

EZEMIBE

Ezetimibe Tablet 10 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Ezemibe.

This leaflet answers some common questions about Ezemibe.

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 Ezemibe 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.

What Ezemibe is used for

Ezemibe helps to lower cholesterol levels in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

Ezemibe is used to treat:

- Primary hypercholesterolemia
- Homozygous familial hypercholesterolemia (HoFH)

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol.

LDL cholesterol is often called 'bad' cholesterol because it can build up

in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to narrowing of the arteries.

This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called 'good' cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

This medicine belongs to a group of medicines called selective cholesterol-absorption inhibitors.

How Ezemibe works

Ezemibe contains the active ingredient ezetimibe.

It may be taken alone, or with other cholesterol-lowering medicines known as statins.

Ezemibe works by decreasing the absorption of cholesterol in the small intestine. Statins lower cholesterol in a different way – they work in the liver. Ezemibe adds to the cholesterol lowering effect of statins.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you take Ezemibe

When you must not take it

Do not take Ezemibe if you have an allergy to:

- any medicine containing ezetimibe
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine with fenofibrate (another medicine used to lower blood fat levels) if you also have gall bladder disease.

Do not take this medicine with any other medicines called statins (other medicines that lowers cholesterol levels if you are pregnant or breastfeeding. The combinations may affect your baby if you take it during pregnancy or while breastfeeding.

Do not take this medicine with any other medicines called statins (other medicines that lowers cholesterol levels) if you also have active liver disease or your blood tests for serum transaminases are always high.

Do not give this medicine to a child under the age of 10 years. Safety and effectiveness in children younger than 10 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- **unexplained muscle pain, tenderness or weakness not caused by exercise. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.**
Your doctor may do a blood test to check for certain muscle problems.
- **liver disease or liver problems.**
- **are taking Fenofibrate medication and have pre-existing gallbladder disease.**

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Ezemibe.

Taking other medicines

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

Some medicines and Ezemibe may interfere with each other. These include:

- other medicines taken to lower high cholesterol and lipid levels, such as bile acid sequestrants (e.g. cholestyramine) and fibrates (e.g. bezafibrate, gemfibrozil)
- cyclosporine, a medicine taken to suppress the immune system

- anticoagulants such as warfarin or fluindione, medicines taken to prevent blood clots

These medicines may be affected by Ezemibe or may affect how well it works, or you may need to take the medicines several hours apart. You may need different amounts of your medicines, or you may need to take different medicines.

The use of ezetimibe co-administered with simvastatin in children and adolescent patients (10-17 years old) is recommended only for patients with Heterozygous Familial Hypercholesterolaemia (HeFH) or Homozygous Familial Hypercholesterolaemia (HoFH). Doses greater than 10 mg ezetimibe with 40 mg simvastatin have not been studied in this population and are not recommended.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Ezemibe

Follow all directions given to you by your doctor or 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.

How much to take

The usual dose is 10 mg (one tablet) taken once a day.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

Your doctor may ask you to take Ezemibe with other cholesterol lowering medicines, such as statins, to help you better control your cholesterol.

If you are taking a statin, Ezemibe can be taken at the same time as the statin.

If you are taking a bile acid sequestrant (such as cholestyramine) take Ezemibe either at least two hours before or four hours after taking the bile acid sequestrant.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

You may have to take cholesterol lowering medicine for the rest of your life. If you stop taking Ezemibe, 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 medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

While you are taking Ezemibe

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ezemibe.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some blood tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are prescribed Ezetimibe with a statin, your doctor will do blood tests to check that there are no problems with your liver.

Things you must not do

Do not take Ezemibe to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of Ezemibe causing liver problems.

Be careful driving or operating machinery until you know how Ezemibe affects you.

This medicine may cause dizziness, drowsiness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

High cholesterol can be treated in two main ways

Lifestyle Changes: This includes a cholesterol-lowering diet, increasing physical activity, and weight management. Ask your doctor for

advice before increasing physical activity.

Medicines: Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Ezemibe. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- dizziness
- diarrhoea
- flatulence
- feeling tired
- headache
- depression
- stomach pain and discomfort
- constipation

- tingling or numbness of the hands and feet
- hot flush
- cough
- dry mouth
- nausea
- joint pain.

Tell your doctor as soon as possible if you notice any of the following:

- unexplained muscle aches, tenderness, weakness or pain, not caused by exercise
- skin rash, itchiness or swellings on the skin and hives
- unusual tiredness or weakness
- sudden intense abdominal pain which may be caused by an inflamed pancreas or gallbladder, or gallstones
- bleeding or bruising more easily than normal.

The above list includes serious side effects that may require medical attention. Serious side effects are uncommon.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- signs of liver problem such as generally feeling unwell, yellowing of the skin and eyes and dark coloured urine
- chest pain
- painful itchy rash that appears and extends over 5 to 7 days
- painful rash that blisters.
- flu-like symptoms.
- Blistering or peeling of the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects such as changes to liver function only be found when your doctor does tests from time to time to check your progress.

- lactose monohydrate
- croscarmellose sodium
- hypromellose
- crospovidone
- microcrystalline cellulose
- sodium lauryl sulphate
- magnesium stearate.

After taking Ezemibe

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Ezemibe or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Ezemibe is a white to off-white, capsule shaped bevelled edge tablet debossed with "M" on one side and "EE 1" on other side.

Ezemibe is supplied in HDPE Bottle with a PP Cap and absorbent cotton. Pack-sizes of 30

Ingredients

Active ingredient(s):

Ezemibe contains 10 mg of ezetimibe as the active ingredient.

Inactive ingredient(s):

Ezemibe also contains:

Contains lactose.If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Ezemibe is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Eilerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

26 January 2024
(Based on datasheet dated 26 January 2024)