

Consumer Medicine Information

Ezetimibe Sandoz®

Ezetimibe 10 mg tablet

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Ezetimibe Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ezetimibe Sandoz against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

You should also read any information provided with other medicines you are currently taking.

WHAT EZETIMIBE SANDOZ IS USED FOR

- Ezetimibe Sandoz is a cholesterol-lowering medicine.
- Ezetimibe Sandoz is for adults and adolescents (10 to 17 years of age) whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.
- Ezetimibe Sandoz reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.
- Ezetimibe Sandoz may be taken with other cholesterol-lowering medicines known as statins or alone, in addition to diet.

Cholesterol

Some of the reasons cholesterol is needed by the body include; building cell walls, making bile acids (which help to digest food) and certain hormones. However, too much cholesterol can be a problem.

Your body makes cholesterol, but it also comes from food.

Normally the body balances the cholesterol it makes with the cholesterol it gets from food. This means if more cholesterol comes from food, less is made by the body. However, if you eat a diet high in fat, your body may not keep this balance and your cholesterol levels rise.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol, it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed. Over time, this can form hard areas, called plaque, on the walls of blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to coronary heart disease (such as heart attack and angina), and stroke.

There are different types of cholesterol, called LDL and HDL cholesterol. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol is often called 'good' cholesterol because it helps to keep the bad cholesterol from building up in the arteries and protects against heart disease. If you have sitosterolaemia, your doctor has prescribed Ezetimibe Sandoz to lower the level of plant sterols in your blood.

Triglycerides

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

How Ezetimibe Sandoz Works

Ezetimibe Sandoz reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.

Ezetimibe Sandoz works by decreasing the absorption of cholesterol in the small intestine. Statins lower cholesterol in a different way; by reducing the amount of cholesterol made in the liver.

Ezetimibe Sandoz adds to the cholesterol-lowering effect of statins.

BEFORE YOU TAKE EZETIMIBE SANDOZ

When you must not take it

Do not take Ezetimibe Sandoz if:

- you have an allergy to ezetimibe, or to any of the ingredients listed at the end of this leaflet
- you are under 10 years of age. Ezetimibe Sandoz is not recommended in children under age 10
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work.

Do not take Ezetimibe Sandoz together with a statin if:

- you have active liver disease
- you are pregnant or breast feeding.

Do not take Ezetimibe Sandoz together with fenofibrate if:

- you have gall bladder disease.

If you are not sure whether you should start taking Ezetimibe Sandoz, talk to your doctor.

Before you start to take it

Tell your doctor if:

- you are pregnant or plan to become pregnant, Ezetimibe Sandoz may not be right for you
- you are breast-feeding; Ezetimibe Sandoz may be passed in your milk to your baby
- you have any medical problems (including liver disease or liver problems) you have now or have had in the past
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you take any Ezetimibe Sandoz.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Ezetimibe Sandoz may interfere with each other.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Ezetimibe Sandoz.

HOW TO TAKE EZETIMIBE SANDOZ

How much to take

- Adults and adolescents (10 to 17 years of age): Take one 10 mg tablet by mouth each day, at any time of day.
- Take Ezetimibe Sandoz with or without food.
- Your doctor may have you take Ezetimibe Sandoz along with other medicines, known as statins, to help you better control your cholesterol.
- If you are taking a statin, Ezetimibe Sandoz can be taken at the same time as the statin.
- If your doctor has prescribed Ezetimibe Sandoz along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, Ezetimibe Sandoz should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Ezetimibe Sandoz should be taken as directed by your health care provider. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop. Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take it

Take Ezetimibe Sandoz once a day, at any time of day.

How long to take it

Ezetimibe Sandoz helps lower your cholesterol. It does not cure your condition. Therefore, you must continue to take it as directed by your doctor if you expect to lower your cholesterol and keep it down. If you stop taking Ezetimibe Sandoz, your cholesterol levels may rise again.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Ezetimibe Sandoz. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE TAKING EZETIMIBE SANDOZ

Things you must do

If you become pregnant while taking Ezetimibe Sandoz, talk to your doctor.

It is important that you continue taking Ezetimibe Sandoz daily as prescribed by your doctor.

Even if you are taking medication to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

Things you must not do

Do not give Ezetimibe Sandoz to anyone else, even if they have the same condition as you.

Things to be careful of

There have been side effects reported with Ezetimibe Sandoz that may affect your ability to drive or operate machinery. Individual responses to Ezetimibe Sandoz may vary. (See Adverse Effects.)

How can high cholesterol be treated?

High cholesterol can be treated in two main ways:

- Lifestyle Changes - including a cholesterol-lowering diet, increased physical activity, and weight management.
- Medication - Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol. Your doctor has prescribed Ezetimibe Sandoz to help lower your cholesterol.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ezetimibe Sandoz.

Ezetimibe Sandoz helps most people with high cholesterol, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

In clinical studies, ezetimibe was generally well tolerated. The adverse effects were usually mild and similar in type and frequency to adverse effects in patients who were given a placebo (a pill containing no medication). Adverse effects generally did not cause patients to stop taking ezetimibe.

Tell your doctor if you notice any of the following and they worry you:

Ezetimibe Sandoz used alone:

These are the more common adverse effects reported with the use of Ezetimibe Sandoz when used alone:

- abdominal pain
- diarrhoea
- flatulence
- feeling tired

These are uncommon adverse effects that have been reported with the use of Ezetimibe Sandoz when used alone:

- elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function
- cough
- indigestion
- heartburn
- nausea
- joint pain
- muscle spasms
- neck pain
- decreased appetite
- pain
- chest pain

- hot flush
- high blood pressure

Ezetimibe Sandoz used with a statin:

These are the more common adverse effects reported with the use of Ezetimibe Sandoz when used in combination with a statin:

- elevations in some laboratory blood tests of liver function (transaminases)
- headache
- aching muscles/muscle pain, tenderness or weakness

These are uncommon adverse effects reported with the use of Ezetimibe Sandoz when used in combination with a statin:

- tingling sensation
- dry mouth
- itching
- rash
- hives
- back pain
- muscle weakness
- pain in arms and legs
- unusual tiredness or weakness
- swelling, especially in the hands and feet

Tell your doctor immediately if you notice any of the following:

Ezetimibe Sandoz used alone or with a statin:

- 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
- aching muscles, muscle tenderness or weakness, not caused by exercise
- unusual tiredness or weakness
- yellowing of the skin/eyes which may indicate hepatitis
- dizziness
- tingling sensation
- depression
- sudden and intense abdominal pain which may be caused by an inflamed pancreas or gallbladder, or gallstones
- constipation
- bruising more easily than normal

These may be serious adverse effects of Ezetimibe Sandoz. You may need urgent medical attention.

Serious adverse effects are rare.

In adolescent patients (10 to 17 years of age) there have been no studies longer than one year of the effect of taking ezetimibe in combination with simvastatin on bone development, growth, social and emotional development, or fertility.

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking Ezetimibe Sandoz.

These may be serious adverse effects. On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

Talk to your doctor anytime you have a medical problem you think may be related to Ezetimibe Sandoz.

If you are prescribed Ezetimibe Sandoz with a statin, your healthcare professional may want to conduct routine blood tests to check your liver function before and after starting treatment.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

AFTER TAKING EZETIMIBE SANDOZ

Storage

Keep Ezetimibe Sandoz in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Ezetimibe Sandoz or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

PRODUCT DESCRIPTION

What it looks like

Ezetimibe Sandoz comes as a white to almost white, oval tablet (7.4 mm x 4.1 mm) with debossing "10" on one side and "EZT" on the other side.

A box of Ezetimibe Sandoz contains 30 tablets.

Ingredients

Active ingredient:

Active ingredient: Ezetimibe

Inactive ingredients:

lactose monohydrate, hypromellose, croscarmellose sodium, microcrystalline cellulose, sodium lauryl sulfate, magnesium stearate.

Supplier/Distributor

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