

Package leaflet: Information for the patient

Ezetimibe/Simvastatin Accord 10 mg / 20 mg tablets

Ezetimibe/Simvastatin Accord 10 mg / 40 mg tablets

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

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

Ezetimibe/Simvastatin Accord contains the active substances ezetimibe and simvastatin. Ezetimibe/Simvastatin Accord 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 Accord raises levels of “good” cholesterol (HDL cholesterol).

Ezetimibe/Simvastatin Accord works to reduce your cholesterol in two ways. The active ingredient ezetimibe reduces the cholesterol absorbed in your digestive tract. The active ingredient 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 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 Accord 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 Accord 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 Accord reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization for chest pain.

Ezetimibe/Simvastatin Accord does not help you lose weight.

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

Do not take Ezetimibe/Simvastatin Accord if:

- you are allergic (hypersensitive) to ezetimibe, simvastatin, or any of the other ingredients of this medicine (listed in Section 6: Contents of the pack and other information)
- you currently have liver problems
- you are pregnant or breast-feeding
- you are taking medicine(s) with one or more than one of the following active ingredients:
 - 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 to treat 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).
- 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 Accord can lead to serious muscle problems (rhabdomyolysis).

Do not take more than 10/40mg Ezetimibe/Simvastatin Accord 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

Tell your doctor:

- about all your medical conditions including allergies.
- if you drink large amounts of alcohol or have ever had liver disease. Ezetimibe/Simvastatin Accord may not be right for you.
- if you are due to have an operation. You may need to stop taking Ezetimibe/Simvastatin Accord tablets for a short time.
- if you 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 Accord and if you have any symptoms of liver problems while you take Ezetimibe/Simvastatin Accord. 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 Accord.

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 Accord and fibrates (certain medicines for lowering cholesterol) should be avoided since the combined use of Ezetimibe/Simvastatin Accord 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 rare deaths have occurred.

The risk of muscle breakdown is greater at higher doses of <invented name>, particularly the 10/80mg 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

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.

Children and adolescents

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

Other medicines and Ezetimibe/Simvastatin Accord

Tell your doctor if you are taking, have recently taken or might take any other medicine(s) with any of the following active ingredients. Taking Ezetimibe/Simvastatin Accord with any of the following medicines can increase the risk of muscle problems (some of these have already been listed in the above section "Do not take Ezetimibe/Simvastatin Accord if").

- **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 Accord. Taking Ezetimibe/Simvastatin Accord 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 ingredient like itraconazole, ketoconazole, fluconazole, posaconazole, or voriconazole (used to treat fungal infections)
- fibrates with active ingredients 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 ingredient 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 (a drug 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 Accord.) Your doctor may decide that you stop taking Ezetimibe/Simvastatin Accord 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).

As well as the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken 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 ingredient 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 Accord works
- fenofibrate (also used to lower cholesterol)
- rifampicin (used to treat tuberculosis)
- ticagrelor (antiplatelet medicine).

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

Ezetimibe/Simvastatin Accord with food and drink

Grapefruit juice contains one or more components that alter the metabolism of some medications,

including Ezetimibe/Simvastatin Accord. Consuming grapefruit juice should be avoided as it may increase your risk of muscle problems.

Pregnancy and breast-feeding

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

Ezetimibe/Simvastatin Accord contains lactose

Ezetimibe/Simvastatin Accord tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ezetimibe/Simvastatin Accord

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 Accord, you should be on a diet to lower your cholesterol.
 - You should keep on this cholesterol-lowering diet while taking Ezetimibe/Simvastatin Accord.
- Adults: The dose is **1 tablet** Ezetimibe/Simvastatin Accord by mouth once a day.

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

The Ezetimibe/Simvastatin Accord 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.

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

If your doctor has prescribed Ezetimibe/Simvastatin Accord along with another medicine for lowering cholesterol containing the active ingredient colestyramine or any other bile acid sequestrant, you should take

Ezetimibe/Simvastatin Accord at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you take more Ezetimibe/Simvastatin Accord than you should:

- Please contact your doctor or pharmacist.

If you forget to take Ezetimibe/Simvastatin Accord:

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

If you stop taking Ezetimibe/Simvastatin Accord:

- 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, Ezetimibe/Simvastatin Accord can cause side effects, although not everybody gets them (see section 2, **What you need to know before you take Ezetimibe/Simvastatin Accord**).

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

Additionally, the following side effects have been reported in people taking either Ezetimibe/Simvastatin Accord or medicines containing the active ingredients 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 1000 people),
- rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions) (which each may affect up to 1 in 10000 people),
- hypersensitivity reactions including some of the following: 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), 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). A serious very rare allergic reaction (which may affect up to 1 in 10000 people) may occur that causes difficulty in breathing or dizziness and requires immediate treatment (anaphylaxis).

- muscle pain, tenderness, weakness or cramps; muscle breakdown; muscle rupture (which may affect up to 1 in 10000 people); tendon problems, sometimes complicated by rupture of the tendon.
- gynecomastia (breast enlargement in men) (which may affect up to 1 in 10000 people),
- decreased appetite
- hot flush; high blood pressure
- pain
- erectile dysfunction
- depression
- alterations in some laboratory blood tests for liver function
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing) (frequency cannot be estimated from the available data)
- Ocular myasthenia (a disease causing eye muscle weakness) (frequency cannot be estimated from the available data)

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.

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 Accord (frequency not known).

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 rare deaths have occurred.

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 HPRA 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 Accord

- 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 or container after [EXP].
- This medicine does not require any special 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 Ezetimibe/Simvastatin Accord contains

The active substances are ezetimibe and simvastatin.

- Each uncoated tablet contains 10mg of Ezetimibe and 20mg of Simvastatin
- Each uncoated tablet contains 10mg of Ezetimibe and 40mg of Simvastatin
- Each uncoated tablet contains 10mg of Ezetimibe and 80mg of Simvastatin

The other ingredients are: Lactose monohydrate, Iron oxide red (E172), Croscarmellose sodium, Microcrystalline cellulose, Citric acid monohydrate, Hypromellose 2910 3cps, Propyl gallate, Butylated hydroxy anisole, Ascorbic acid, Magnesium stearate.

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

Ezetimibe/Simvastatin Accord 10mg of Ezetimibe and 20mg of Simvastatin uncoated tablets are presented as Light pink to pink colored with mosaic appearance, capsule shaped biconvex uncoated tablets '336' on one side and plain on other side. The size of the tablet is approximately 11.00 x 5.50 mm.

Ezetimibe/Simvastatin Accord 10mg of Ezetimibe and 40mg of Simvastatin uncoated tablets are presented as Light pink to pink colored with mosaic appearance, capsule shaped biconvex uncoated tablets '337' on one side and plain on other side. The size of the tablet is approximately 13.90 x 6.90 mm.

Ezetimibe/Simvastatin Accord 10mg of Ezetimibe and 80mg of Simvastatin uncoated tablets are presented as Light pink to pink colored with mosaic appearance, capsule shaped biconvex uncoated tablets '338' on one side and plain on other side. The size of the tablet is approximately 17.25 x 8.30 mm.

The tablets are not scored and should not be divided.

Pack sizes:

Pack sizes: 28, 30, 50, 90, 98 or 100 tablets

Not all pack sizes may be marketed.

Marketing Authorization Holder

Accord Healthcare Ireland Limited,
Euro House, Euro Business Park,
Cork, T45 K857,
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Manufacturer

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Ul. Lutomska 50,
95-200,Pabianice,
Poland

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

Name of member state	Name of the medicinal product
DE	Ezetimib/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, 10 mg/80 mg Tabletten
AT	Ezetimib/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg,10 mg/40 mg, 10 mg/80 mg Tabletten
IT	Ezetimibe e Simvastatina Accord
CY	Ezetimibe/Simvastatin Accord 10mg/10mg, 10mg/20mg Tablets
RO	Ezetimib/Simvastatină Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg comprimate
CZ	Ezetimibe/Simvastatin Accord
BG	Ezetimibe/Simvastatin Accord 10 mg /10 mg таблетки
IE	Ezetimibe/Simvastatin Accord 10mg/20mg, 10mg/40mg, 10mg/80mg Tablets
SE	Ezetimibe/Simvastatin Accord
DK	Ezetimibe/Simvastatin Accord
NO	Ezetimibe/Simvastatin Accord
NL	Ezetimibe/Simvastatine Accord 10mg/20mg, 10mg/40mg, 10mg/80mg, tabletten
FR	EZETIMIBE/SIMVASTATINE ACCORD 10 mg/20 mg, 10 mg/40 mg, comprimé
UK	Ezetimibe/Simvastatin 10mg/20mg, 10mg/40mg, 10mg/80mg Tablets

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