

APO-EZETIMIBE TABLETS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-EZETIMIBE?

APO-EZETIMIBE contains the active ingredient ezetimibe. APO-EZETIMIBE is used to lower cholesterol levels.

For more information, see Section [1. Why am I using APO-EZETIMIBE?](#) in the full CMI.

2. What should I know before I use APO-EZETIMIBE?

Do not use if you have ever had an allergic reaction to ezetimibe, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-EZETIMIBE](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-EZETIMIBE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-EZETIMIBE?

- The recommended dose is 10 mg taken once a day, at any time of the day.
- Take tablets with a glass of water.

More instructions can be found in Section [4. How do I use APO-EZETIMIBE?](#) in the full CMI.

5. What should I know while using APO-EZETIMIBE?

Things you should do	<ul style="list-style-type: none">• Have your blood fats check when your doctor tells you to.• If you are prescribed APO-EZETIMIBE with a statin, have a blood test to check there is no problem with your liver.• If you become pregnant while taking APO-EZETIMIBE, tell your doctor.
Things you should not do	<ul style="list-style-type: none">• Do not give APO-EZETIMIBE to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Side effects have been reported that may affect your ability to drive or operate machinery. Be careful driving or operating machinery until you know how this medicine affects you.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while taking this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.

For more information, see Section [5. What should I know while using APO-EZETIMIBE?](#) in the full CMI.

6. Are there any side effects?

Common side effects: nausea, diarrhoea, wind or excessive gas, indigestion, heartburn, decrease appetite, dry mouth, abdominal pain, constipation, inflammation of pancreas, dizziness, headache, tingling/ numbness of the hands or feet, gallstones, inflammation of gallbladder, elevation of some laboratory blood tests, unusual tiredness, muscle spasms, pain in neck/ chest/ arm/ legs/ or back, hot flushes, high blood pressure, swelling of hands or feet, depression, cough.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-EZETIMIBE TABLETS

Active ingredients: Ezetimibe 10 mg

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-EZETIMIBE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-EZETIMIBE**

Where to find information in this leaflet:

1. Why am I using APO-EZETIMIBE?
2. What should I know before I use APO-EZETIMIBE?
3. What if I am taking other medicines?
4. How do I use APO-EZETIMIBE?
5. What should I know while using APO-EZETIMIBE?
6. Are there any side effects?
7. Product details

1. Why am I using APO-EZETIMIBE?

APO-EZETIMIBE contains the active ingredient ezetimibe.

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

APO-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), APO-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.

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 APO-EZETIMIBE works

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

APO-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.

APO-EZETIMIBE adds to the cholesterol-lowering effect of statins.

For patients with heart disease and a history of heart attack or hospitalisation for unstable angina (chest pain), APO-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 APO-EZETIMIBE for another reason.

Ask your doctor if you have any questions about why APO-EZETIMIBE has been prescribed for you.

APO-EZETIMIBE is not addictive.

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

Use in Children and Adolescents

APO-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).

APO-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 whether if APO-EZETIMIBE is suitable for your child. Depending on the pubertal development of your child, APO-EZETIMIBE may not be suitable for him or her.

2. What should I know before I use APO-EZETIMIBE?

When you must not take it

Do not take APO-EZETIMIBE if

- you have an allergy to APO-EZETIMIBE or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips, mouth, tongue or throat.
- 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 APO-EZETIMIBE together with a statin if:

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

Do not take APO-EZETIMIBE together with fenofibrate if:

- you have gall bladder disease.

If you are not sure whether you should start taking APO-EZETIMIBE, talk to your doctor.

Before you start to take it

Tell your doctor if:

- **you are pregnant or intend to become pregnant**

If there is a need to consider using APO-EZETIMIBE during pregnancy, your doctor will discuss the risks and benefits of taking it.

- **you are breast-feeding**

It is not known if APO-EZETIMIBE passes into breast milk.

- **you have, or have had, any medical conditions, including liver disease or liver problems**

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

- **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 APO-EZETIMIBE.

3. What if I am 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 should not be taken with APO-EZETIMIBE, including:

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

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

Some medicines and APO-EZETIMIBE may interfere with each other, including:

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

These medicines may be affected by APO-EZETIMIBE, may affect how well it works, or may increase the risk of side effects with APO-EZETIMIBE. You may need different amounts of your medicine, or you may need to take

different medicines or take your medicines at different times.

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

4. How do I use APO-EZETIMIBE?

How much to take

Take APO-EZETIMIBE only when prescribed by your doctor.

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

Swallow APO-EZETIMIBE with a glass of water.

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, ask your doctor or pharmacist for help.

When to take it

APO-EZETIMIBE may be taken at any time of the day.

It does not matter if you take APO-EZETIMIBE with or without food.

However, take it about the same time each day.

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

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

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

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

How long to take it

APO-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 APO-EZETIMIBE, 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 APO-EZETIMIBE

If you think that you have used too much APO-EZETIMIBE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
 - contact your doctor, or
 - go to the Emergency Department at your nearest hospital.
- Do this even if there are no signs of discomfort or poisoning.**

5. What should I know while using APO-EZETIMIBE?

Things you must do

If you become pregnant while taking APO-EZETIMIBE, tell your doctor.

Have your blood fats checked when your doctor says, to make sure APO-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 about to be started on any new medicine, tell your doctor and pharmacist that you are taking APO-EZETIMIBE.

If you are prescribed APO-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 give APO-EZETIMIBE to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how APO-EZETIMIBE 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.

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.

Looking after your medicine

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well. **Keep APO-EZETIMIBE in a cool dry place where the temperature stays below 25°C.**

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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.

Getting rid of any unwanted medicine

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

6. Are there any side effects?

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

APO-EZETIMIBE 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 treatment if you get some of the side effects.

Less serious side effects

Less serious side effects	What to do
Muscle/skeleton-related: <ul style="list-style-type: none">• muscle spasms• neck pain• back pain• pain in arms and legs• elevations in some laboratory blood test of liver or muscle function Gastrointestinal-related: <ul style="list-style-type: none">• nausea• diarrhoea• wind or excessive gas in the stomach or bowel• indigestion• heartburn• dry mouth• abdominal pain• constipation Liver-related: <ul style="list-style-type: none">• gallstones• inflammation of the gallbladder	Speak to your doctor if you have any of these less serious side effects and they worry you.

<ul style="list-style-type: none"> elevations in some laboratory blood test of liver or muscle function <p>Heart and circulation-related:</p> <ul style="list-style-type: none"> hot flush high blood pressure swelling, especially in the hands and feet <p>Skin related:</p> <ul style="list-style-type: none"> itching <p>Metabolism and nutrition-related:</p> <ul style="list-style-type: none"> decreased appetite inflammation of the pancreas <p>Head and nervous system-related:</p> <ul style="list-style-type: none"> dizziness headache tingling or numbness of the hands or feet <p>Mood related:</p> <ul style="list-style-type: none"> depression <p>Respiratory related:</p> <ul style="list-style-type: none"> cough <p>General conditions:</p> <ul style="list-style-type: none"> unusual tiredness or weakness fatigue chest pain pain 	
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Serious side effects

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

Serious side effects	What to do
<ul style="list-style-type: none"> swelling of the face, lips, mouth, throat, or tongue which may cause difficulty in swallowing or breathing 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 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 	<p>Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of these serious side effects.</p>

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

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available with a doctor's prescription.

What APO-EZETIMIBE contains

Active ingredient (main ingredient)	Ezetimibe
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> lactose povidone carmellose sodium sodium lauryl sulfate magnesium stearate polysorbate 80
Potential allergens	Contains lactose.

Do not take this medicine if you are allergic to any of these ingredients.

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.

Who distributes APO-EZETIMIBE

Arrotex Pharmaceuticals Pty Ltd
 15-17 Chapel Street
 Cremorne VIC 3121
www.arrotex.com.au

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.

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