

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 ATOZET?

ATOZET contains the active ingredients ezetimibe and atorvastatin. ATOZET is used in people whose cholesterol and triglyceride levels are too high and when diet alone cannot lower these levels adequately.

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

2. What should I know before I use ATOZET?

Do not use if you have ever had an allergic reaction to ezetimibe or atorvastatin 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 ATOZET?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ATOZET 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 ATOZET?

- The recommended dose in adults (18 years and over) is one ATOZET 10/10 mg, 10/20 mg, 10/40 mg or 10/80 mg tablet once a day. For the best effect take ATOZET at about the same time each day.

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

5. What should I know while using ATOZET?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking ATOZET. • If you become pregnant while taking ATOZET, tell your doctor immediately. • Have any blood tests your doctor requests to make sure ATOZET is right for you.
Things you should not do	• Do not give ATOZET to anyone else, even if they have the same condition as you.
Driving or using machines	• 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 ATOZET affects you.
Drinking alcohol	• Drinking large quantities of alcohol while taking ATOZET may increase your chance of getting liver problems.
Looking after your medicine	• Keep ATOZET in a cool dry place where the temperature stays below 30°C.

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

6. Are there any side effects?

Common side effects of ATOZET are diarrhoea and muscle pain.

Allergic reactions to ezetimibe, atorvastatin or other ingredients of ATOZET occur very rarely.

Serious side effects are rare, but may need urgent medical attention.

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.

ATOZET®

Active ingredient(s): ezetimibe and atorvastatin calcium trihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using ATOZET. **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 ATOZET.**

Where to find information in this leaflet:

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

1. Why am I using ATOZET?

ATOZET contains the active ingredients ezetimibe and atorvastatin. ATOZET helps to lower cholesterol and triglyceride levels.

ATOZET is used in people whose cholesterol and triglyceride levels are too high and when diet alone cannot lower these levels adequately.

What is high 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.

Heart Disease

If you have heart disease and a history of heart attack or hospitalisation for unstable angina (chest pain), ATOZET reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization for chest pain.

How ATOZET works

ATOZET contains two different medicines. One is ezetimibe and the other is atorvastatin (atorvastatin calcium trihydrate). ATOZET reduces elevated total-cholesterol, LDL ('bad') cholesterol and triglycerides and increases HDL ('good') cholesterol.

ATOZET works by decreasing the absorption of cholesterol in the small intestine and by reducing the amount of cholesterol made in the liver.

Your doctor may have prescribed ATOZET for another reason.

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

ATOZET is not addictive.

ATOZET does not help you lose weight.

2. What should I know before I use ATOZET?

Warnings

Do not use ATOZET if:

- you are allergic to ezetimibe, atorvastatin, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin. Always check the ingredients to make sure you can use this medicine.
- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.
- you are pregnant or intend to become pregnant or you are breastfeeding.
- you have active liver disease or repeated blood tests indicating possible liver problems.
- you are taking fenofibrate and you have gall bladder disease.
- you are taking fusidic acid (an antibiotic).

Before you start to take ATOZET

Your doctor will ask you to have your liver function tested.

Check with your doctor if you:

- have any other medical conditions
- have, or have had liver problems. Your doctor will do blood tests sometimes to make sure you have no problems with your liver.
- have, or have had kidney problems
- have 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.
- have had a type of stroke called a haemorrhagic stroke or a type of stroke called a lacunar stroke. If you have had one of these strokes before, this medicine may increase the risk of you having a haemorrhagic stroke.

- have or have had breathing problems
- have or have had myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used for breathing) or ocular myasthenia (a disease causing eye muscle weakness) as statins may lead to occurrence of myasthenia or aggravate the condition.
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- take any medicines for any other condition

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.

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

ATOZET is contraindicated (i.e., should not be used) during pregnancy and breastfeeding. If you take this medicine during pregnancy and breastfeeding your baby may absorb this medicine and it may affect your baby's normal development causing foetal malformations (birth defects) or irreversible damage.

If you are a woman of child-bearing age and are taking ATOZET, use a proven method of birth control to avoid pregnancy.

Use in children

ATOZET is not recommended for use in children, as there have been no studies of its effects in children.

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 may be affected by ATOZET, or may affect how well it works, or may increase the risk of side effects with ATOZET. You may need different amounts of your medicines, or you may need to take different medicines or take your medicines at different times. Your doctor will advise you.

Tell your doctor if you are taking any of the following::

- bile acid sequestrants, such as cholestyramine, used to lower cholesterol levels
- other medicines to lower cholesterol or triglyceride levels, for example, gemfibrozil, fenofibrate, other fibrates, Vitamin B3 (niacin)
- warfarin or fluindione or ticagrelor, used to prevent blood clots
- erythromycin, clarithromycin, rifampicin or fusidic acid, antibiotics used to treat infection
- some medicines used to treat certain fungal infections, such as ketoconazole or itraconazole

- efavirenz and protease inhibitors such as fosamprenavir and combinations of lopinavir/ritonavir, darunavir/ritonavir and saquinavir/ritonavir for the treatment of HIV infections
- hepatitis C antiviral agents, such as, telaprevir, boceprevir, elbasvir or grazoprevir
- phenytoin, used to treat epilepsy (seizures)
- ciclosporin, used to suppress the immune system
- colchicine, used for gout
- spironolactone, used to treat high blood pressure and certain types of swelling
- diltiazem used to treat angina
- digoxin, used to treat heart failure
- oral contraceptives for birth control
- antacids and cimetidine, used to treat reflux or ulcers
- St. John's Wort (*hypericum perforatum*) (a medicine to treat depression)
- daptomycin, used to treat complicated skin and skin structure infections and bacteraemia

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ATOZET. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ATOZET.

4. How do I take ATOZET?

How much to take

- The recommended dose in adults (18 years and over) is one ATOZET 10/10 mg, 10/20 mg, 10/40 mg or 10/80 mg tablet once a day. Swallow the tablet whole with a full glass of water.
- Take ATOZET only when prescribed by your doctor.
- Take ATOZET every day and continue taking it for as long as your doctor tells you. ATOZET helps to lower your cholesterol levels but does not cure your condition. If you stop taking ATOZET your cholesterol levels may rise again.
- Follow the instructions provided. If you do not understand these instructions, ask your doctor or pharmacist for help.
- If you are currently taking a medicine that contains ezetimibe and/or atorvastatin which are contained in ATOZET: stop taking your current medicine(s) that contain ezetimibe and/or atorvastatin as this may result in you taking more medicine than you need; take the remaining medicine(s) to your pharmacist for safe disposal

When to take ATOZET

- ATOZET can be taken at any time of the day. However, ATOZET should be taken 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.
- Take ATOZET with or without food.

Taking ATOZET with other cholesterol-lowering agents

Your doctor may ask you to take ATOZET with other cholesterol-lowering agents such as bile acid sequestrants.

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

If you forget to take ATOZET

ATOZET should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your tablet as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting a side effect.

- If you are not sure what to do, talk to your doctor or pharmacist.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much ATOZET

If you think that you have used too much ATOZET, 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 ATOZET?

Call your doctor straight away and stop taking ATOZET if you become pregnant while you are taking ATOZET.

Remind any doctor, dentist or pharmacist you visit that you are using ATOZET. If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ATOZET.

Things you should do

Keep all your doctor's appointments.

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.

Your doctor will ask you to have your liver function tested from time to time while you are taking ATOZET to make

sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- Do not take ATOZET to treat any other conditions unless your doctor tells you to.
- Do not give ATOZET to anyone else, even if they have the same condition as you

Things to be careful of

Avoid drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including ATOZET. Drinking very large quantities (over 1.2 litres) of grapefruit juice each day while taking ATOZET increases your chance of getting side effects.

Things that may help your condition

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 ATOZET affects you.

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

Drinking alcohol

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol while taking ATOZET may increase your chance of getting liver problems.

Looking after your medicine

- Keep ATOZET in a cool dry place where the temperature stays below 30°C.

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

Store it 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.

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. 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
Muscle/skeleton related: - muscle aches, spasms, tiredness or weakness - aches and pain - stiffness - pain in arms and legs - elevation in some laboratory blood tests of muscle function - leg cramps Gastrointestinal-related: - diarrhoea - constipation - frequent bowel movements - nausea - stomach or belly pain - heartburn, indigestion or wind Liver-related: - elevation in some laboratory blood tests of liver function Heart and circulation-related: - slow heart beat - hot flush Skin-related: - acne - rash that occurs on the skin or sores in the mouth (lichenoid drug eruptions) Metabolism and nutrition-related: - diabetes (this is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while taking this medicine.)	Speak to your doctor if you have any of these less serious side effects and they worry you. [Insert appropriate action]

Less serious side effects	What to do
Head and nervous system-related: - taste disturbance - tingling or numbness of the hands or feet - dizziness - headache - poor memory - confusion Mood-related: - depression - trouble sleeping Respiratory-related: - cough - shortness of breath Eye-related: - visual disturbance Ear-related: - hearing loss Infections: - influenza General conditions: - unusual tiredness or weakness - generally feeling unwell - swelling - weight gain - sexual difficulties	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reaction: 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 ATOZET. You may need urgent medical attention or hospitalisation. These side effects are very rare.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
Heart and circulation-related: - chest pain - sudden severe headache, which may be accompanied by nausea, vomiting, loss of sensation, tingling in any part of the body or ringing in the ears. - Purple skin lesions (signs of blood vessel inflammation, vasculitis) Skin-related: - severe skin problems Muscle-related: - unexpected muscle pain, tenderness, or weakness not caused by exercise and particularly, if at the same time, you feel unwell or have a high temperature while taking or after your doctor has advised you to stop taking ATOZET.. 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.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
- skin rash and hives - raised red rash, sometimes with circle-shaped lesions - steady abdominal pain with nausea and vomiting - joint pain - tendon injury - bleeding or bruising more easily than normal - yellowing of the skin and eyes - dark coloured urine - light coloured bowel motions - problems with breathing including shortness of breath, persistent cough and fever that may also occur with fatigue or unexplained weight loss. - weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath (symptoms of myasthenia).	Tell your doctor immediately if you notice any of these side effects. These may be serious side effects and you may need urgent medical attention.

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. If you are prescribed ATOZET, your healthcare professional may want to conduct routine blood tests to check your liver function before and after starting treatment.

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 ATOZET contains

Active ingredients (main ingredients)	ezetimibe 10 mg per tablet atorvastatin (as calcium trihydrate) 10, 20, 40 or 80 mg per tablet
Other ingredients (inactive ingredients)	calcium carbonate silicon dioxide croscarmellose sodium hypromellose lactose monohydrate magnesium stearate microcrystalline cellulose polysorbate 80 povidone sodium lauryl sulfate hypromellose macrogol 8000 titanium dioxide purified talc
Potential allergens	ATOZET contains lactose.

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

What ATOZET looks like

ATOZET comes in four different strengths:

ATOZET 10/10 mg

ATOZET 10/20 mg

ATOZET 10/40 mg

ATOZET 10/80 mg

ATOZET 10/10 mg is a white to off-white capsule-shaped, biconvex, film-coated tablet with code 257 on one side and plain on the other (AUST R 216961).

ATOZET 10/20 mg is a white to off-white, capsule-shaped, biconvex, film-coated tablet with code 333 on one side and plain on the other side (AUST R 216956).

ATOZET 10/40 mg is a white to off-white, capsule-shaped, biconvex, film-coated tablet with 337 on one side and plain on the other (AUST R 216958).

ATOZET 10/80 mg is a white to off-white, capsule-shaped, biconvex, film-coated tablet with code 357 on one side and plain on the other (AUST R 216962).

Who distributes ATOZET

Organon Pharma Pty Limited
Level 5, 66 King St
Sydney NSW 2000
Australia

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