

Package leaflet: Information for the patient

Ezehron Duo 20 mg/10 mg, tablet

Ezehron Duo 10 mg/10 mg, tablet

Ezehron Duo 5 mg/10 mg, tablet

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 Ezehron Duo tablets is and what it is used for
2. What you need to know before you take Ezehron Duo tablets
3. How to take Ezehron Duo tablets
4. Possible side effects
5. How to store Ezehron Duo tablets
6. Contents of the pack and other information

1. What Ezehron Duo tablets is and what it is used for

Ezehron Duo tablets contains two different active substances in one tablet. One of the active substances is rosuvastatin, belonging to the group of so called statins, the other active substance is ezetimibe.

Ezehron Duo tablets is a medicine used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol) and fatty substances called triglycerides in your 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.

Ezehron Duo tablets 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 Ezehron Duo tablets if you are already taking both rosuvastatin and ezetimibe at the same dose level.

Ezehron Duo tablets is used if you have:

- a raised cholesterol level in your blood (primary hypercholesterolemia)
- heart disease, Ezehron Duo reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization for chest pain

Ezehron Duo tablets does not help you lose weight.

2. What you need to know before you take Ezechron Duo tablets

Do not take Ezechron Duo tablets 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).
- 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).
- are pregnant or breast-feeding. If you become pregnant while taking Ezechron Duo tablets stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Ezechron Duo tablets by using suitable contraceptive measures (see below: Pregnancy and breast feeding),
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Rosuvastatin/Ezetimibe tablets or other related medicines.

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 Ezechron Duo tablets 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 of Ezechron Duo tablets 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 Ezechron Duo tablets”.
- have severe respiratory failure.
- take other medicines called fibrates to lower your cholesterol. Please see “Other medicines and Ezechron Duo tablets”.
- regularly drink large amounts of alcohol.
- have thyroid gland that is not working properly (hypothyroidism).
- are over 70 (as your doctor needs to choose the right dose of Ezechron Duo tablets 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 Ezechron Duo tablets 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 Ezechron Duo tablets.

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 out this blood test (liver function test) during treatment with Ezechron Duo tablets. 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.

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

Children and adolescents

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

Other medicines and Ezechron Duo tablets

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 with concomitant use). **Do not take Ezechron Duo tablets while taking ciclosporin;**
- Blood thinners e.g. warfarin, acenocoumarol, fluindione (their blood thinning effect and the risk of bleeding may be increased while taken concomitantly with Ezechron Duo tablets), ticagrelor or clopidogrel;
- Other medicines to lower your cholesterol called fibrates, which correct also blood triglyceride levels (e.g. gemfibrozil and other fibrates). During concomitant use, the effect of rosuvastatin is increased;
- Colestyramine (a medicine for lowering cholesterol), because it affects the way ezetimibe works;
- Darolutamide, Regorafenib (used to treat cancer);
- Fostamatinib (used to treat a low platelet count);
- Febuxostat (used to treat and prevent high levels of uric acid in the blood);
- Teriflunomide (used in the treatment of multiple sclerosis);
- Capmatinib (used to treat cancer);
- Roxadustat (a medicine used to treat symptomatic anemia associated with chronic kidney disease);
- Daptomycin (a medicine used to treat complicated skin and skin structure infections and bacteraemia);
- Tafamidis (a medicine used to treat cardiomyopathy -enlarged and thickened heart muscle);
- 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;
- 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 decreased with their concomitant use;
- 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 Ezechron Duo tablets. Taking Ezechron Duo tablets 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

Ezehron Duo tablets.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, are trying to get pregnant or think you may be pregnant ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

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

Breast feeding

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

Driving and using machines

Ezehron Duo tablets are 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 Ezechron Duo tablets. If you get dizzy, talk to your doctor before driving or using machines.

Ezehron Duo tablets contain lactose monohydrate

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

Ezehron Duo tablets contain sodium

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

3. How to take Ezechron Duo tablets

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 Ezechron Duo tablets.

The recommended daily dose for adults is one tablet of the given strength.

Take Ezechron Duo tablets once daily.

You can take it at any time of the day, with or without food. Swallow each tablet whole with a drink of water. Take your medicine at the same time every day.

Ezehron Duo tablets 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 Ezechron Duo tablets 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 Ezechron Duo tablets 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 Ezechron Duo tablets

Don't 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 Ezechron Duo tablets

Talk to your doctor if you want to stop taking Ezechron Duo tablets. Your cholesterol levels might increase again if you stop taking Ezechron Duo tablets.

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 Ezechron Duo tablets and seek medical help immediately if you experience any of the following:

- Allergic reactions: swelling of the face, lips, tongue and/or throat, which may cause difficulty in breathing and swallowing;
- 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);
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Contact your doctor immediately if you have any 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.

The following terms are used to describe how often side effects have been reported:

- Very common (may affect more than 1 of 10 patients)
- Common (may affect up to 1 of 10 patients)
- Uncommon (may affect up to 1 of 100 patients)
- Rare (may affect up to 1 of 1,000 patients)
- Very rare (may affect up to 1 of 10,000 patients, including isolated reports).

Common side effects

- 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

- Rash, itching, hives;
- An increase in the amount of protein in the urine may occur – this usually returns to normal on its own without having to stop taking rosuvastatin;
- 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,
- back pain;
- muscle weakness,
- pain in arms and legs;
- swelling, especially in the hands and feet.

Rare side effects:

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

Very rare side effects:

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:

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 ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ezehron Duo tablets

Store in the original package in order to protect from light. This medicinal product does not require any special temperature 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 box and the blister. The expiry date refers to the last day of the 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 Ezehron Duo tablets contains

The active substances are rosuvastatin (as rosuvastatin calcium) and ezetimibe. The tablets contain rosuvastatin calcium equivalent either to 5 mg, 10 mg or 20 mg rosuvastatin. Each tablet contains 10 mg of ezetimibe.

The other ingredients are: Lactose monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Crospovidone type A, Povidone K-30, Sodium laurilsulfate and Magnesium stearate

What Ezehron Duo tablets looks like and contents of the pack

Ezehron Duo 20 mg/10 mg tablet: white to off-white, round, biconvex, uncoated tablet. The diameter of the tablet is 11 mm.

Ezehron Duo 10 mg/10 mg tablet: white to off-white, oval, biconvex, uncoated tablet, engraved E1 on one side and 1 on the other side. The dimensions of the tablet are 15 mm x 7 mm

Ezehron Duo 5 mg/10 mg tablet: white to off-white, round, flat, uncoated tablet, engraved E2 on one side and 2 on the other side. The diameter of the tablet is 10 mm.

Packs of 7, 10, 14, 28, 30, 56, 60, 84 90, 98 and 100 in blister (PA/AL/PVC // Al) put into cardboard box with Patient Information Leaflet. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Adamed Sp. z o.o. Pieńków 149, 05-152 Czostów Poland

Manufacturer

Adamed Pharma S.A., Pieńków, ul. Mariana Adamkiewicza 6A, 05-152 Czostów, Poland

Special Product's Line S.p.A. Via Fratta Rotonda Vado Largo 1, 03012 Anagni (FR), Italy

This leaflet was last revised in 10.2025