

ATOZET[®] film-coated tablets

Ezetimibe/atorvastatin (10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg)

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What ATOZET tablet is used for

Your doctor has prescribed ATOZET tablet to reduce the amount of cholesterol and triglycerides in your blood. 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 are another form of fat in your blood that may increase your risk for heart disease.

If you have heart disease, ATOZET reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization for chest pain.

How ATOZET tablet works

High cholesterol can be treated in

two main ways:

Lifestyle Changes – including a cholesterol-lowering diet, increased physical activity, and weight management.

Medication – Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol. Your doctor has prescribed ATOZET to help lower your cholesterol.

Before you take ATOZET tablet

When you must not take it

Do not take ATOZET tablet if you:

- are hypersensitive (allergic) to ezetimibe, atorvastatin, or any of the other ingredients of ATOZET tablets
- have active liver disease
- are pregnant or breast-feeding

Before you start to take it

It is important that you continue taking ATOZET daily as prescribed by your doctor.

Even if you are taking medication to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

Muscle Weakness

Tell your doctor if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used for breathing) or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.

Pregnancy, breast-feeding and fertility

Do not use ATOZET if you are pregnant, trying to become pregnant or suspect that you are pregnant. If you become pregnant while taking ATOZET, stop taking it and contact your physician immediately. You should use effective birth control

(contraception) while you are taking ATOZET. Do not use ATOZET if you are breast-feeding. Atorvastatin, which is one of the medicines in ATOZET, can pass into your breast milk and may harm your baby.

Children

ATOZET is not recommended in children.

Elderly

No special precautions.

Taking other medicines

Tell your doctor about all the medicines you are taking or plan to take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

It is especially important to tell your doctor if you take any of the following:

- Cyclosporine (a medicine often used in organ transplant patients)
- Erythromycin, clarithromycin, fusidic acid, or rifampin (medicines for bacterial infections)
- Some calcium channel blockers used for angina or high blood pressure, e.g., amlodipine and diltiazem
- HIV protease inhibitors (medicines for AIDS)
- Oral contraceptives (medicines for preventing pregnancy)
- Antacids (indigestion products containing aluminium or magnesium)
- Cimetidine (used for heartburn and peptic ulcers)
- Hepatitis C antiviral agents such as boceprevir, telaprevir, elbasvir, or grazoprevir (used to treat hepatitis C virus infection)
- Medicines such as:
 - ketoconazole or itraconazole (medicines for fungal infections)
 - fibrates, colestipol, cholestyramine

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- (medicines for lowering cholesterol)
- digoxin (a medicine to regulate your heart rhythm)
- warfarin or fluindione (medicines to prevent blood clots)
- Daptomycin (a medicine used to treat complicated skin and skin structure infections and bacteremia)

How to take ATOZET tablet

How much to take

Take one ATOZET 10/10, 10/20, 10/40, or 10/80 tablet by mouth each day, at any time of the day.

When to take it

Take ATOZET with or without food.

If your doctor has prescribed ATOZET along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, ATOZET should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

How long to take it

ATOZET should be taken as directed by your health care provider. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop.

If you forget to take it

Try to take ATOZET as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

If you take too much (overdose)

Take ATOZET only as prescribed for you. If you take more ATOZET than you were prescribed, contact your doctor or pharmacist right away.

While you are taking ATOZET tablet

Things you must do

Medical Problems or Allergies

Tell your doctor [or pharmacist] about any medical conditions (including liver disease or liver problems) you have or have had and about any allergies.

Alcohol

Tell your doctor if you consume substantial quantities of alcohol or have a past history of liver disease.

You may obtain further information from your doctor or pharmacist, who has more detailed information.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give ATOZET to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving or using machines

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

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects.

In clinical studies, ATOZET was generally well tolerated. The side effects were usually mild, temporary, and similar in type and frequency to side effects in patients who were given ezetimibe alone or atorvastatin alone.

The following common side effects were reported: diarrhea and muscle aches.

The following uncommon side effects were reported: flu;

depression; trouble sleeping; sleep disorder; dizziness; headache; taste disturbance; tingling sensation; slow heartbeat; hot flush; shortness of breath; abdominal discomfort, bloating, pain (including upper and lower abdomen); constipation; indigestion; flatulence; frequent bowel movements; inflammation of the stomach; nausea; stomach discomfort; acne; hives; joint pain; back pain; muscle tiredness, spasms, or weakness; pain in extremity; unusual weakness; feeling tired; generally feeling unwell; swelling especially in the ankles (oedema); build up of fluid; elevations in blood tests of liver or muscle (CK) function; weight increased.

Additionally, the following side effects have been reported in people taking either ATOZET or ezetimibe or atorvastatin tablets:

- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (which may require treatment right away), rash, and hives; severe skin problems; unexpected bleeding or bruising; tendon injury; muscle pain, tenderness, or weakness (that in very rare cases may not go away after stopping ATOZET); unusual tiredness; alterations in some laboratory blood and urine tests; liver problems; inflammation of the pancreas; gallstones; inflammation of the gallbladder; vomiting; cough; heartburn; neck pain; decreased appetite; loss of appetite; chest pain; pain; high blood pressure; inflammation of the nasal passages; pain in the throat; nose bleed; having nightmares; reduction of sensation to pain or touch; dry mouth; loss of memory; confusion; ringing in the ears and/or head; belching; skin

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rash and itching; hair loss; fever; blurred vision; visual disturbance; hearing loss; gynecomastia (breast enlargement in men and women).

The following side effects have been reported with some statins (medicines of the same type):

- sexual difficulties
- depression
- breathing problems including persistent cough and/or shortness of breath or fever
- 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.)

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness 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 is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

Unknown frequency:

- myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing),
- ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience 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.

Talk to your doctor anytime you have a medical problem you think may be related to ATOZET.

If you are prescribed ATOZET, your healthcare professional should conduct blood tests to check your liver before you start taking ATOZET and if you have any symptoms of liver problems while you take ATOZET. Call your doctor right away if you have the following symptoms of liver problems:

- feel tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of your skin or the whites of your eyes

Ask your doctor or pharmacist for more information. Both have a more complete list of side effects. Tell your doctor [or pharmacist] promptly about these or any other unusual symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ATOZET

Storage

- Do not store above 30°C.
- Store in original package

Disposal

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

What it looks like

ATOZET tablet is a film-coated tablet.

Capsule shaped, biconvex, film coated tablets, white to off white.

ATOZET[®] 10 mg/ 10 mg:
"257" debossed on one side

ATOZET[®] 10 mg/ 20 mg:
"333" debossed on one side

ATOZET[®] 10 mg/ 40 mg:
"337" debossed on one side

ATOZET[®] 10 mg/ 80 mg:
"357" debossed on one side

It is available in 30's pack size.

Ingredients

Active ingredient:

ATOZET is available for oral use as tablets containing 10 mg of ezetimibe and:

- 10.9 mg of atorvastatin calcium (crystalline trihydrate), equivalent to 10 mg of atorvastatin (ATOZET 10 mg/10 mg);
- 21.7 mg of atorvastatin calcium (crystalline trihydrate), equivalent to 20 mg of atorvastatin (ATOZET 10 mg/20 mg)
- 43.4 mg of atorvastatin calcium (crystalline trihydrate), equivalent to 40 mg of atorvastatin (ATOZET 10 mg/40 mg); or
- 86.8 mg of atorvastatin calcium (crystalline trihydrate), equivalent to 80 mg of atorvastatin (ATOZET 10 mg/80 mg).

Inactive ingredient:

Each film-coated tablet of ATOZET contains the following inactive ingredients: calcium carbonate, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate, povidone, and sodium lauryl sulfate.

The film coating contains:

hydroxypropyl methylcellulose/hypromellose, macrogol/polyethylene glycol, titanium dioxide, and talc.

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MAL number

Atozet 10mg/10mg
MAL 17035025ACRZ

Atozet 10mg/20mg
MAL 17035022ACRZ

Atozet 10mg/40mg
MAL 17035021ACRZ

Atozet 10mg/80mg
MAL 17035026ACRZ

Manufacturer

MSD International GmbH
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Product Registration Holder

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