

PATIENT INFORMATION

EZETIMIBE (ee-ZET-ah-mybe) AND SIMVASTATIN (sim-vah-STAH-tin) TABLETS

Read this Patient Information carefully before you start taking ezetimibe and simvastatin tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about ezetimibe and simvastatin tablets, ask your doctor. Only your doctor can determine if ezetimibe and simvastatin tablets are right for you.

What are ezetimibe and simvastatin tablets?

Ezetimibe and simvastatin tablets are a prescription medicine that contains 2 cholesterol-lowering medicines, ezetimibe and simvastatin.

Ezetimibe and simvastatin tablets are used along with diet to:

- lower the level of your “bad” cholesterol (LDL)
- increase the level of your “good” cholesterol (HDL)
- lower the level of fat in your blood (triglycerides)

Ezetimibe and simvastatin tablets are for patients who cannot control their cholesterol levels by diet and exercise alone.

Ezetimibe and simvastatin tablets have not been shown to reduce heart attacks or strokes more than simvastatin alone.

It is not known if ezetimibe and simvastatin tablets are safe and effective in children under 10 years of age or in girls who have not started their period (menses).

The usual dose of ezetimibe and simvastatin tablets is 10 mg/10 mg to 10 mg/40 mg 1 time each day.

Ezetimibe and simvastatin tablets 10 mg/80 mg increase your chance of developing muscle damage.

The 10 mg/80 mg dose should only be used by people who:

- have been taking ezetimibe and simvastatin tablets 10 mg/80 mg chronically (such as 12 months or more) without having muscle damage
- do not need to take certain other medicines with ezetimibe and simvastatin tablets that would increase your chance of getting muscle damage.

If you are unable to reach your LDL-cholesterol goal using ezetimibe and simvastatin tablets 10 mg/40 mg, your doctor should switch you to another cholesterol-lowering medicine.

Who should not take ezetimibe and simvastatin tablets?

Do not take ezetimibe and simvastatin tablets if you take:

- Certain anti-fungal medicines including:
 - itraconazole
 - ketoconazole
 - posaconazole
 - voriconazole
- HIV protease inhibitors (indinavir, nelfinavir, ritonavir, saquinavir, tipranavir, or atazanavir)
- Certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
- Certain antibiotics, including:
 - erythromycin
 - clarithromycin
 - telithromycin
- nefazodone
- medicines containing cobicistat
- A fibric acid medicine for lowering cholesterol called gemfibrozil
- cyclosporine
- danazol

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Also do not take ezetimibe and simvastatin tablets if you:

- are allergic to ezetimibe or simvastatin or any of the ingredients in ezetimibe and simvastatin tablets. See the end of this leaflet for a complete list of ingredients in ezetimibe and simvastatin tablets.
- have liver problems.
- are pregnant or plan to become pregnant. Ezetimibe and simvastatin tablets may harm your unborn baby. If you are a woman of childbearing age, you should use an effective method of birth control to prevent pregnancy while using ezetimibe and simvastatin tablets. If you become pregnant while taking ezetimibe and simvastatin tablets, stop taking ezetimibe and simvastatin tablets and call your doctor.
- are breastfeeding or plan to breastfeed. It is not known if ezetimibe and simvastatin pass into your breast milk. You and your doctor should decide the best way to feed your baby if you take ezetimibe and simvastatin tablets.

What should I tell my doctor before and while taking ezetimibe and simvastatin tablets?

Tell your doctor if you:

- have unexplained muscle aches or weakness
- have kidney problems
- have or have had liver problems or drink more than 2 glasses of alcohol daily
- have thyroid problems
- are 65 years of age or older
- are Chinese

Also see “What are the possible side effects of ezetimibe and simvastatin tablets?”

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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

Talk to your doctor before you start taking any new medicines.

Taking ezetimibe and simvastatin tablets with certain other medicines may affect each other causing side effects. Ezetimibe and simvastatin tablets may affect the way other medicines work, and other medicines may affect how ezetimibe and simvastatin tablets work.

Taking ezetimibe and simvastatin tablets with certain substances can increase the risk of muscle problems.

It is especially important to tell your doctor if you take:

- fibric acid derivatives (such as fenofibrate)
- amiodarone or dronedarone (drugs used to treat an irregular heartbeat)
- verapamil, diltiazem, amlodipine, or ranolazine (drugs used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions)
- grapefruit juice (which should be avoided while taking ezetimibe and simvastatin tablets)
- colchicine (a medicine used to treat gout)
- 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

Tell your doctor if you are taking niacin or a niacin-containing product, as this may increase your risk of muscle problems, especially if you are Chinese.

It is also important to tell your doctor if you are taking coumarin anticoagulants (drugs that prevent blood clots, such as warfarin).

Tell your doctor about all the medicines you take, including any prescription and nonprescription medicines, vitamins, and herbal supplements.

How should I take ezetimibe and simvastatin tablets?

- Take ezetimibe and simvastatin tablets exactly as your doctor tells you to take them.
- Do not change your dose or stop taking ezetimibe and simvastatin tablets without talking to your doctor.
- Take ezetimibe and simvastatin tablets 1 time each day in the evening.
- Take ezetimibe and simvastatin tablets with or without food.
- While taking ezetimibe and simvastatin tablets, continue to follow your cholesterol-lowering diet and to exercise as your doctor told you to.
- If you miss a dose, do not take an extra dose. Just resume your usual schedule.
- Your doctor should do fasting blood tests to check your cholesterol while you take ezetimibe and simvastatin tablets. Your doctor may change your dose of ezetimibe and simvastatin tablets if needed.
- If you take too many ezetimibe and simvastatin tablets, call your doctor or Poison Control Center 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 doctor 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 doctor has advised you to stop taking ezetimibe and simvastatin tablets. Your doctor 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, particularly the 10 mg/80 mg dose
- are Chinese
- **Liver problems.** Your doctor 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 doctor right away if you have the following symptoms of liver problems:
 - loss of appetite
 - upper belly pain
 - dark urine
 - yellowing of your skin or the whites of your eyes
 - feel tired or weak

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

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

Additional side effects that have been reported in general use with ezetimibe and simvastatin tablets or with ezetimibe or simvastatin tablets (tablets that contain the active ingredients of ezetimibe and simvastatin tablets) 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, hives; joint pain; inflammation of the pancreas; nausea; dizziness; tingling sensation; depression; gallstones; trouble sleeping; poor memory; memory loss; confusion; erectile dysfunction; breathing problems including persistent cough and/or shortness of breath or fever.

Tell your doctor 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. For more information, ask your doctor or pharmacist.

Call your doctor about 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 their original container until you use them.
- Keep ezetimibe and simvastatin tablets in a tightly closed container, and keep ezetimibe and simvastatin tablets out of light.

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

General Information about the safe and effective use of ezetimibe and simvastatin tablets.

Ezetimibe and simvastatin tablets work to reduce your cholesterol in two ways. They reduce the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself.

Ezetimibe and simvastatin tablets do not help you lose weight.

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 they were not prescribed. Do not give ezetimibe and simvastatin tablets to other people, even if they have the same condition that you have. They may harm them.

This Patient Information summarizes the most important information about ezetimibe and simvastatin tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about ezetimibe and simvastatin tablets that is written for health professionals.

For more information, call 1-888-375-3784.

What are the ingredients in ezetimibe and simvastatin tablets?

Active Ingredients: ezetimibe and simvastatin

Inactive ingredients:

Butylated hydroxyanisole, citric acid monohydrate, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and propyl gallate.

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

To reorder additional Patient Information sheets, please contact Dr. Reddy’s Customer Service at 1-866-733-3952.

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