

ATOZET®

ezetimibe and atorvastatin calcium trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Atozet. 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 Atozet 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 Atozet is used for

Atozet helps to lower cholesterol and triglyceride levels. It 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 Ezetrol (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.

Atozet is available only with a doctor's prescription.

Use in children

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

Before you take Atozet

When you must not take it

Do not take Atozet if:

- **you have an allergy to Atozet 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
- **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.** **If you are a woman of child-bearing age and are taking Atozet, use a proven method of birth control to avoid pregnancy.** 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 fetal malformations (birth defects) or irreversible damage.

- **you have active liver disease or repeated blood tests indicating possible liver problems.**
- **the expiry date on the pack has passed or if the packaging is torn or shows signs of tampering.**

If you take Atozet after the expiry date has passed, it may not work.

Return any expired or damaged Atozet to your pharmacist for disposal

Do not take Atozet together with fenofibrate if you have gall bladder disease.

Do not take Atozet together with fusidic acid (an antibiotic).

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

Before you start to take it

Your doctor will ask you to have your liver function tested before you start to take Atozet.

Tell your doctor if:

- **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

you have, or have had, any medical condition, including:

- **liver problems**
Your doctor will do blood tests sometimes to make sure you have no problems with your liver.
- **kidney problems**
- **you 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.

- **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.

- **breathing problems**
- **you drink alcohol regularly.**

If you have not told your doctor about any of the above, tell him/her before you start taking Atozet.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any 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...

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, 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)

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

If you have not told your doctor about any of the above, tell them before you start taking Atozet.

How to take Atozet

Take Atozet only when prescribed by your doctor.

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 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

Check with your doctor if you are not sure about the medicines you are taking.

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.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

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.

How long to take it

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.

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 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 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 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 Atozet. Do this even if there are no signs of discomfort or poisoning.

You or anyone else may need urgent medical attention.

While you are taking Atozet

Things you must do

If you become pregnant while you are taking Atozet, stop taking it and tell your doctor immediately.

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.

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

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

Things you must 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 alcohol.

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

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.

Be careful driving or operating machinery 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.

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.

Side effects

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

Atozet helps most people with high cholesterol levels or triglyceride levels, 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 if...

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

- diarrhoea
- muscle aches, spasms, tiredness or weakness
- constipation
- frequent bowel movements
- nausea
- stomach or belly pain
- heartburn, indigestion or wind
- aches and pain
- stiffness
- leg cramps
- taste disturbance
- depression
- trouble sleeping
- influenza
- dizziness
- headache
- tingling or numbness of the hands or feet
- slow heart beat

- hot flush
- shortness of breath
- unusual tiredness or weakness
- generally feeling unwell
- elevation in some laboratory blood tests of liver or muscle function
- weight gain
- acne
- pain in arms and legs
- swelling
- poor memory
- confusion
- hearing loss
- visual disturbance
- sexual difficulties
- 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.)

The above list includes the more common and uncommon side effects of your medicine. They are usually mild and short-lived.

Tell your doctor immediately if...

Tell your doctor immediately if you notice any of the following:

- 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.

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

Go to hospital if...

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.
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.
- chest pain
- 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.
- 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.
- serious illness with severe peeling and swelling of the skin, severe blisters and bleeding of the lips, eyes, mouth, nose or genitals and skin rash with pink-red blotches especially on palms of hands or soles of feet, which may blister.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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.

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.

After taking Atozet

Storage

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Atozet 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 Atozet or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it 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.

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.

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.

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.

Ingredients

Active ingredients:

Atozet 10/10 mg -
Ezetimibe 10 mg / Atorvastatin (as calcium trihydrate) 10 mg per tablet.

Atozet 10/20 mg -
Ezetimibe 10 mg / atorvastatin (as calcium trihydrate) 20 mg per tablet

Atozet 10/40 mg -
Ezetimibe 10 mg / atorvastatin (as calcium trihydrate) 40 mg per tablet

Atozet 10/80 mg -
Ezetimibe 10 mg / atorvastatin (as calcium trihydrate) 80 mg per tablet

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

Date of Preparation

This Consumer Medicine Information was prepared in November 2017.

Ask your pharmacist about any updates.

Supplier

Atozet is supplied in Australia by:
Merck Sharp & Dohme (Australia) Pty Limited
ABN 14 000 173 508
Level 1, Building A
26 Talavera Road
Macquarie Park

NSW 2113
Australia

Australian Registration Numbers

Atozet 10/10 mg - Aust R 216961

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Atozet 10/80 mg - Aust R 216962

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