

Patient Information
Ezetimibe and Simvastatin Tablets
(e-ZET-i-mibe / SIM-va-STAT-in)

Read this Information carefully before you start taking ezetimibe and simvastatin tablets and each time you get a ezetimibe and simvastatin tablets.

There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you have any questions about ezetimibe and simvastatin tablets, ask your healthcare provider. Only your healthcare provider can determine if ezetimibe and simvastatin tablets is right for you.

What is ezetimibe and simvastatin tablets?

Ezetimibe and simvastatin tablets is a prescription medicine that contains the cholesterol lowering medicines, simvastatin and ezetimibe:

- Ezetimibe and simvastatin tablets is used along with diet to lower elevated low-density lipoprotein cholesterol (LDL-C) or bad cholesterol in:
 - adults with primary hyperlipidemia (high level of fats in your blood).
 - adults and children 10 years of age and older with heterozygous familial hypercholesterolemia (HeFH). HeFH is an inherited condition that causes high levels of bad cholesterol.
- Ezetimibe and simvastatin tablets is also used with other cholesterol lowering treatments to lower elevated LDL-C levels in adults with homozygous familial hypercholesterolemia (HoFH). HoFH is an inherited condition that causes high levels of bad cholesterol.
- Simvastatin when used as a component of ezetimibe and simvastatin tablets is used to lower:
 - the risk of death by lowering the risk of heart disease death.
 - the risk of heart attacks and strokes.
 - the need for certain types of heart and blood vessel procedures to improve blood flow called arterial revascularization in people with known heart, cerebrovascular disease (conditions that affect blood flow and the blood vessels in the brain), peripheral vascular disease (a blood circulation disorder that causes the blood vessels outside of your heart and brain to narrow, block, or spasm), and diabetes, who are at high risk for heart disease problems.

The safety and effectiveness of ezetimibe and simvastatin tablets has not been established in children younger than 10 years of age with inherited heterozygous familial hypercholesterolemia (HeFH) or other types of hyperlipidemia.

Do not take ezetimibe and simvastatin tablets if you:

- take certain medicines called CYP3A4 inhibitors such as:
 - certain antifungal medicines (such as itraconazole, ketoconazole, posaconazole, voriconazole).
 - certain antibiotics (including erythromycin, clarithromycin, telithromycin).
 - HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, saquinavir, tipranavir, or atazanavir and cobicistat-containing products such as (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate).
 - certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir).
 - the antidepressant nefazodone.
- take medicines called cyclosporine, danazol, or gemfibrozil.
- have liver problems.
- are allergic to simvastatin, ezetimibe, or any of the ingredients in ezetimibe and simvastatin tablets. See the end of this Patient Information leaflet for a complete list of ingredients in ezetimibe and simvastatin tablets.

Ask your healthcare provider or pharmacist if you are not sure if your medicine is listed above.

Before you take ezetimibe and simvastatin tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have unexplained muscle aches or weakness.
- have or have had myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used for breathing), ocular myasthenia (a disease causing eye muscle weakness).
- have kidney problems.
- have liver problems or drink more than 2 glasses of alcohol daily.
- have thyroid problems.
- are 65 years of age or older.
- are of Chinese descent.
- are pregnant or plan to become pregnant. If you become pregnant while taking ezetimibe and simvastatin tablets, call your healthcare provider right away to discuss stopping ezetimibe and simvastatin tablets.
- are breastfeeding or plan to breastfeed. It is not known if ezetimibe and simvastatin tablets passes into your breast milk.
Do not breastfeed while taking ezetimibe and simvastatin tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the- counter medicines, vitamins, and herbal supplements. Talk to your healthcare provider before you start taking any new medicines.

Tell your healthcare provider who prescribes ezetimibe and simvastatin tablets if another healthcare provider increases the dose of another medicine you are taking.

Ezetimibe and simvastatin tablets may affect the way other medicines work, and other medicines may affect how ezetimibe and simvastatin tablets works. Especially tell your healthcare provider if you take:

- digoxin (a drug used to treat irregular heartbeat).
- coumarin anticoagulants (drugs that prevent blood clots, such as warfarin).
- fibric acid derivatives (such as fenofibrate).

Taking ezetimibe and simvastatin tablets with certain substances can also increase the risk of muscle problems. Especially tell your healthcare provider if you take:

- amiodarone or dronedarone (medicines used to treat an irregular heartbeat).
- verapamil, diltiazem, amlodipine, or ranolazine (medicines used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions).
- lomitapide (a medicine used to treat a serious and rare genetic cholesterol condition).
- daptomycin (a drug used to treat complicated skin and bloodstream infections).
- large doses of niacin or nicotinic acid, especially if you are of Chinese descent.
- colchicine (a medicine used to treat gout).
- grapefruit juice.

Ask your healthcare provider or pharmacist for a list of medicines if you are not sure. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ezetimibe and simvastatin tablets?

- Take ezetimibe and simvastatin tablets exactly as your healthcare provider tells you to take it.
- **Do not** change your dose or stop taking ezetimibe and simvastatin tablets without talking to your healthcare provider.
- Take ezetimibe and simvastatin tablets 1 time each day in the evening.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take 2 doses of ezetimibe and simvastatin tablets at the same time. Talk with your healthcare provider if you have questions about a missed dose.
- While taking ezetimibe and simvastatin tablets, continue to follow your cholesterol-lowering diet and to exercise as your healthcare provider told you to.

- Your healthcare provider may do blood tests to check your cholesterol while you take ezetimibe and simvastatin tablets. Your healthcare provider may change your dose of ezetimibe and simvastatin tablets if needed.

If you take too much ezetimibe and simvastatin tablets, call your healthcare provider or Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of ezetimibe and simvastatin tablets?

Ezetimibe and simvastatin tablets may cause serious side effects including:

- **Muscle pain, tenderness, and weakness (myopathy).** Muscle problems, including muscle breakdown, can be serious in some people and rarely cause kidney damage that can lead to death.

Tell your healthcare provider right away if:

- **you have unexplained muscle pain, tenderness, or weakness, especially if you have a fever or feel more tired than usual, while you take ezetimibe and simvastatin tablets.**
- you have muscle problems that do not go away even after your healthcare provider has advised you to stop taking ezetimibe and simvastatin tablets. Your healthcare provider may do further tests to diagnose the cause of your muscle problems.

Your chances of getting muscle problems are higher if you:

- are taking certain other medicines while you take ezetimibe and simvastatin tablets.
- are 65 years of age or older.
- are female.
- have thyroid problems (hypothyroidism) that are not controlled.
- have kidney problems.
- are taking higher doses of ezetimibe and simvastatin tablets.
- are Chinese.
- **Liver problems.** Your healthcare provider should do blood tests to check your liver before you start taking ezetimibe and simvastatin tablets and if you have any symptoms of liver problems while you take ezetimibe and simvastatin tablets. Call your healthcare provider right away if you have the following symptoms of liver problems:
 - feeling tired or weak
 - loss of appetite
 - right-sided upper belly pain
 - dark urine
 - yellowing of your skin or the whites of your eyes
- **increase in blood sugar (glucose) levels).** Ezetimibe and simvastatin tablets may cause an increase in your blood sugar levels.

The most common side effects of ezetimibe and simvastatin tablets include:

- headache
- increased liver enzyme levels
- muscle pain
- upper respiratory infection
- diarrhea

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of ezetimibe and simvastatin tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ezetimibe and simvastatin tablets?

- Store ezetimibe and simvastatin tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep ezetimibe and simvastatin tablets in its original container until you use it.

- Keep ezetimibe and simvastatin tablets in a tightly closed container.

Keep ezetimibe and simvastatin tablets and all medicines out of the reach of children.

General information about safe and effective use of ezetimibe and simvastatin tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ezetimibe and simvastatin tablets for a condition for which it was not prescribed. Do not give ezetimibe and simvastatin tablets to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about ezetimibe and simvastatin tablets that is written for health professionals.

For more information, call 1-877-272-7901.

What are the ingredients in ezetimibe and simvastatin tablets?

Active Ingredients: ezetimibe, USP and simvastatin, USP

Inactive Ingredients: Lactose Monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Sodium Lauryl Sulfate, Hypromellose, Citric Acid Monohydrate, Propyl Gallate, Butylated Hydroxy Anisole and Magnesium Stearate.

This Patient Information has been approved by the U.S. Food and Drug Administration.

For Patient Information, please visit:
http://www.ascendlaboratories.com/pti/ezetim_simvatablets.pdf

Manufactured by:

Alkem Laboratories Ltd.
Mumbai - 400 013, INDIA.

Distributed by:

Ascend Laboratories, LLC
Parsippany, NJ 07054

Revised: May, 2024