

Patient Information

Ezetimibe Tablets

(ě-zět'-ě-mīb)

Read this information carefully before you start taking ezetimibe tablets and each time you get more ezetimibe tablets. 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 tablets, ask your doctor. Only your doctor can determine if ezetimibe tablets are right for you.

What are Ezetimibe Tablets?

Ezetimibe tablets are medicines used to lower levels of total cholesterol and LDL (bad) cholesterol in the blood. Ezetimibe tablets are for patients who cannot control their cholesterol levels by diet and exercise alone. It can be used by itself or with other medicines to treat high cholesterol. You should stay on a cholesterol-lowering diet while taking this medicine.

Ezetimibe tablets work to reduce the amount of cholesterol your body absorbs. Ezetimibe tablets do not help you lose weight. Ezetimibe tablets have not been shown to prevent heart disease or heart attacks.

For more information about cholesterol, see the “What should I know about high cholesterol?” section that follows.

Who should not take Ezetimibe Tablets?

- Do not take ezetimibe tablets if you are allergic to ezetimibe, the active ingredient in ezetimibe tablets, or to the inactive ingredients. For a list of inactive ingredients, see the “Inactive ingredients” section that follows.
- If you have active liver disease, do not take ezetimibe tablets while taking cholesterol-lowering medicines called statins.
- If you are pregnant or breast-feeding, do not take ezetimibe tablets while taking a statin.
- If you are a woman of childbearing age, you should use an effective method of birth control to prevent pregnancy while using ezetimibe tablets added to statin therapy.

Ezetimibe tablets have not been studied in children under age 10.

What should I tell my doctor before and while taking Ezetimibe Tablets?

Tell your doctor about any prescription and non-prescription medicines you are taking or plan to take, including natural or herbal remedies.

Tell your doctor about all your medical conditions including allergies.

Tell your doctor if you:

- ever had liver problems. Ezetimibe tablets may not be right for you.
- are pregnant or plan to become pregnant. Your doctor will discuss with you whether ezetimibe tablets are right for you.
- are breast-feeding. We do not know if ezetimibe can pass to your baby through your milk. Your doctor will discuss with you whether ezetimibe tablets are right for you.
- experience unexplained muscle pain, tenderness, or weakness.

How should I take Ezetimibe Tablets?

- Take ezetimibe tablets once a day, with or without food. It may be easier to remember to take your dose if you do it at the same time every day, such as with breakfast, dinner, or at bedtime. If you also take another medicine to reduce your cholesterol, ask your doctor if you can take them at the same time.
- If you forget to take ezetimibe tablets, take it as soon as you remember. However, do not take more than one dose of ezetimibe tablets a day.
- Continue to follow a cholesterol-lowering diet while taking ezetimibe tablets. Ask your doctor if you need diet information.
- Keep taking ezetimibe tablets unless your doctor tells you to stop. It is important that you keep taking ezetimibe tablets even if you do not feel sick.

See your doctor regularly to check your cholesterol level and to check for side effects. Your doctor may do blood tests to check your liver before you start taking ezetimibe tablets with a statin and during treatment.

What are the possible side effects of Ezetimibe Tablets?

In clinical studies patients reported few side effects while taking ezetimibe tablets. These included diarrhea, joint pains, and feeling tired.

Patients have experienced severe muscle problems while taking ezetimibe tablets, usually when ezetimibe tablets were added to a statin drug. If you experience unexplained muscle pain, tenderness, or weakness while taking ezetimibe tablets, contact your doctor immediately. You need to do this promptly, because on rare occasions, these muscle problems can be serious, with muscle breakdown resulting in kidney damage.

Additionally, the following side effects have been reported in general use: allergic reactions (which may require treatment right away) including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing, rash, and hives; raised red rash, sometimes with target-shaped lesions; joint pain; muscle aches; alterations in some laboratory blood tests; liver problems; stomach pain; inflammation of the pancreas; nausea; dizziness; tingling sensation; depression; headache; gallstones; inflammation of the gallbladder.

Tell your doctor if you are having these or any other medical problems while on

ezetimibe tablets. For a complete list of side effects, ask your doctor or pharmacist.

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

What should I know about high cholesterol?

Cholesterol is a type of fat found in your blood. Your total cholesterol is made up of LDL and HDL cholesterol.

LDL cholesterol is called “bad” cholesterol because it can build up in the wall of your arteries and form plaque. Over time, plaque build-up can cause a narrowing of the arteries. This narrowing can slow or block blood flow to your heart, brain, and other organs. High LDL cholesterol is a major cause of heart disease and one of the causes for stroke.

HDL cholesterol is called “good” cholesterol because it keeps the bad cholesterol from building up in the arteries.

Triglycerides also are fats found in your blood.

General information about Ezetimibe Tablets

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ezetimibe tablets for a condition for which it was not prescribed. Do not give ezetimibe tablets to other people, even if they have the same condition you have. It may harm them.

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

For further information, go to www.accordhealthcare.us or call Accord Healthcare at 1-866-941-7875.

Ingredients:

Active Ingredient: Ezetimibe

Inactive ingredients: Croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone K-30, polysorbate 80 and sodium lauryl sulfate.

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

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