

Package leaflet: Information for the patient

Ezetimibe/Simvastatin Rowex 10 mg/20 mg tablets
Ezetimibe/Simvastatin Rowex 10 mg/40 mg tablets
Ezetimibe/Simvastatin Rowex 10 mg/80 mg tablets

ezetimibe/simvastatin

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

1. What Ezetimibe/Simvastatin Rowex is and what it is used for

Ezetimibe/Simvastatin Rowex is a medicine used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, Ezetimibe/Simvastatin Rowex raises levels of “good” cholesterol (HDL cholesterol).

Ezetimibe/Simvastatin Rowex contains the active substances ezetimibe and simvastatin.

Ezetimibe/Simvastatin Rowex works to reduce your cholesterol in two ways. The active substance ezetimibe reduces the cholesterol absorbed in your digestive tract. The active substance simvastatin belonging to the class of “statins” inhibits the production of 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 the 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.

Ezetimibe/Simvastatin Rowex 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.

Ezetimibe/Simvastatin Rowex 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]) or elevated fat levels in your blood (mixed hyperlipidaemia):
 - that is not well controlled with a statin alone

- 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.
- heart disease. Ezetimibe/Simvastatin Rowex reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Ezetimibe/Simvastatin Rowex does not help you lose weight.

2. What you need to know before you take Ezetimibe/Simvastatin Rowex

Do not take Ezetimibe/Simvastatin Rowex:

- if you are allergic to ezetimibe, simvastatin or any of the other substances of this medicine (listed in section 6)
- if you currently have liver problems
- if you are pregnant or breast-feeding
- if you are taking medicine(s) with one or more than one of the following active substances:
 - itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections)
 - erythromycin, clarithromycin, or telithromycin (used to treat infections)
 - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are used for HIV infections)
 - boceprevir or telaprevir (used to treat hepatitis C virus infections)
 - nefazodone (used to treat depression)
 - cobicistat
 - gemfibrozil (used to lower cholesterol)
 - ciclosporin (often used in organ transplant patients)
 - danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- if 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 Ezetimibe/Simvastatin Rowex can lead to serious muscle problems (rhabdomyolysis).

Do not take more than 10 mg/40 mg Ezetimibe/Simvastatin Rowex if you are taking lomitapide (used to treat a serious and rare genetic cholesterol condition).

Ask your doctor if you are not sure if your medicine is listed above.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ezetimibe/Simvastatin Rowex if you:

- have any medical conditions including allergies.
- drink large amounts of alcohol or have ever had liver disease. Ezetimibe/Simvastatin Rowex may not be right for you.
- are due to have an operation. You may need to stop taking Ezetimibe/Simvastatin Rowex tablets for a short time.
- are Asian, because a different dose may be applicable to you.
- if 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).

Your doctor should do a blood test before you start taking Ezetimibe/Simvastatin Rowex and if you have any symptoms of liver problems while you take Ezetimibe/Simvastatin Rowex. This is to check how well your liver is working.

Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Ezetimibe/Simvastatin Rowex.

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.

Tell your doctor if you have severe lung disease.

The combined use of Ezetimibe/Simvastatin Rowex and fibrates (certain medicines for lowering cholesterol) should be avoided since the combined use of Ezetimibe/Simvastatin Rowex and fibrates has not been studied.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rarely deaths have occurred.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

The risk of muscle breakdown is greater at higher doses of Ezetimibe/Simvastatin Rowex, particularly the 10 mg/80 mg dose.

The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- you have kidney problems
- you have thyroid problems
- you are 65 years or older
- you are female
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called “statins” (like simvastatin, atorvastatin, and rosuvastatin) or fibrates (like gemfibrozil and bezafibrate)
- you or close family members have a hereditary muscle disorder.

Children and adolescents

Ezetimibe/Simvastatin Rowex is not recommended for children under age 10.

Other medicines and Ezetimibe/Simvastatin Rowex

Tell your doctor if you are taking, have recently taken or might take any other medicines with any of the following active substances. Taking Ezetimibe/Simvastatin Rowex with any of the following medicines can increase the risk of muscle problems (some of these have already been listed in the above sections “Do not take Ezetimibe/Simvastatin Rowex and “Warnings and precautions”).

- **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 Ezetimibe/Simvastatin Rowex. Taking Ezetimibe/Simvastatin Rowex with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.**
- ciclosporin (often used in organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- medicines with an active substance like itraconazole, ketoconazole, fluconazole, posaconazole, or voriconazole (used to treat fungal infections)
- fibrates with active substances like gemfibrozil and bezafibrate (used to lower cholesterol)
- erythromycin, clarithromycin, or telithromycin (used to treat bacterial infections)
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (used to treat AIDS)
- hepatitis C antiviral agents such as boceprevir, telaprevir, elbasvir, or grazoprevir (used to treat hepatitis C virus infection)
- nefazodone (used to treat depression)
- medicines with the active substance cobicistat
- amiodarone (used to treat an irregular heartbeat)

- verapamil, diltiazem, or amlodipine (used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions)
- lomitapide (used to treat a serious and rare genetic cholesterol condition)
- daptomycin (used to treat complicated skin and skin structure infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin (e.g. Ezetimibe/Simvastatin Rowex). Your doctor may decide that you stop taking Ezetimibe/Simvastatin Rowex for a while.
- large amounts (1 gram or more each day) of niacin or nicotinic acid (also used to lower cholesterol)
- colchicine (used to treat gout)
- ticagrelor (used in patients who had a heart attack or angina or chest pain that is not well controlled).

As well as the medicines listed above, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those obtained without prescription. In particular, tell your doctor if you are taking any of the following:

- medicines with an active substance to prevent blood clots, such as warfarin, fluindione, phenprocoumon or acenocoumarol (anticoagulants)
- colestyramine (also used to lower cholesterol), because it affects the way Ezetimibe/Simvastatin Rowex works
- fenofibrate (also used to lower cholesterol)
- rifampicin (used to treat tuberculosis).

You should also tell any doctor who is prescribing a new medicine for you that you are taking Ezetimibe/Simvastatin Rowex.

Ezetimibe/Simvastatin Rowex with food and drink

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including Ezetimibe/Simvastatin Rowex. Consuming grapefruit juice should be avoided as it may increase your risk of muscle problems.

Pregnancy and breast-feeding

Do not take Ezetimibe/Simvastatin Rowex if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking Ezetimibe/Simvastatin Rowex, stop taking it immediately and tell your doctor.

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

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

Driving and using machines

Ezetimibe/Simvastatin Rowex 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 Ezetimibe/Simvastatin Rowex.

Ezetimibe/Simvastatin Rowex contains lactose and sodium

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

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

3. How to take Ezetimibe/Simvastatin Rowex

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

The tablets are not scored and should not be divided.

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 Ezetimibe/Simvastatin Rowex, you should be on a diet to lower your cholesterol.
- You should keep on this cholesterol-lowering diet while taking Ezetimibe/Simvastatin Rowex.

Adults: The dose is **1 tablet** by mouth once a day.

Use in children and adolescents

Adolescents (10 to 17 years of age): The dose is **1 tablet** by mouth once a day (a maximum dose of 10 mg/40 mg once daily must not be exceeded).

The Ezetimibe/Simvastatin Rowex 10 mg/80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

If optimal dosing cannot be achieved using Ezetimibe/Simvastatin Rowex, your doctor may prescribe other tablets containing ezetimibe/simvastatin.

Take Ezetimibe/Simvastatin Rowex in the evening. You can take it with or without food.

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

If you take more Ezetimibe/Simvastatin Rowex than you should

Please contact your doctor or pharmacist.

If you forget to take Ezetimibe/Simvastatin Rowex

Do not take a double dose to make up for a forgotten tablet, just take your normal amount of Ezetimibe/Simvastatin Rowex at the usual time the next day.

If you stop taking Ezetimibe/Simvastatin Rowex

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.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, muscle rupture, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rarely deaths have occurred.

The following common side effects were reported (may affect up to 1 in 10 people):

- muscle aches
- elevations in laboratory blood tests of liver (transaminases) and/or muscle (CK) function.

The following uncommon side effects were reported (may affect up to 1 in 100 people):

- elevations in blood tests of liver function; elevations in blood uric acid; elevations in the time it takes for blood to clot; protein in urine; weight decreased
- dizziness; headache; tingling sensation
- abdominal pain; indigestion; flatulence; nausea; vomiting; abdominal bloating; diarrhoea; dry mouth; heartburn
- rash; itching; hives

- joint pain; muscle pain, tenderness, weakness or spasms; neck pain; pain in arms and legs; back pain
- unusual tiredness or weakness; feeling tired; chest pain; swelling, especially in the hands and feet
- sleep disorder; trouble sleeping.

The following not known side effects were reported (frequency cannot be estimated from the available data):

- 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.

Additionally, the following side effects have been reported in people taking either Ezetimibe/Simvastatin Rowex or medicines containing the active substance ezetimibe or simvastatin:

- low red blood cell count (anaemia); reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia)
- numbness or weakness of the arms and legs; poor memory, memory loss, confusion
- breathing problems including persistent cough and/or shortness of breath or fever
- constipation
- inflammation of the pancreas often with severe abdominal pain
- inflammation of the liver with the following symptoms: yellowing of the skin and eyes; itching, dark coloured urine or pale coloured stool, feeling tired or weak, loss of appetite; liver failure; gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting)
- hair loss; raised red rash, sometimes with target-shaped lesions (erythema multiforme)
- blurred vision and impaired vision (which each may affect up to 1 in 1,000 people)
- rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions) (which each may affect up to 1 in 10,000 people)
- hypersensitivity reactions including some of the following: hypersensitivity (allergic) reactions including swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing and requires treatment immediately (angioedema). A serious very rare allergic reaction (which may affect up to 1 in 10,000 people) may occur that causes difficulty in breathing or dizziness and requires immediate treatment (anaphylaxis).
- pain or inflammation of the joints, inflammation of blood vessels, unusual bruising, skin eruptions and swelling, hives, skin sensitivity to the sun, fever, flushing, shortness of breath and feeling unwell, lupus-like disease picture (including rash, joint disorders, and effects on white blood cells)
- muscle pain, tenderness, weakness or cramps; muscle breakdown; muscle rupture (which may affect up to 1 in 10,000 people); tendon problems, sometimes complicated by rupture of the tendon
- gynecomastia (breast enlargement in men) (which may affect up to 1 in 10,000 people)
- decreased appetite
- hot flush; high blood pressure
- pain
- erectile dysfunction
- depression
- alterations in some laboratory blood tests for liver function.

Additional possible side effects reported with some statins:

- sleep disturbances, including nightmares
- sexual difficulties
- 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.
- muscle pain, tenderness, or weakness that is constant that may not go away after stopping Ezetimibe/Simvastatin Rowex (frequency not known: cannot be estimated from the available data).

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: HPRRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ezetimibe/Simvastatin Rowex

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 blister, tablet container and carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.

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 Ezetimibe/Simvastatin Rowex contains

- The active substances are ezetimibe and simvastatin.
Each tablet contains 10 mg of ezetimibe and 20 mg of simvastatin.
Each tablet contains 10 mg of ezetimibe and 40 mg of simvastatin.
Each tablet contains 10 mg of ezetimibe and 80 mg of simvastatin.
- The other ingredients are: *Tablet core*: lactose monohydrate, hypromellose, croscarmellose sodium, microcrystalline cellulose, ascorbic acid, citric acid anhydrous, butylated hydroxyanisole, propyl gallate, magnesium stearate. *Pigment blend*: lactose monohydrate, iron oxide yellow (E172), iron oxide red (E172) and iron oxide black (E172).

What Ezetimibe/Simvastatin Rowex looks like and contents of the pack

Ezetimibe/Simvastatin Rowex 10 mg/20 mg tablets:

Light tan, mottled, round, 8 mm in diameter, biconvex tablets, marked with "512" on one side.

Ezetimibe/Simvastatin Rowex 10 mg/40 mg tablets:

Light tan, mottled, round, 10 mm in diameter, biconvex tablets, marked with "513" on one side.

Ezetimibe/Simvastatin Rowex 10 mg/80 mg tablets:

Light tan, mottled, capsule shaped, 17.5 x 7.55 mm, biconvex tablets, marked with "515" on one side.

The tablets are packed in OPA/Alu/PVC/Alu blisters or are packed in a HDPE tablet container with PP cap and silica gel desiccant and inserted in a carton.

Pack sizes:

Blister: 10, 14, 28, 30, 50, 90, 100 tablets

HDPE tablet container: 100 tablets

Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Balkanpharma-Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria.

Lek Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, Sachsen-Anhalt, 39179 Barleben, Germany.

Actavis Ltd., BLB015-016, Bulebel Industrial Estate, Zejtun ZTN 3000, Malta.

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Ezetimib/Simvastatin Sandoz
Austria	Ezetimibe/Simvastatin Sandoz 10 mg/10 mg – Tabletten Ezetimibe/Simvastatin Sandoz 10 mg/20 mg – Tabletten Ezetimibe/Simvastatin Sandoz 10 mg/40 mg – Tabletten Ezetimibe/Simvastatin Sandoz 10 mg/80 mg - Tabletten
Belgium	Ezetimibe/ Simvastatine Sandoz 10mg/10mg tabletten Ezetimibe/ Simvastatine Sandoz 10mg/20mg tabletten Ezetimibe/ Simvastatine Sandoz 10mg/40mg tabletten Ezetimibe/ Simvastatine Sandoz 10mg/80mg tabletten
France	Ezétimibe/Simvastatine Sandoz 10 mg/20 mg, comprimé Ezétimibe/Simvastatine Sandoz 10 mg/40 mg, comprimé
Germany	EzesimvaHEXAL 10 mg/10 mg Tabletten EzesimvaHEXAL 10 mg/20 mg Tabletten EzesimvaHEXAL 10 mg/40 mg Tabletten EzesimvaHEXAL 10 mg/80 mg Tabletten
Greece	Ezetimibe+Simvastatin/Sandoz (10+10) mg δισκία Ezetimibe+Simvastatin/Sandoz (10+20) mg δισκία Ezetimibe+Simvastatin/Sandoz (10+40) mg δισκία Ezetimibe+Simvastatin/Sandoz (10+80) mg δισκία
Ireland	Ezetimibe/Simvastatin Rowex 10 mg/20 mg tablets Ezetimibe/Simvastatin Rowex 10 mg/40 mg tablets Ezetimibe/Simvastatin Rowex 10 mg/80 mg tablets
Italy	Ezetimibe e simvastatina Sandoz
Luxemburg	Ezetimibe/ Simvastatine Sandoz 10mg/10mg comprimés Ezetimibe/ Simvastatine Sandoz 10mg/20mg comprimés Ezetimibe/ Simvastatine Sandoz 10mg/40mg comprimés Ezetimibe/ Simvastatine Sandoz 10mg/80mg comprimés
Norway	Ezetimib/Simvastatin Sandoz
Portugal	Sinvastatina + Ezetimiba Sandoz
Spain	Eztimiba/Simvastatina Sandoz 10 mg/10 mg comprimidos EFG Eztimiba/Simvastatina Sandoz 10 mg/20 mg comprimidos EFG Eztimiba/Simvastatina Sandoz 10 mg/40 mg comprimidos EFG Eztimiba/Simvastatina Sandoz 10 mg/80 mg comprimidos EFG
The Netherlands	Ezetimibe/Simvastatine Sandoz 10 mg/10 mg, tabletten Ezetimibe/Simvastatine Sandoz 10 mg/20 mg, tabletten Ezetimibe/Simvastatine Sandoz 10 mg/40 mg, tabletten Ezetimibe/Simvastatine Sandoz 10 mg/80 mg, tabletten

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