

Package leaflet: information for the user
ATOZET 10 mg/10 mg film-coated tablets
ATOZET 10 mg/20 mg film-coated tablets
ATOZET 10 mg/40 mg film-coated tablets
ATOZET 10 mg/80 mg film-coated tablets
ezetimibe/atorvastatin

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is ATOZET and what is it used for?

ATOZET is a medicine for lowering elevated cholesterol. This medicine contains ezetimibe and atorvastatin.

This medicine is used in adults to lower the levels of total cholesterol, 'bad' cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. Additionally, this medicine increases the levels of 'good' cholesterol (HDL cholesterol).

This medicine lowers cholesterol in two ways. It reduces the cholesterol absorbed in the gastrointestinal tract and also reduces the cholesterol your body produces.

Cholesterol is one of several fatty substances present in the bloodstream. Your total cholesterol mainly consists of LDL and HDL cholesterol.

LDL cholesterol is often called 'bad' cholesterol because it can build up in the walls of your blood vessels, forming 'plaque'. Eventually, this 'plaque' can grow and lead to a narrowing of the blood vessels. This narrowing can slow down or block the blood flow to vital organs, such as the heart or the brain. This blockage of blood flow can lead to a heart attack or a stroke.

HDL cholesterol is often called 'good' cholesterol because it helps prevent bad cholesterol from building up in the blood vessels, thus protecting against cardiovascular diseases.

Triglycerides are another form of fat in your blood that can increase the risk of cardiovascular diseases.

This medicine is used for patients whose cholesterol is not sufficiently lowered by diet alone. When using this medicine, you should continue your cholesterol-lowering diet.

This medicine is used in addition to your cholesterol-lowering diet if you:

- have an elevated concentration of cholesterol in your blood (heterozygous familial and non-familial primary hypercholesterolemia) or have too high a fat content in your blood (mixed hyperlipidemia)

 - and this is not sufficiently lowered by a statin alone

 - for which you have used a statin and ezetimibe as separate tablets.

- has a hereditary condition (homozygous familial hypercholesterolemia) that increases the cholesterol level in your blood. You may also receive other treatments.

- has cardiovascular disease. This medicine reduces the risk of a heart attack, stroke, surgery to increase blood flow to the heart, or hospitalization due to chest pain.

- This medicine does not help you lose weight.

2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

- You have a disease that affects the liver or have ever had one.

- Unexplained abnormal liver function values have emerged from blood tests.

- You are a woman of childbearing age who does not use reliable contraception.

- You are pregnant, want to become pregnant, or are breastfeeding.

- You are using the combination glecaprevir/pibrentasvir for the treatment of hepatitis C.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if you have previously had a stroke with bleeding in the brain or fluid in the brain due to previous strokes,

- if you have kidney problems,

- if you have reduced thyroid function (hypothyroidism),

- if you have had repeated or unexplained muscle pain or a history of muscle problems, yourself or in the family,

- if you have previously had muscle problems during treatment with other lipid-lowering medicines (e.g., other statins or fibrates),

- if you regularly drink a large amount of alcohol,

- if you have a history of liver disease,

- if you are older than 70 years,

- if your doctor has told you that you cannot tolerate certain sugars, contact your doctor before using this medicine,

- if you are currently using a medicine orally or by injection, or have used it in the past 7 days, called fusidic acid (a medicine for a bacterial infection). The combination of fusidic acid and ATOZET can lead to serious muscle problems (rhabdomyolysis),

- if you have or have had myasthenia (a disease where general muscle weakness occurs, in some cases also in muscles used for breathing) or ocular myasthenia (a disease that causes eye muscle weakness), as statins can sometimes worsen the condition or lead to the occurrence of myasthenia (see section 4)

Contact your doctor immediately if you experience unexplained pain, tenderness, or weakness of the muscles while using this medicine. This is because in rare cases muscle problems can be serious, including muscle breakdown that can lead to kidney damage. Atorvastatin is known to cause muscle problems. Muscle problems have also been reported with ezetimibe.

Also contact your doctor or pharmacist if you constantly experience muscle weakness. Additional tests and medications may be needed to demonstrate and treat this.

Consult your doctor or pharmacist before taking this medicine:
if you have a severe lung disease.

If any of the above points apply to you (or if you are in doubt), contact your doctor or pharmacist before using this medicine, as your doctor will need to perform a blood test before and possibly during your treatment with this medicine to predict your risk of muscle side effects. It is known that the risk of muscle side effects, e.g. rhabdomyolysis, increases when certain medicines are taken simultaneously (see section 2 'Are you taking any other medicines?').

During the period you are using this medicine, your doctor will closely monitor whether you have diabetes, or if you are at increased risk of developing diabetes. You may be at increased risk of developing diabetes if you have high blood sugar and fat levels, if you are overweight, and if you have high blood pressure.

Tell your doctor about all your medical conditions including allergies.

The combined use of this medicine and fibrates (medicines that lower cholesterol) should be avoided because the use of this medicine together with fibrates has not been studied.

Children and adolescents up to 18 years

This medicine is not recommended for children and adolescents up to 18 years.

Are you taking any other medicines?

Are you taking any other medicines besides ATOZET, have you done so recently, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

Some medicines can affect the efficacy of this medicine or can be affected by this medicine (see section 3). Such interactions can make one or both medicine(s) less effective.

Additionally, this can increase the risk of side effects or the severity thereof, including the serious condition that breaks down muscles known as 'rhabdomyolysis', as described in section 4:

ciclosporin (a medicine often used in organ transplants),
erythromycin, clarithromycin, telithromycin, fusidic acid**, rifampicin (antibiotics used against bacterial infections),
ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole (antifungal agents)
gemfibrozil, other fibrates, niacin-like substances, colestipol, cholestyramine (medicines to regulate lipid levels),

some calcium channel blockers used against chest pain (angina pectoris) or high blood pressure, e.g., amlodipine, diltiazem, digoxin, verapamil, amiodarone (used for the treatment of an irregular heartbeat), medicines for the treatment of HIV and AIDS, e.g., ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination tipranavir/ritonavir, etc., some medicines used in the treatment of hepatitis C, e.g., telaprevir, boceprevir, and the combination elbasvir/grazoprevir
daptomycin (a medicine used for the treatment of difficult-to-treat infections of the skin and skin tissues and bacteremia (where bacteria are present in your blood)).

** If you need to take fusidic acid orally to treat a bacterial infection, you must temporarily stop using this medicine. Your doctor will tell you when it is safe to use ATOZET again. The use of ATOZET with fusidic acid can in rare cases lead to muscle weakness, tenderness, or pain (rhabdomyolysis). For more information on rhabdomyolysis see section 4.

Other medicines known to interact with this medicine
oral contraceptives (medicines to prevent pregnancies),
stiripentol (a seizure medicine used in epilepsy),
cimetidine (used for heartburn and gastrointestinal ulcers),
phenazone (a painkiller),
antacids (stomach acid-binding agents containing aluminum or magnesium),
warfarin, phenprocoumon, acenocoumarol or fluindione (medicines to prevent blood clots),
colchicine (a medicine for the treatment of gout),
St. John's wort (an over-the-counter remedy for the treatment of depression).

What should you pay attention to with food, drink, and alcohol?

See section 3 for instructions on how to use this medicine. Pay attention to the following:

Grapefruit juice

Do not drink more than one or two small glasses of grapefruit juice per day, as large amounts of grapefruit juice can alter the effects of this medicine.

Alcohol

Avoid drinking too much alcohol while using this medicine. See section 2 'When should you be extra careful with this medicine?' for more information.

Pregnancy and breastfeeding

Do not use this medicine if you are pregnant, trying to become pregnant, or think you might be pregnant. Do not use this medicine if you can become pregnant unless you take reliable contraceptive measures. If you become pregnant while using this medicine, stop taking it immediately and tell your doctor.

Do not use this medicine if you are breastfeeding.

The safety of this medicine during pregnancy and breastfeeding has not yet been proven.

Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines

This medicine is not expected to affect your ability to drive or use machines. However, you should be aware that some people may feel dizzy after taking this medicine.

ATOZET contains lactose

ATOZET tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

ATOZET contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say it is essentially 'sodium-free' is.

3. How to take this medicine?

Always take this medicine exactly as your doctor has told you. Your doctor will determine the correct tablet strength for you, depending on your current treatment and your personal risk status. If you are unsure about the correct use, contact your doctor or pharmacist.

Before starting this medicine, you must follow a cholesterol-lowering diet.

You must continue this cholesterol-lowering diet while using this medicine.

How much to take

The recommended dosage is 1 tablet of this medicine orally once a day.

When to take

This medicine can be taken at any time of the day. You can take this medicine with or without food.

If your doctor has prescribed this medicine together with another cholesterol-lowering medicine containing the active substance cholestyramine or another bile acid-binding resin, you must take this medicine at least 2 hours before or 4 hours after taking the bile acid-binding resin.

Have you taken too much of this medicine?

Contact your doctor or pharmacist.

Have you forgotten to take this medicine?

Do not take a double dose to make up for a forgotten dose, but continue with the usual schedule the next day.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects or symptoms, stop taking your tablets and contact your doctor immediately or go to the emergency department of the nearest hospital.

a severe allergic reaction causing swelling of the face, tongue, and throat, which may lead to severe breathing problems

a serious condition with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals, and fever; rash with pink-red spots, especially on palms or soles, possibly with blisters

muscle weakness, tenderness, pain, or rupture, or reddish-brown discoloration of the urine, especially if you feel unwell or have a high body temperature at the same time. This may be caused by abnormal muscle breakdown that can be life-threatening and lead to kidney problems (rhabdomyolysis).

lupus-like syndrome (a condition where the immune system attacks the body with symptoms such as rash, joint complaints, inflammation/abnormality of blood cells, inflammation of blood vessels).

If you experience unexpected or unusual bleeding or bruising, this may indicate a liver disorder. Consult your doctor as soon as possible.

The following side effects were commonly reported (occur in less than 1 in 10 users):

diarrhea,
muscle pain.

The following side effects were sometimes reported (occur in less than 1 in 100 users):

the flu,
depression; difficulty sleeping; sleep disorder,
dizziness; headache; tingling sensation,
slow heartbeat,
hot flashes,
shortness of breath,
abdominal pain; bloating; constipation; indigestion; flatulence; more frequent bowel movements; gastritis; nausea; stomach discomfort; upset stomach,
acne; hives (urticaria),
joint pain; back pain; leg cramp; fatigue, spasm or weakness of the muscles; pain in the arms and legs,
unusual weakness; feeling tired or unwell; swelling, especially in the ankles (edema),
higher results of some blood tests to check liver or muscle function (CK),
weight gain.

The following side effects were reported with frequency 'unknown' (the frequency cannot be determined from the available data):

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

Contact your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping eyelids, difficulty swallowing or shortness of breath.

Additionally, the following side effects have been reported in people who have used this medicine, or tablets with ezetimibe or atorvastatin:

allergic reactions including swelling of the face, lips, tongue and/or throat, which may lead to difficulty breathing or swallowing (requiring immediate treatment),
increased red rash, sometimes with target-like spots on the skin,
liver problems,
cough,
heartburn,
decreased appetite; loss of appetite,
high blood pressure,
skin rash and itching; allergic reactions including rash and hives (urticaria),
tendon injury,
gallstones or inflammation of the gallbladder (which can cause abdominal pain, nausea, and vomiting),
inflammation of the pancreas, often with severe abdominal pain,
reduction in the number of blood cells, which can cause bruising/bleeding (thrombocytopenia),
sinusitis; nosebleed,
neck pain; pain; chest pain; sore throat,
increase and decrease in blood glucose levels (if you have diabetes, you should closely monitor your blood sugar levels),
nightmares,
numbness or tingling sensation in fingers and toes,
reduction in pain sensation or sense of touch,
change in taste; dry mouth,
memory loss,
ringing in ears and/or head; hearing loss,
vomiting,
belching,
hair loss,
increased body temperature,
urine tests that are positive for white blood cells,
blurred vision; vision problems,
gynecomastia (enlargement of the breasts in men).

With some statins, the following possible side effects have also been reported:

sexual problems,
depression,
breathing problems, including persistent cough and/or shortness of breath or fever, diabetes. This occurs more often 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 you are using this medication.
constant pain, tenderness, or weakness of the muscles, especially if you feel unwell at the same time or have a high temperature, which may not disappear after stopping this medication (frequency not known).

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medication.

5. How to store this medication?

Keep out of the sight and reach of children.

Do not use this medication after the expiry date. This can be found on the packaging after EXP. It includes a month and a year. The last day of that month is the expiry date. Store in the original packaging to protect against oxygen.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medication?

The active substances in this medication are ezetimibe and atorvastatin. Each film-coated tablet contains 10 mg ezetimibe and 10, 20, 40, or 80 mg atorvastatin (as atorvastatin calcium trihydrate).

The other substances in this medication are: calcium carbonate, colloidal anhydrous silica, sodium croscarmellose, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 80, povidone, sodium lauryl sulfate.

The film coating contains: hypromellose, macrogol 8000, titanium dioxide (E171), talc.

What does ATOZET look like and what is in a package?

White to off-white, capsule-shaped, biconvex, film-coated tablets.

ATOZET 10 mg/10 mg tablets: on one side is embossed with '257'.

ATOZET 10 mg/20 mg tablets: one side is embossed with '333'.

ATOZET 10 mg/40 mg tablets: one side is embossed with '337'.

ATOZET 10 mg/80 mg tablets: one side is embossed with '357'.

Package sizes:

Blister packs of 10, 30, 90, and 100 film-coated tablets in nitrogen-flushed aluminum/aluminum blisters (oPA-AI-PVC forming foil with aluminum lidding foil).

Unit dose packs of 30x1 and 45x1 film-coated tablets in nitrogen-flushed aluminum/aluminum blisters (oPA-AI-PVC forming foil with aluminum lidding foil).

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:

N.V. Organon

Kloosterstraat 6

5349 AB Oss

Netherlands

Tel.: 00800 66550123

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Manufacturer:
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Waarderweg 39
2031 BN Haarlem
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Organon Heist bv
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2220 Heist-op-den-Berg
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Kloosterstraat 6
5349 AB Oss
Netherlands

Registered under:

ATOZET 10 mg/10 mg, film-coated tablets	RVG 114373
ATOZET 10 mg/20 mg, film-coated tablets	RVG 114374
ATOZET 10 mg/40 mg, film-coated tablets	RVG 114375
ATOZET 10 mg/80 mg, film-coated tablets	RVG 114376

This medicine is registered in EEA member states under the following names:
ATOZET: Belgium, Bulgaria, Denmark, Germany, Ireland, Iceland, Italy, Croatia, Luxembourg, Malta, Netherlands, Norway, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden
LIPTRUZET: Cyprus, France, Greece, Hungary
ZOLETORV: Czech Republic

This leaflet was last approved in July 2023.

More information about this medicine is available on the website of the Medicines Evaluation Board (www.cbg-meb.nl).