

BTC EZETIMIBE

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 BTC Ezetimibe?

BTC Ezetimibe contains the active ingredient ezetimibe. BTC Ezetimibe is used to lower cholesterol levels.

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

2. What should I know before I use BTC 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 BTC Ezetimibe?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BTC 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 BTC Ezetimibe?

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

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

5. What should I know while using BTC Ezetimibe?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using BTC Ezetimibe.• Have your blood fats check when your doctor tells you to.• If you are prescribed BTC Ezetimibe with a statin, have a blood test to check there is no problem with your liver.• Tell your doctor if you are pregnant.
Things you should not do	<ul style="list-style-type: none">• Do not give BTC Ezetimibe to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• 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 30°C.

For more information, see Section [5. What should I know while using BTC 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.

Serious side effects: swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing, dark coloured urine, light coloured bowel motions, yellowing of the skin and eyes, bleeding or bruising more easily than normal, unexplained muscle aches, tenderness or weakness, not caused by exercise/ skin rash and hives.

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.

BTC Ezetimibe

Active ingredient(s): *ezetimibe*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BTC 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 BTC Ezetimibe.**

Where to find information in this leaflet:

- [1. Why am I using BTC Ezetimibe?](#)
- [2. What should I know before I use BTC Ezetimibe?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use BTC Ezetimibe?](#)
- [5. What should I know while using BTC Ezetimibe?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using BTC Ezetimibe?

BTC Ezetimibe contains the active ingredient ezetimibe.

BTC 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.

BTC 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), BTC 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 BTC Ezetimibe works

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

BTC 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.

BTC Ezetimibe adds to the cholesterol lowering effect of statins.

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

Ask your doctor if you have any questions about why BTC Ezetimibe has been prescribed for you.

BTC Ezetimibe is not addictive.

2. What should I know before I use BTC Ezetimibe?

Warnings

Do not use BTC Ezetimibe if:

- you are allergic to ezetimibe, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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 BTC Ezetimibe together with a statin if:

- you have active liver disease or unexplained persistent elevation in serum transaminases
- you are pregnant or breastfeeding.

Do not take BTC Ezetimibe together with a fenofibrate if:

- you have a gall bladder disease.

Before you start to take it

Check with your doctor if you:

- are pregnant or intend to become pregnant
- are breastfeeding
- have, or have had, any other medical conditions, including
 - liver disease or liver problems.

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

- take any medicines for any other condition
- have 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 BTC Ezetimibe.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

If there is a need to consider taking BTC Ezetimibe during pregnancy, your doctor will discuss the risks and benefits of taking it.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if BTC Ezetimibe passes into breast milk.

Use in Children and Adolescents

- BTC Ezetimibe is used in children and adolescents (10 to 17 years of age) to treat familial hypercholesterolemia, a type of high cholesterol that is hereditary (i.e. passed on through families).
- BTC 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 BTC Ezetimibe is suitable for your child. Depending on the pubertal development of your child, BTC Ezetimibe may not be suitable for him or her.

3. What if I am taking other medicines?

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

Some medicines should not be taken with BTC Ezetimibe. This includes:

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

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

Some medicines may interfere with BTC Ezetimibe and affect how it works. This includes:

- 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 BTC Ezetimibe, may affect how well it works, or may increase the risk of side effects with BTC 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 BTC Ezetimibe.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BTC Ezetimibe.

4. How do I use BTC Ezetimibe?

How much to take

- **Take BTC Ezetimibe only when prescribed by your doctor.**
- The recommended dose is 10 mg taken once a day, at any time of the day with or without food.
- **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, ask your doctor or pharmacist for help.

When to take BTC Ezetimibe

- **BTC Ezetimibe may be taken at any time of the day.** It does not matter if you take BTC Ezetimibe with or without food.
- **However, take it about the same time each day.** Taking BTC 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 BTC Ezetimibe with other cholesterol lowering medicines, such as statins, to help you better control your cholesterol.

- **If you are taking a statin, BTC Ezetimibe can be taken at the same time as the statin.**
- **If you are taking bile acid sequestrants, such as cholestyramine, take your BTC Ezetimibe either at least two hours before or four hours after taking the bile acid sequestrant.**

How to take BTC Ezetimibe

- Swallow BTC Ezetimibe with a glass of water.

How to long to take BTC Ezetimibe

- BTC 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 BTC Ezetimibe, your cholesterol levels may rise again.

If you forget to use BTC Ezetimibe

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 you missed.

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

If you use too much BTC Ezetimibe

If you think that you have used too much BTC 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.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using BTC Ezetimibe?

Things you should do

- **If you become pregnant while taking BTC Ezetimibe, tell your doctor.**
- **Have your blood fats checked when your doctor says, to make sure BTC 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 BTC Ezetimibe.**
- **If you are prescribed BTC Ezetimibe with a statin, your doctor will do blood tests to check that there are no problems with your liver.**

Remind any doctor, dentist or pharmacist you visit that you are using BTC Ezetimibe.

Things you should not do

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

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BTC Ezetimibe affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place below 30°C 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 young 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 you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. BTC 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. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gut or Gastrointestinal related:</p> <ul style="list-style-type: none"> nausea diarrhoea wind or excessive gas in the stomach or bowel indigestion heartburn decreased appetite dry mouth abdominal pain constipation inflammation of the pancreas gallstones inflammation of the gallbladder <p>General Disorders:</p> <ul style="list-style-type: none"> unusual tiredness or weakness fatigue dizziness headache <p>Muscles and bone related:</p> <ul style="list-style-type: none"> muscle spasms neck pain chest pain pain pain in arms and legs back pain tingling or numbness of the hands or feet <p>Allergy related:</p> <ul style="list-style-type: none"> itching swelling, especially in the hands and feet <p>Others:</p> <ul style="list-style-type: none"> hot flush high blood pressure depression cough elevations in some laboratory blood test of liver or muscle function 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking BTC Ezetimibe.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy-related:</p> <ul style="list-style-type: none"> swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing 	<p>Call your doctor straight away, or go straight to the Emergency Department at</p>

<p>Skin related:</p> <ul style="list-style-type: none"> skin rash and hives severe skin problems <p>Liver related:</p> <ul style="list-style-type: none"> dark coloured urine light coloured bowel motions yellowing of the skin and eyes <p>Gut or Gastrointestinal related:</p> <ul style="list-style-type: none"> steady abdominal pain with nausea and vomiting <p>Muscles related:</p> <ul style="list-style-type: none"> 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. joint pain <p>Blood related:</p> <ul style="list-style-type: none"> bleeding or bruising more easily than normal 	<p>your nearest hospital if you notice any of these serious side effects.</p>
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In adolescent patients (10 to 17 years of age) there have been no studies longer than one year of the effect of taking BTC Ezetimibe in combination with simvastatin on bone development, growth, social and emotional development, or fertility.

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 only available with a doctor's prescription.

What BTC Ezetimibe contains

Active ingredient (main ingredient)	ezetimibe
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactose monohydrate • microcrystalline cellulose • hypromellose • croscarmellose sodium • sodium lauryl sulfate • magnesium stearate
Potential allergens	<ul style="list-style-type: none"> • lactose <p>BTC Ezetimibe does not contain gluten, sucrose, tartrazine or any other azo dyes.</p>

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

What BTC Ezetimibe looks like

BTC Ezetimibe – white to almost white oval tablets with debossing “10” on one side and “EZT” on the other side. Pack size of 30 (Aust R 391682).

Who distributes BTC Ezetimibe

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

This leaflet was revised in December 2023.