

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called "bad" cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries.

This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

It is used for patients who cannot control their cholesterol levels by diet alone. You should always stay on a cholesterol-lowering diet while taking this medicine.

Rozesta is used in addition to your cholesterol lowering diet if you have:

- A raised cholesterol level in your blood (primary hypercholesterolaemia [heterozygous familial and non-familial])
  - for which you have used a statin and ezetimibe as separate tablets.
  - a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You may also receive other treatments.

Rozesta does not help you lose weight.

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. If you correct your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

You need to keep taking Rozesta, even if it has got your cholesterol to the right level, because it prevents your cholesterol levels from creeping up again and causing build-up of fatty deposits**.**

However, you should stop if your doctor tells you to do so, or you have become pregnant.

2. What you need to know before you take Rozesta

Do not take Rozesta if you

- are allergic to ezetimibe, rosuvastatin or any of the other ingredients of this medicine (listed in section 6).
- currently have liver problems.
- are pregnant or breast-feeding. If you become pregnant while taking Rozesta stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Rozesta by using suitable contraceptive measures.
- have severe kidney problems.
- have repeated or unexplained muscle aches or pains (myopathy).
- take a drug combination of sofosbuvir/velpatasvir/voxilaprevir (used for viral infection of the liver called hepatitis C).
- 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.

In addition, do not take Rozesta 40 mg / 10 mg (the highest dose) if

- you have moderate kidney problems (if in doubt, please ask your doctor).
- your thyroid gland is not working properly (hypothyroidism).
- you have had any 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.
- you regularly drink large amounts of alcohol.
- you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- you take other medicines called fibrates to lower your cholesterol (see section "Other medicines and Rozesta").
- 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 or lead to the occurrence of myasthenia (see section 4).

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 Rozesta if

- you have problems with your kidneys.
- you drink large amounts of alcohol or have ever had liver disease. Rozesta may not be right for you.
- you 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.
- your thyroid gland is not working properly.
- you have severe respiratory failure.
- you take medicines used to fight the HIV infection e.g. ritonavir with lopinavir and/or atazanavir (please see "Other medicines and Rozesta").
- you are over 70 (as your doctor needs to choose the right start dose of Rozesta to suit you).
- you take other medicines called fibrates to lower your cholesterol (please see "Other medicines and Rozesta").
- you are due to have an operation. You may need to stop taking Rozesta for a short time.
- you are of Asian origin – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of Rozesta to suit you.
- 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 Rozesta can lead to serious muscle problems (rhabdomyolysis).
- you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking [Invented name] or other related medicines.

Take special care with [Invented name]:

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.

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.

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 Rozesta. It is important to go to the doctor for the prescribed laboratory checks.

Children and adolescents

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

Other medicines and Rozesta

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking medicine(s) with any of the following active ingredients:

- Ciclosporin (often used in organ transplant patients). **Do not take Rozesta while taking ciclosporin.**
- Darolutamide (used to treat cancer).
- Medicines with an active ingredient to prevent blood clots, such as warfarin or clopidogrel, phenprocoumon, acenocoumarol, fluindione or ticagrelor (anticoagulants).
- Colestyramine (also used to lower cholesterol), because it affects the way Rozesta works.
- Fibrates such as gemfibrozil, fenofibrate (also used to lower cholesterol) or any other medicine used to lower cholesterol (such as ezetimibe). **Do not take the Rozesta 40 mg / 10 mg tablets with concomitant use of a fibrate.**
- Indigestion remedies containing aluminium and magnesium (used to neutralise acid in your stomach).
- Erythromycin (an antibiotic).
- An oral contraceptive (the pill).
- Hormone replacement therapy.
- Regorafenib (used to treat cancer).
- 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.
- 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 Rozesta. Taking Rozesta with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

You should also tell any doctor who is prescribing a new medicine for you that you are taking Rozesta.

Rozesta with alcohol

Do not take Rozesta 40 mg / 10 mg tablets (the highest dose), if you regularly drink large amounts of alcohol.

Pregnancy and breast-feeding

Do not take Rozesta if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking Rozesta, stop taking it immediately and tell your doctor. Women should use contraceptive measures during the treatment with Rozesta.

Do not take Rozesta if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

Driving and using machines

Rozesta is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people may get dizzy after taking Rozesta. If you get dizzy, talk to your doctor before driving or using machines.

Rozesta contains lactose monohydrate (a type of sugar) and sodium

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

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

3. How to take Rozesta

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

- Before starting Rozesta, you should be on a diet to lower your cholesterol.
- You should keep on this cholesterol lowering diet whilst taking Rozesta.

Your doctor will determine the appropriate tablet strength for you, depending on your current treatment and your personal risk status.

The recommended dose is 1 Rozesta tablet once a day.

Rozesta is not suitable to start a treatment. Treatment initiation or dose adjustment if necessary should only be done by giving the active substances separately as monocomponents and after setting the appropriate doses the switch to Rozesta of the appropriate strength is possible.

The maximum daily dose of rosuvastatin is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

Try to take your tablet at the same time every day to help you to remember it. You can take it with or without food. Swallow each tablet whole with a drink of water.

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

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 the medicine that is right for you.

If you take more Rozesta 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 Rozesta

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 tablet.

If you stop taking Rozesta

Talk to your doctor or pharmacist because your cholesterol may rise again.

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.

Stop taking Rozesta and seek medical help immediately if you have any of the following adverse 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). These might be signs of **severe allergic reaction**.
- Any unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems, including muscle breakdown resulting in kidney damage, can be serious and may become a potentially life-threatening condition.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).
- Muscle rupture.

- 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 - a life-threatening allergic reaction).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Common (may affect up to 1 in 10 people):

Diarrhoea; flatulence; feeling tired; elevations in some laboratory blood tests of liver function (transaminases); 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 Rozesta (only rosuvastatin 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 (may affect up to 1 in 100 people):

Elevations in some laboratory blood tests of muscle (CK) function; 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; itching; rash; hives or other skin reactions; back pain; muscle weakness; pain in arms and legs; swelling, especially in the hands and feet; an increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking Rozesta (only rosuvastatin 10 mg and 20 mg).

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

Reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia); a severe stomach pain (inflamed pancreas).

Very rare (may affect up to 1 in 10 000 people):

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); memory loss; gynecomastia (breast enlargement in men).

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

Shortness of breath; swelling; sleep disturbances including sleeplessness and nightmares; sexual difficulties; depression; breathing problems including persistent cough and/or shortness of breath or fever; tendon injury; muscle weakness that is constant; raised red rash, sometimes with target shaped lesions (erythema multiforme); muscle tenderness; gallstones or inflammation of the gallbladder (which may cause abdominal pain, 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 or pharmacist. 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 Rozesta

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 blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture and light. This medicinal product does not require any special temperature storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Rozesta contains

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

The other ingredients are: Cellulose microcrystalline (E460), Colloidal anhydrous silica (E551), Magnesium stearate (E572), Povidone (E1201), Croscarmellose sodium (E468), Sodium laurilsulfate (E514), Lactose monohydrate, Hypromellose,
Opadry yellow (5 mg / 10 mg): Hypromellose (E464),Titanium Dioxide (E171), Macrogol 4000 (E1521),Iron Oxide Yellow (E172),Talc (E553b), Iron Oxide Red (E172),
Opadry beige (10 mg / 10 mg):Hypromellose (E464), Titanium Dioxide (E171), Macrogol 4000 (E1521),Iron Oxide Yellow (E172),Talc (E553b),
Vivacoat Yellow (20 mg / 10 mg): Hypromellose (E464),Titanium Dioxide (E171), Talc (E553b), Macrogol 4000 (E1521), Ferric Oxide yellow (E172)
Opadry white (40 mg / 10 mg): Lactose monohydrate, Hypromellose (E464),Titanium Dioxide (E171), Macrogol 4000 (E1521)

What Rozesta looks like and contents of the pack

Rozesta 5 mg / 10 mg: Light yellow, round, biconvex film-coated tablets with a diameter of 10 mm approximately and “EL5” embossed on one side.

Rozesta 10 mg / 10 mg: Beige, round, biconvex film-coated tablets with a diameter of 10 mm approximately and “EL4” embossed on one side.
Rozesta 20 mg / 10 mg: Yellow, round, biconvex film-coated tablets with a diameter of 10 mm approximately and “EL3” embossed on one side.
Rozesta 40 mg / 10 mg: White, round, biconvex film-coated tablets with a diameter of 10 mm approximately and “EL2” embossed on one side.

Rozesta 5 mg / 10 mg and 10 mg / 10 mg film-coated tablets
Pack sizes: 10, 15, 30, 60 and 100 film-coated tablets.

Rozesta 20 mg / 10 mg and 40 mg / 10 mg film-coated tablets
Pack sizes: 30, 60 and 100 film coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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In het register ingeschreven onder:

Rozesta 5 mg/10 mg filmomhulde tabletten	RVG 124610
Rozesta 10 mg/10 mg filmomhulde tabletten	RVG 124611
Rozesta 20 mg/10 mg filmomhulde tabletten	RVG 124612
Rozesta 40 mg/10 mg filmomhulde tabletten	RVG 124613

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

Netherlands, Estonia, Latvia, Poland: Rozesta
Czech Republic, Portugal, Romania: Rozetin
Bulgaria: Розетин

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2023