

Package leaflet: Information for the patient

Ezetimibe/Atorvastatine Egis 10 mg/10 mg harde capsules

Ezetimibe/Atorvastatine Egis 10 mg/20 mg harde capsules

Ezetimibe/Atorvastatine Egis 10 mg/40 mg harde capsules

ezetimibe and atorvastatin

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Ezetimibe/Atorvastatine Egis is and what it is used for
2. What you need to know before you take Ezetimibe/Atorvastatine Egis
3. How to take Ezetimibe/Atorvastatine Egis
4. Possible side effects
5. How to store Ezetimibe/Atorvastatine Egis
6. Contents of the pack and other information

1. What Ezetimibe/Atorvastatine Egis is and what it is used for

Ezetimibe/Atorvastatine Egis contains two different active substances in one capsule. One of the active substances is ezetimibe, the other active substance is atorvastatin, belonging to the group of so called statins.

Ezetimibe/Atorvastatine Egis is a medicine used in adults to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol) and fatty substances called triglycerides in your blood. In addition, it also raises levels of “good” cholesterol (HDL cholesterol).

This medicine works to reduce your cholesterol in two ways: it reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself.

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. By lowering your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

Ezetimibe/Atorvastatine Egis is used in patients whose cholesterol levels cannot be controlled by a cholesterol lowering diet alone. You should stay on your cholesterol lowering diet while taking this medicine.

Your doctor may prescribe Ezetimibe/Atorvastatine Egis if you are already taking both ezetimibe and atorvastatin at the same dose level.

Ezetimibe/Atorvastatine Egis does not help you lose weight.

2. What you need to know before you take Ezetimibe/Atorvastatine Egis

Do not take Ezetimibe/Atorvastatine Egis:

- if you are allergic to ezetimibe, atorvastatin or any of the other ingredients of this medicine (listed in section 6)
- if you have or have ever had a disease which affects the liver
- if you have had any unexplained abnormal blood tests for liver function
- if you are a woman able to have children and not using reliable contraception
- if you are pregnant or trying to become pregnant
- if you are breast-feeding
- if you use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C

Warnings and precautions

Talk to your doctor or pharmacist before taking Ezetimibe/Atorvastatine Egis:

- if you have severe respiratory failure
- if you are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and Ezetimibe/Atorvastatine Egis can lead to serious muscle problems (rhabdomyolysis). (See section “Other medicines and Ezetimibe/Atorvastatine Egis”.)
- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- if you have kidney problems
- if you have an under-active thyroid gland (hypothyroidism)
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other “statin” or “fibrate” medicines)
- if you regularly drink a large amount of alcohol.
- if you have a history of liver disease
- are older than 70 years

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking Ezetimibe/Atorvastatine Egis. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage. Atorvastatin is known to cause muscle problems, and cases of muscle problems have also been reported with ezetimibe.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Tell your doctor about all your medical conditions including allergies.

The combined use of Ezetimibe/Atorvastatine Egis and fibrates (medicines for lowering cholesterol) is not recommended, since the combined use of Ezetimibe/Atorvastatine Egis and fibrates has not been studied.

Children and adolescents

The use of Ezetimibe/Atorvastatine Egis is not recommended in children and adolescents under the age of 18 years.

Other medicines and Ezetimibe/Atorvastatine Egis

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

There are some medicines that may change the effect of Ezetimibe/Atorvastatine Egis or their effect may be changed by Ezetimibe/Atorvastatine Egis. This type of interaction could make one or both of the medicines less effective. Alternatively it could increase the risk or severity of side effects, including the important muscle wasting condition known as “rhabdomyolysis” described in section 4:

- Medicines used to alter the way your immune system works, e.g. ciclosporin
- Certain antibiotics, e.g. erythromycin, clarithromycin, telithromycin, rifampicin (medicines for bacterial infections)
- Certain antifungal medicines, e.g. ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, nicotinic acid derivatives, colestipol, colestyramine
- Some calcium channel blockers used for angina or high blood pressure, e.g., amlodipine, diltiazem
- Medicines to regulate your heart rhythm, e.g. digoxin, verapamil, amiodarone
- Letemovir, a medicine that helps stop you from getting ill from cytomegalovirus
- Medicines used in the treatment of HIV, e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, efavirenz, fosamprenavir, delavirdine, the combination of tipranavir/ritonavir, etc.
- Some medicines used in the treatment of hepatitis C (inflammation of the liver), e.g. telaprevir, boceprevir and the combination of elbasvir/grazoprevir, ledipasvir/sofosbuvir
- Fusidic acid. If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Ezetimibe/Atorvastatine Egis. Taking Ezetimibe/Atorvastatine Egis with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
- Other medicines known to interact with Ezetimibe/Atorvastatine Egis
 - warfarin, phenprocoumon, acenocoumarol or fluindione (medicines to prevent blood clots)
 - oral contraceptives
 - stiripentol (an anticonvulsant medicine for epilepsy)
 - cimetidine (a medicine used for heartburn and peptic ulcers)
 - phenazone (a painkiller)
 - colchicine (used to treat gout)
 - antacids (indigestion products containing aluminium or magnesium)
 - St John's Wort (a medicine to treat depression)

Ezetimibe/Atorvastatine Egis with food and alcohol

See section 3 for instructions on how to take Ezetimibe/Atorvastatine Egis. Please note the following:

Grapefruit juice

Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of Ezetimibe/Atorvastatine Egis.

Alcohol

Avoid drinking too much alcohol while taking this medicine. See Section 2 “Warnings and precautions” for details.

Pregnancy and breast-feeding

Do not take Ezetimibe/Atorvastatine Egis if you are pregnant, are trying to get pregnant or think you may be pregnant. Women of childbearing potential must not take Ezetimibe/Atorvastatine Egis, unless they use reliable contraceptive measures. If you get pregnant while taking Ezetimibe/Atorvastatine Egis, stop taking it immediately and tell your doctor.

Do not take Ezetimibe/Atorvastatine Egis if you are breast-feeding.

The safety of Ezetimibe/Atorvastatine Egis during pregnancy and breast-feeding has not yet been proven. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Ezetimibe/Atorvastatine Egis is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people may get dizzy after taking Ezetimibe/Atorvastatine Egis. If you get dizzy, talk to your doctor before driving or using machines.

Ezetimibe/Atorvastatine Egis contains sucrose and sodium

Each Ezetimibe/Atorvastatine Egis 10 mg/10 mg capsule contains 13 mg, each Ezetimibe/Atorvastatine Egis 10 mg/20 mg capsule contains 26 mg and each Ezetimibe/Atorvastatine Egis 10 mg/40 mg capsule contains 51.5 mg sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Ezetimibe/Atorvastatine Egis

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should keep on being on a low-cholesterol diet while taking Ezetimibe/Atorvastatine Egis.

The recommended daily dose for adults is one capsule of the given strength.

Take Ezetimibe/Atorvastatine Egis once daily.

The capsules can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

Swallow each capsule whole with a drink of water.

Ezetimibe/Atorvastatine Egis is not suitable to start a treatment. Treatment initiation or dose adjustment if necessary should only be done by giving the active substances separately and after setting the appropriate doses the switch to Ezetimibe/Atorvastatine Egis of the appropriate strength is possible.

If your doctor has prescribed Ezetimibe/Atorvastatine Egis along with another medicine for lowering cholesterol containing the active ingredient colestyramine or any other medicine containing bile acid sequestrant, you should take Ezetimibe/Atorvastatine Egis at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you take more Ezetimibe/Atorvastatine Egis than you should

If you accidentally take too many capsules (more than your recommended daily dose), contact your doctor or nearest hospital for advice.

If you forget to take Ezetimibe/Atorvastatine Egis

If you forget to take a dose, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ezetimibe/Atorvastatine Egis

Talk to your doctor if you want to stop taking Ezetimibe/Atorvastatine Egis. Your cholesterol levels might increase again if you stop taking Ezetimibe/Atorvastatine Egis.

If you have any further questions on the use of this medicine, ask 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 this medicine and tell your doctor immediately or go to the nearest hospital accident and emergency department:

Rare (may affect up to 1 in 1 000 people)

- Serious allergic reaction which causes swelling of the face, tongue and throat that can cause great difficulty in breathing.
- Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister.
- Muscle weakness, tenderness, pain or rupture, or red-brown discolouration of urine and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (rhabdomyolysis). The abnormal muscle breakdown does not always go away, even after you have stopped taking Ezetimibe/Atorvastatine Egis, and it can be life-threatening and lead to kidney problems.

Very rare (may affect up to 1 in 10 000 people)

- If you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint. You should consult your doctor as soon as possible.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Other possible side effects**Common (may affect up to 1 in 10 people)**

- common cold (nasopharyngitis)
- allergic reactions
- high levels of sugar in your blood
- headache
- throat pain
- nosebleed
- constipation
- flatulence (excess gas in the intestinal tract)
- dyspepsia
- feeling sick (nausea)
- diarrhoea
- abdominal ache
- muscle pain

- joint pain
- pain in arms and legs
- muscle spasm
- joint swelling
- back pain
- feeling tired (fatigue)
- elevations in some laboratory blood tests of muscle (CK) function
- abnormal liver function test results, elevations in some laboratory blood tests of liver function (transaminases)

Uncommon (may affect up to 1 in 100 people)

- low levels of sugar in your blood
- weight gain
- decreased or loss of appetite
- nightmare
- sleeplessness
- dizziness
- numbness or tingling in the fingers and toes
- reduction of sensation to pain or touch
- taste disturbance
- loss of memory
- blurred vision
- ringing in the ears
- hot flush
- high blood pressure
- cough
- vomiting
- belching
- inflammation of the pancreas, which causes a severe stomach pain which can extend to the back
- heartburn
- dry mouth
- inflammation of the stomach (gastritis)
- inflammation of the liver (hepatitis)
- hives
- itching
- skin rash
- hair loss
- neck pain
- muscle weakness
- malaise (a feeling of overall weakness)
- asthenia (lack of energy and strength)
- chest pain
- pain
- swelling, especially in the hands and feet
- fever
- urine tests that are positive for white blood cells
- increased level of a liver enzyme in your blood

Rare (may affect up to 1 in 1 000 people)

- reduction in blood platelets, which increases the risk of bruising/bleeding (thrombocytopenia)

- damage to the nerves of your legs and arms (such as numbness)
- visual disturbance
- cholestasis (yellowing of the skin and the whites of the eyes)
- raised red rash, sometimes with target shaped lesions (erythema multiforme)
- muscle disease with muscle weakness (myopathy)
- muscle inflammation
- tendon injury

Very rare (may affect up to 1 in 10 000 people)

- hearing loss
- breast enlargement in men (gynecomastia)

Not known (frequency cannot be estimated from the available data)

- depression
- shortness of breath
- gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting)
- muscle weakness that is constant (immune-mediated necrotizing myopathy)

Possible side effects reported with some statins

- sexual difficulties
- 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 you are taking this medicine

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via het Nederlands Bijwerken Centrum Lareb, website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ezetimibe/Atorvastatine Egis

Keep this medicine out of the sight and reach of children.

Store below 30 °C in the original packaging in order to protect from moisture.

Do not use this medicine after the expiry date (EXP) which is stated on the package. The expiry date refers to the last day of that month.

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.

6. Contents of the pack and other information

What Ezetimibe/Atorvastatine Egis contains

- The active substances are ezetimibe and atorvastatin (as atorvastatin calcium trihydrate). Each capsule contains 10 mg of ezetimibe and 10 mg, 20 mg or 40 mg atorvastatin.
- The other ingredients are:

Core: calcium carbonate (E170), hydroxypropylcellulose (E463), polysorbate 80 (E433), croscamellose sodium (E468), sugar spheres, talc (E553B), mannitol (E421), microcrystalline cellulose (E460(i)), low-substituted hydroxypropyl cellulose (E463), povidone (E1201), sodium laurilsulfate (E487), magnesium stearate (E572)

Capsule shell:

Cap of Ezetimibe/Atorvastatine Egis 10 mg/10 mg harde capsules: titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172), gelatine (E441).

Cap of Ezetimibe/Atorvastatine Egis 10 mg/20 mg harde capsules: titanium dioxide (E171), red iron oxide (E172), gelatine (E441)

Cap of Ezetimibe/Atorvastatine Egis 10 mg/40 mg harde capsules: titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172), gelatine (E441)

Capsule body for all strengths: titanium dioxide (E171), yellow iron oxide (E172), gelatine (E441)

What Ezetimibe/Atorvastatine Egis looks like and contents of the pack

Ezetimibe/Atorvastatine Egis 10 mg/10 mg harde capsules: Unmarked self-closing size 0, hard gelatine capsule with caramel coloured cap and yellow coloured body, filled with pellets and a tablet.

Ezetimibe/Atorvastatine Egis 10 mg/20 mg harde capsules: Unmarked self-closing size 0, hard gelatine capsule with reddish brown coloured cap and yellow coloured body, filled with pellets and a tablet.

Ezetimibe/Atorvastatine Egis 10 mg/40 mg harde capsules: Unmarked self-closing size 0, hard gelatine capsule with dark brown coloured cap and yellow coloured body, filled with pellets and a tablet.

30, 60, 70, 80, 90, 100 or 120 hard capsules in OPA/Al/PVC//Al blister enclosed in folded cardboard box. Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen

Egis Pharmaceuticals PLC
1106 Boedapest, Keresztúri út 30-38.
Hongarije

Fabrikanten

Egis Pharmaceuticals PLC
1165 Boedapest, Bökényföldi út 118-120.
Hongarije

Egis Pharmaceuticals PLC
9900 Körmend, Mátyás király u. 65.
Hongarije

Lek Pharmaceuticals d.d.
1526 Ljubljana, Verovskova 57.
Slovenië

In het register ingeschreven onder:

Ezetimibe/Atorvastatine Egis 10 mg/10 mg harde capsules - RVG 123736

Ezetimibe/Atorvastatine Egis 10 mg/20 mg harde capsules - RVG 123742

Ezetimibe/Atorvastatine Egis 10 mg/40 mg harde capsules - RVG 123743

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland: Ezetimibe/Atorvastatine Egis 10 mg/10 mg harde capsules
Ezetimibe/Atorvastatine Egis 10 mg/20 mg harde capsules
Ezetimibe/Atorvastatine Egis 10 mg/40 mg harde capsules

Oostenrijk: Ezetimibe/Atorvastatine Egis 10 mg/10 mg hartkapseln
Ezetimibe/Atorvastatine Egis 10 mg/20 mg hartkapseln
Ezetimibe/Atorvastatine Egis 10 mg/40 mg hartkapseln

Griekenland: Cholzet (10+10) καψάκια, σκληρά
Cholzet (10+20) καψάκια, σκληρά
Cholzet (10+40) καψάκια, σκληρά

Italië: Ancilleg

Noorwegen: Ezetimibe/Atorvastatine Egis 10 mg/10 mg harde kapsler
Ezetimibe/Atorvastatine Egis 10 mg/20 mg harde kapsler
Ezetimibe/Atorvastatine Egis 10 mg/40 mg harde kapsler

Portugal: Atorvastatina + Ezetimiba Pentafarma 10 mg/10 mg cápsulas
Atorvastatina + Ezetimiba Pentafarma 10 mg/20 mg cápsulas
Atorvastatina + Ezetimiba Pentafarma 10 mg/40 mg cápsulas

Deze bijsluiter is voor het laatst goedgekeurd in november 2021.