

Patient Information
EZETIMIBE TABLETS, USP
(e-zet^z-i-mibe)

Rx only

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

What are ezetimibe tablets, USP?

Ezetimibe tablets, USP are used with a cholesterol lowering diet:

- and with other cholesterol medicines called a statin, or alone (when additional cholesterol lowering treatments are not possible), to lower elevated low-density lipoprotein cholesterol (LDL-C) or bad cholesterol in adults with primary hyperlipidemia (too many fats in your blood), including heterozygous familial hypercholesterolemia (HeFH). HeFH is an inherited condition that causes high levels of bad cholesterol.
- and with a statin to lower LDL-C in adults and children 10 years of age and older with HeFH.
- and with a medicine called fenofibrate to lower elevated LDL-C in adults with mixed hyperlipidemia.
- to lower elevated sitosterol and campesterol levels in adults and in children 9 years of age and older with homozygous familial sitosterolemia (a rare inherited condition that prevents the body from getting rid of cholesterol from plants).

Ezetimibe tablets is also used:

- with a statin and other cholesterol lowering treatments to lower elevated LDL-C levels in adults and patients 10 years of age and older with homozygous familial hypercholesterolemia (HoFH). HoFH is an inherited condition that causes high levels of bad cholesterol.

The safety and effectiveness of ezetimibe tablets has not been established in children:

- younger than 10 years of age with HeFH or HoFH.
- younger than 9 years of age with homozygous familial sitosterolemia.
- with other types of hyperlipemia.

Do not take ezetimibe tablets:

- if you are allergic to ezetimibe or any of the ingredients in ezetimibe tablets. See the end of this Patient Information leaflet for a complete list of ingredients in ezetimibe tablets. Stop using ezetimibe tablets and get medical help right away if you have symptoms of a serious allergic reaction including:
 - o swelling of the face, tongue, or throat
 - o difficulty breathing or swallowing
 - o fainting or feeling dizzy o very fast heartbeat
 - o severe skin rash, hives, and itching
 - o flu-like symptoms including fever, sore throat, cough, tiredness, and joint pain
- with certain statins, fenofibrate, or other LDL-C lowering medicines if your healthcare provider has told you not to take them.

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

- have liver problems. Ezetimibe tablets may not be right for you.
- are pregnant or plan to become pregnant. It is not known if ezetimibe tablets will harm your unborn baby. You and your healthcare provider should decide if you will take ezetimibe tablets while you are pregnant.
- are breastfeeding. It is not known if ezetimibe tablets passes into your breast milk. You and your healthcare provider should decide the best way to feed your baby if you take ezetimibe 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. Taking ezetimibe tablets with certain other medicines may affect each other causing side effects. Ezetimibe tablets may affect the way other medicines work, and other medicines may affect how ezetimibe tablets works.

Especially tell your healthcare provider if you take:

- cyclosporine (a medicine for your immune system)
- fibrates (medicine for lowering cholesterol)
- bile acid sequestrants (medicine for lowering LDL-C)

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 tablets?

- Take ezetimibe tablets 1-time each 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 healthcare provider if you can take them at the same time.
- 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 tablets at the same time.
- While taking ezetimibe tablets, continue to follow your cholesterol-lowering diet and to exercise as your healthcare provider told you to.
- If you take a medicine called a bile acid sequestrant, take ezetimibe tablets at least 2 hours before or 4 hours after you take the bile acid sequestrant.
- Your healthcare provider may do blood tests to check your LDL-C levels as early as 4 weeks after starting treatment with ezetimibe tablets.
- In case of an overdose, get medical help or contact a live Poison Center expert right away at 1-800-222-1222. Advice is also available online at poisonhelp.org.

What are the possible side effects of ezetimibe tablets?

Ezetimibe tablets may cause serious side effects including:

- **increased liver enzymes.** An increase in liver enzymes can happen in people taking ezetimibe tablets alone or with statins. Your healthcare provider may do blood tests to check your liver before

and during treatment. Your healthcare provider may need to change or stop your treatment with ezetimibe tablets because of an increase in liver enzymes.

• **muscle pain, tenderness, and weakness (myopathy).** Muscle problems, including muscle breakdown (rhabdomyolysis) can happen. Tell your healthcare provider right away if:

- o you have unexplained muscle pain, tenderness, weakness, feel more tired than usual, or fever.
- o you have muscle problems that do not go away even after your healthcare provider has advised you to stop taking ezetimibe 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 also taking statins or fibrates.

The most common side effects of ezetimibe tablets taken alone include:

- upper respiratory
- joint pain
- pain in arms or
- flu-like tract infection legs symptoms
- diarrhea
- inflammation of the
- feeling tired sinuses

The most common side effects of ezetimibe tablets taken with a statin include:

- runny nose, sore throat
- joint pain
- flu-like symptoms
- muscle aches and pains
- diarrhea
- pain in arms or legs
- upper respiratory tract infection
- back pain
- feeling tired

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 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 tablets?

- Store ezetimibe tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from moisture. **Keep ezetimibe tablets and all medicines out of the reach of children.**

General information about safe and effective use of ezetimibe tablets. Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. 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 symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ezetimibe tablets that is written for health professionals.

What are the ingredients in Ezetimibe tablets?

Active ingredient: ezetimibe.

Inactive ingredients: Croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone, pregelatinized starch (maize) and sodium lauryl sulfate.

Manufactured by:

Ohm Laboratories Inc.

New Brunswick, NJ 08901

Distributed by:

Sun Pharmaceuticals Industries, Inc.

Cranbury, NJ 08512

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