

# 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.

Ezetimibe may be taken alone or with other cholesterol-lowering medicines known as HMG-CoA reductase inhibitors (or statins), in addition to diet.

In people who have high levels of plant sterols in their blood (which doctors call sitosterolaemia), Ezetimibe helps to lower these levels.

#### 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, which 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 by reducing LDL (bad) cholesterol and triglycerides, and increasing HDL (good) cholesterol.

It works by decreasing the absorption of cholesterol in the small intestine. Ezetimibe adds to the cholesterol-lowering effect of statins, as statins lower cholesterol in a different way, by reducing the amount of cholesterol made in the liver.

**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.

For patients with heart disease and a history of a heart attack or hospitalisation for unstable angina (chest pain). Ezetimibe combined with cholesterol-lowering medicines called statins reduces the risk of heart attack, stroke, surgery to

increase heart blood flow, or hospitalisation for chest pain.

Your doctor may have prescribed Ezetimibe for another reason. Ask your doctor if you have any questions about why Ezetimibe has been prescribed for you.

Ezetimibe is not addictive.

#### 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 or any other similar medicines
- 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 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 e.g. gemfibrozil. However, the fibrate medicine fenofibrate can be taken with ezetimibe.

Some medicines and ezetimibe 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 label, ask your doctor or pharmacist for help.**

#### How much to take

The recommended dose is 10mg taken once a day.

#### How to take it

Swallow the tablets whole with a full glass of water.

#### When to take it

Ezetimibe may be taken at any time of the day. It does not matter if you take this medicine before or after food.

**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.

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 but 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.

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## While you are using this medicine

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### *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 change the dosage without checking with your doctor.**

If you stop taking it suddenly, your condition may worsen. 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.

### *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.

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## Side effects

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**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.

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

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.**

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

- nausea
- diarrhoea
- wind or excessive gas in the stomach or bowel
- indigestion or heartburn
- decreased appetite
- dry mouth
- abdominal pain or constipation
- inflammation of the pancreas
- dizziness or 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
- fatigue; unusual tiredness or weakness
- muscle spasms
- pain, including neck, chest, back or pain in arms and legs
- hot flushes
- high blood pressure
- itching
- swelling, especially in the hands and feet
- depression
- cough

**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:**

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing.
- unexplained muscle aches, tenderness or weakness, not caused by exercise

These may be serious side effects. You may need urgent medical attention or hospitalisation.

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

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.

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.

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## Storage and Presentation

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### *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.**

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## Product description

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### *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 monohydrate
- magnesium stearate

- povidone
- polysorbate 80
- sodium lauryl sulphate

This medicine contain lactose but does not contain gluten.

***Sponsor***

This medicine is supplied in Australia by

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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