

APO-EZETIMIBE

Ezetimibe

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine 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 this medicine is used for

APO-Ezetimibe is used to lower cholesterol levels. It is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

Cholesterol

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and 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 a 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.

Triglycerides

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

How Ezetimibe works

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

Ezetimibe 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 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 not addictive.

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

Use in Children and Adolescents

Ezetimibe is used in children and adolescents (10 to 17 years of age) to treat familial hypercholesterolaemia,

a type of high cholesterol that is hereditary (i.e. passed on through families).

Ezetimibe is not recommended in children under 10 years of age as there have been very few studies of its effects in these children.

Your doctor will assess if Ezetimibe is suitable for your child. Depending on the pubertal development of your child, Ezetimibe may not be suitable for him or her.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

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

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 Ezetimibe together with a statin if:

- you have active liver disease

- you are pregnant or breast feeding.

Do not take Ezetimibe together with fenofibrate if:

- you have gall bladder disease.

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

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:

- Liver disease
- Liver problems

If you are prescribed Ezetimibe with a statin, your doctor will do a blood test to make sure you have no problems with your liver

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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 this medicine.

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 should not be taken with Ezetimibe, including:

- Certain fibrate medicines used to lower cholesterol levels, for example, gemfibrozil. However, the fibrate medicine fenofibrate can be taken with Ezetimibe.

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

- Bile acid sequestrants, such as cholestyramine, used to lower cholesterol levels.
- Cyclosporin, used to suppress the immune system.
- Warfarin or fluindione, used to prevent blood clots.

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take this medicine

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/bottle, ask your doctor or pharmacist for help.

How much to take

The recommended dose is 10mg taken once a day, at any time of the day.

How to take it

Swallow the tablets/capsules whole with a full glass of water.

When to take it

Ezetimibe may be taken at any time of the day.

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 Ezetimibe with other cholesterol-lowering medicines, such as statins, to help you better control your cholesterol.

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

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

How long to take it

Ezetimibe 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.

You may have to take cholesterol lowering medicine for the rest of your life. If you stop taking Ezetimibe, your cholesterol levels may rise again.

If you forget to take it

If it is almost time to take 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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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 of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using this medicine

Things you must do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Have your blood fats checked when your doctor says, to make sure Ezetimibe is working.

Even if you are taking medicines to treat high cholesterol, it is important

to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

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 this medicine 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 lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as (effects of abrupt withdrawal as per PI). If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

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

There have been side effects reported with Ezetimibe that may affect your ability to drive or operate machinery. Individual responses to Ezetimibe may vary.

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

Things that would be helpful for...

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

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.

Side effects

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

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:

- Swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing.

These may be serious side effects. If you have them, you may have had a serious allergic reaction to this medicine. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

- skin rash and hives
- raised red rash, sometimes with target-shaped lesions
- dark coloured urine
- light coloured bowel motions
- yellowing of the skin and eyes
- joint pain

- bleeding or bruising more easily than normal
- steady abdominal pain with nausea and vomiting

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

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

- Unexplained muscle aches, tenderness or weakness, not caused by exercise

This may be a serious side effect. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage. You may need urgent medical attention.

Serious side effects are 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. Tell your doctor if you notice any other effects.

Additionally, the following side effects have been reported with use of this medicine:

- nausea
- diarrhoea
- wind or excessive gas in the stomach or bowel
- indigestion
- heartburn
- decreased appetite
- dry mouth
- abdominal pain
- constipation
- inflammation of the pancreas
- dizziness
- headache
- tingling or numbness of the hands or feet
- gallstones
- inflammation of the gallbladder

- elevations in some laboratory blood test of liver or muscle function
- unusual tiredness or weakness
- fatigue
- muscle spasms
- neck pain
- chest pain
- pain
- pain in arms and legs
- back pain
- hot flush
- high blood pressure
- itching
- swelling, especially in the hands and feet
- depression
- cough

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

Storage and Presentation

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 medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine 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 APO- Ezetimibe looks like

White to off white, capsule shaped, flat faced with beveled edge, uncoated tablets, debossed with "10" on one side and plain on other side.

Blister pack of 7, 10 and 30 tablets.

AUST R 263212

Bottles of 30 tablets.

AUST R 263217

* Not all pack types may be available.

Ingredients

This medicine contains 10 mg of ezetimibe as the active ingredient.

This medicine also contains the following:

- carmellose sodium
- lactose
- magnesium stearate
- povidone
- polysorbate 80
- sodium lauryl sulphate

This medicine contain lactose but does not contain gluten.

Supplier

This medicine is supplied in Australia by:

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

This leaflet was prepared in
June 2018.