

RosuZet[®]

Ezetimibe/Rosuvastatin (10mg/10mg, 10mg/20mg)

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What RosuZet is used for

RosuZet is a medicine used to lower levels of total cholesterol, LDL (bad) cholesterol, and fatty substances called triglycerides in the blood. In addition, RosuZet raises levels of HDL (good) cholesterol. It is used for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

How RosuZet works

RosuZet 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. RosuZet does not help you lose weight.

Before you take RosuZet

It is important that you continue taking RosuZet daily as prescribed by your doctor.

Even if you are taking medication to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

- When you must not take it

Do not take RosuZet if you:

- are hypersensitive (allergic) to ezetimibe, rosuvastatin, or any of the other ingredients of RosuZet tablets
- have active liver disease

- are pregnant or breast-feeding, intend to get pregnant and are not using proper contraceptive methods.

Pregnancy

Do not use RosuZet if you are pregnant, trying to become pregnant or suspect that you are pregnant. If you become pregnant while taking RosuZet, stop taking it and contact your physician immediately. You should use effective birth control (contraception) while you are taking RosuZet.

Breast-feeding

Do not use RosuZet if you are breast-feeding.

Children

RosuZet is not recommended in children.

- Before you start to take it

- **Medical Problems or Allergies:** Tell your doctor [or pharmacist] about any medical conditions you have or have had (including liver disease, problems with your liver, kidney or thyroid) and about any allergies.
- **Muscle Pain/ Muscle Weakness:** Tell your doctor if you experience any unexplained muscle pain, tenderness, or weakness or have a history of muscle problems. Talk to your doctor if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used for breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.
- **Alcohol:** Tell your doctor if you consume substantial quantities of alcohol or have a past history of liver disease.
- **Race:** Tell your doctor if you are Asian or of Asian descent.

You may obtain further information from your doctor or pharmacist, who has more detailed information

- Taking other medicines

Tell your doctor about all the medicines you are taking or plan to take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

It is especially important to tell your doctor if you take any of the following:

- Cyclosporine (a medicine often used in organ transplant patients)
- HIV protease inhibitors (medicines for AIDS)
- Hepatitis C antiviral agents such as elbasvir or grazoprevir (medicines used to treat hepatitis C virus infection)
- Oral contraceptives (medicines for preventing pregnancy)
- Antacids (indigestion products containing aluminum or magnesium)
- Fibrates (including gemfibrozil and fenofibrate), niacin, cholestyramine (medicines for lowering cholesterol)
- Fusidic acid (medicine for bacterial infections)
- Blood-thinning medicines, such as warfarin or fluindione (medicines to prevent blood clots)
- Daptomycin (a medicine used to treat complicated skin and skin structure infections and bacteremia)

How to take RosuZet

- How much to use

Take one RosuZet 10/10mg, or 10/20mg tablet by mouth each day, at any time of the day.

- When to use it

Take RosuZet with or without food.

If your doctor has prescribed RosuZet along with cholestyramine (a bile acid

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sequestrant) or any other bile acid sequestrant, RosuZet should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

How long to use it

RosuZet should be taken as directed by your health care provider. Continue taking your other cholesterol lowering medicines unless your doctor tells you to stop.

If you forget to take it

Try to take RosuZet as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

If you take too much (overdose)

Take RosuZet only as prescribed for you. If you take more RosuZet than you were prescribed, contact your doctor or pharmacist right away.

While you are taking RosuZet

Things you must do

RosuZet should be taken as directed by your health care provider.

If you become pregnant while taking RosuZet, stop taking it and contact your physician immediately. You should use effective birth control (contraception) while you are taking RosuZet.

Things you must not do

Do not give RosuZet to anyone else, even if they have the same symptoms or condition as you.

Do not take other medications together with RosuZet without speaking to your doctor or pharmacist first.

Things to be careful of

Pregnancy:

Do not use RosuZet if you are pregnant, trying to become pregnant

or suspect that you are pregnant. If you become pregnant while taking RosuZet, stop taking it and contact your physician immediately. You should use effective birth control (contraception) while you are taking RosuZet.

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

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects.

In clinical studies, RosuZet was generally well tolerated. The side effects were usually mild, temporary, and similar in type and frequency to side effects in patients who were given ezetimibe alone or rosuvastatin alone.

The following common side effect was reported: itching. The following uncommon side effects were reported: bloating; abdominal pain; constipation; dry mouth; nausea; rash; joint pain; muscle pain, tenderness or weakness; elevations in some laboratory blood tests of liver (transaminases).

Additional side effects that have been reported in people taking RosuZet, ezetimibe or rosuvastatin in clinical studies or general use include: allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (which may require treatment right away), rash, and hives; diabetes, decreased appetite; depression; dizziness; headache; tingling sensation; damage to the nerves and/or numbness or weakness of your legs and arms; poor memory; memory loss; confusion; sleep disturbances, including nightmares; hot flush; high blood pressure; cough; shortness of breath; diarrhea; indigestion; flatulence; heartburn; inflammation of the pancreas; yellowing of skin or the whites of eyes; liver problems; gallstones;

inflammation of the gallbladder; raised red rash, sometimes with target-shaped lesions; Stevens-Johnson syndrome (serious blistering condition of the skin, mouth, eyes and genitals) severe skin problems; hives; back pain; muscle spasms; muscle pain, tenderness; or weakness (that in very rare cases may not go away after stopping RosuZet); neck pain; pain in arms and legs; breast enlargement in men; unusual weakness; chest pain; feeling tired; swelling especially in the hands and feet; elevations in some laboratory blood tests of muscle (CK) function; increase in protein in urine; traces of blood in urine; increases in levels of sugars in blood.

Additional possible side effects reported with some statins: sexual difficulties; inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever; tendon problems, sometimes complicated by rupture of the tendon.

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking RosuZet.

This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

If you have muscle problem that do not go away even after your doctor has told you to stop taking RosuZet, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

The risk of muscle problems is greater in people who are 65 years of age or older, or who already have thyroid or kidney problems. The chance of muscle problems may be increased if you are taking certain other medicines with RosuZet.

Unknown frequency:

RosuZet®

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- 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.

Talk to your doctor anytime you have a medical problem you think may be related to RosuZet.

If you are prescribed RosuZet, your healthcare professional should conduct blood tests to check your liver before you start taking RosuZet and if you have any symptoms of liver problems while you take RosuZet. Call your doctor right away if you have the following symptoms of liver problems:

- feel unusually tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of your skin or the whites of your eyes

Ask your doctor or pharmacist for more information. Both have a more complete list of side effects. Tell your doctor [or pharmacist] promptly about these or any other unusual symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of RosuZet

- Storage

Store below 30°C. Keep product in the original blister package until use, to protect from light.

Keep RosuZet and all medications safely away from children.

- Disposal

Do not use this medicine after the date shown following EX (or EXP) on the container.

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

The tablets are supplied in following two strengths:

- RosuZet® (EZETIMIBE 10MG / ROSUVASTATIN 10MG) FILM-COATED TABLET
- RosuZet® (EZETIMIBE 10MG / ROSUVASTATIN 20MG) FILM-COATED TABLET

- What it looks like

RosuZet is a film coated tablet.

RosuZet® (EZETIMIBE 10MG / ROSUVASTATIN 10MG) FILM-COATED TABLET

Pale yellowish pink oval tablet debossed with “R10” on one face.

RosuZet® (EZETIMIBE 10MG / ROSUVASTATIN 20MG) FILM-COATED TABLET

Pink oval tablet debossed with “R20” on one face.

RosuZet is available in pack size of 30 tablets.

- Ingredients

Active ingredients:

RosuZet® (EZETIMIBE 10MG / ROSUVASTATIN 10MG) FILM-COATED TABLET:
10 mg of ezetimibe and 10.4 mg of rosuvastatin calcium, equivalent to 10 mg of rosuvastatin

RosuZet® (EZETIMIBE 10MG / ROSUVASTATIN 20MG) FILM-COATED TABLET:
10 mg of ezetimibe and 20.8 mg of rosuvastatin calcium, equivalent to 20 mg of rosuvastatin

Inactive ingredients:

Each tablet of RosuZet contains the following inactive ingredients: lactose monohydrate, sodium lauril sulfate, croscarmellose sodium, povidone, cellulose microcrystalline, crospovidone, magnesium stearate, and mannitol.

The film coating contains: hypromellose, polyethylene glycol 6000/macrogol 8000, talc, titanium dioxide, iron oxide yellow, and iron oxide red..

- MAL number:

RosuZet® (EZETIMIBE 10MG / ROSUVASTATIN 10MG) FILM-COATED TABLET
MAL23126008ACZ
RosuZet® (EZETIMIBE 10MG / ROSUVASTATIN 20MG) FILM-COATED TABLET
MAL23126009ACZ
Manufacturer

Hanmi Pharmaceutical Co., Ltd.
214 Muha-ro, Paltan-myeon,
Hwaseong-si Gyeonggi-do,
Republic of Korea

Product Registration Holder

Organon Malaysia Sdn. Bhd.
3A-08-02, Level 8,
Corporate Tower 3A,
Pavilion Damansara Heights,
No. 3, Jalan Damansara
50490 Kuala Lumpur, Malaysia.

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