

Package leaflet: Information for the patient

[Invented name] 5 mg / 10 mg film-coated tablets
[Invented name] 10 mg / 10 mg film-coated tablets

Amlodipine / Atorvastatin

Read all of this leaflet carefully before you start using 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 your 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 [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] is used for prevention of cardiovascular incidents (such as angina pains, heart attacks) in patients with high blood pressure, who have an additional risk factor of heart diseases, such as, for example, cigarette smoking, overweight, high blood level of cholesterol, family history of heart disease or diabetes. The presence of such risk factors in combination with high blood pressure increases the risk of cardiovascular incidents.

[Invented name] is a medicine that contains two active ingredients: amlodipine (calcium antagonist) and atorvastatin (statin). Amlodipine is used to treat high blood pressure (hypertension), and atorvastatin reduces the blood cholesterol level.

Hypertension is a disease of the cardiovascular system characterized by continuous or periodic high blood pressure. It is one of the risk factors for the occurrence of cardiovascular incidents (angina, heart attack and stroke).

Cholesterol is a naturally occurring substance in the body which is needed for the normal development of the body. Too much cholesterol in the blood can, however, cause its deposition in the walls of the blood vessels, thereby increasing the risk of blood clots and cardiovascular incidents. This is one of the most common causes of heart disease.

It is given in situations where it is advisable to use both of these medicines simultaneously.

2. What you need to know before you take [Invented name]

Do not take [Invented name]:

- if you are allergic to amlodipine or other calcium channel blockers that are derived from dihydropyridine, if you are allergic to atorvastatin or any of the other ingredients of this medicine (listed in section 6);
- if you are presently suffering from any liver disease (if you have previously suffered from a liver disease, you should read the section on: “Warnings and precautions” below);
- if you have been told that you have an unexplained, abnormal liver function test results;
- if you are pregnant or planning to become pregnant;
- if you are breast-feeding;
- if you are taking any of the following medicines: ketoconazole, itraconazole (medicines used for the treatment of fungal infections), telithromycin (an antibiotic);
- if you have very low blood pressure (hypotension);
- if you suffer from narrowing of the aortic valve (aortic stenosis) or condition in which the heart does not supply enough blood to the body (cardiogenic shock);
- if you suffer from heart failure after a heart attack
- 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 the medicine:

- if you have cardiac insufficiency;
- if you have had recently a heart attack;
- if you suffer from kidney disease;
- if you suffer from hypothyroidism (underactivity of the thyroid gland);
- if you have had repeated or unexplained muscle pain in the past, or, a personal history or family history of muscle problems;
- if you have had previous muscular problems during treatment with other cholesterol (lipid)-lowering medicines (e.g. statins or fibrates);
- if you regularly drink a large amount of alcohol;
- if you have suffered from a liver disease in the past;
- if you are above 70 years of age;
- if you have had a previous stroke with bleeding into the brain, or you have small pockets of fluid in the brain from a previous stroke;
- if you have severe breathing problems;
- if you have diabetes or are at risk of developing diabetes.
While you are on this medicine your doctor will monitor you closely. 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.
- 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 [Invented name] can lead to serious muscle problems (rhabdomyolysis).

In each of these cases, before you start treatment with [Invented name] (and possibly during treatment), your doctor will recommend that you carry out a blood test to estimate the risk of muscle-related side effects. It has been observed that the risk of muscle-related side effects e.g. rhabdomyolysis (breakdown of muscle cells) increases when certain medicines are taken together (see section 2 “Other medicines and [Invented name]”).

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.

Children and adolescents

The use of [Invented name] in children and adolescents is not recommended.

Other medicines and [Invented name]

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

Some medicines may interact with [Invented name]. Such interactions may reduce the effectiveness of one or both of these medicines. Besides, there could be an increase in the risk of the occurrence or intensification of side-effects, including a significant destructive disease of the muscles known as rhabdomyolysis and myopathy (described in section 4):

- certain **antibiotics** e.g. rifampin or so-called macrolide antibiotics e.g. erythromycin, clarithromycin, telithromycin, fusidic acid or some other medicines used in the treatment of fungal infections, among others, ketoconazole, itraconazole;
- medicines used to **regulate the level of lipids**: fibrates (e.g. gemfibrozil) or colestipol;
- medicines used to suppress abnormal beating of the heart (antiarrhythmics) e.g. amiodarone, diltiazem and verapamil;
- medicines that are used to **alter the way your immune system works**, e.g. cyclosporine, tacrolimus;
- protease inhibitors used in the **treatment of HIV**, e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, nelfinavir, efavirenz, delavirdine;
- medicines used to treat **depression**, e.g. imipramine;
- medicines used for the treatment of **mental health problems**, e.g. neuroleptics;
- medicines **used in heart failure**, e.g. medicines called beta-blockers;
- medicines **used in the treatment of high blood pressure**, e.g. angiotensin II receptor antagonists, angiotensin converting enzyme (ACE) inhibitors, verapamil and diuretics;
- alpha-blockers used to treat **high blood pressure and diseases of the prostate** (e.g. prazosin, alfuzosin, doxazosin, tamsulosin, terazosin);
- amifostine (used in the treatment of **tumours**);
- sildenafil (used to treat **erectile dysfunction**);
- dantrolene and baclofen (**muscle relaxants**);
- **steroids**;
- **St. John's wort**;
- ezetimibe (which **lowers cholesterol levels**);
- warfarin (which **reduces blood clotting**);
- oral **contraceptives**;
- stiripentol (an **anticonvulsant** used to treat epilepsy);
- cimetidine (used to treat **heartburn and peptic ulcers**);
- phenazone (a **painkiller**);
- some medicines used in the treatment of hepatitis C e.g. telaprevir, boceprevir and the combination of elbasvir/grazoprevir;
- **antacids** (containing magnesium or aluminium and used to treat indigestion).

If you need to take orally or by injection 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 [Invented name]. Taking [Invented name] with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

[Invented name] with food, drink and alcohol

[Invented name] can be taken at any time of day, with or without food.

Grapefruit juice

Do not take more than one or two glasses of grapefruit juice a day because large quantities of grapefruit juice can change the effect of [Invented name].

Alcohol

Avoid drinking too much alcohol while taking this medicine (see section 2 "Warnings and precautions").

Pregnancy, breast-feeding and fertility

Do not take [Invented name] 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 any medicine.

If you are of child bearing potential, you must use appropriate contraception while taking [Invented name].

Driving and using machines

If you experience dizziness, feeling sick, headache or fatigue after taking this medicine, you should not drive or operate machines.

3. How to take [Invented name]

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

Adults

The usual starting dose of [Invented name] in adults is one tablet (5 mg / 10 mg) per day. If necessary, the doctor may increase the dose of [Invented name] to one tablet (10 mg / 10 mg) a day.

[Invented name] tablets should be swallowed whole, with a drink of water. [Invented name] can be taken orally at any time of day, with or without food. However, you should try to take the medicine at the same time each day.

You should follow your doctor's recommendations on diet, especially in the case of fat-restricted diets; avoid cigarette smoking and exercise regularly.

If you think that the effect of [Invented name] is too strong or too weak, talk to your doctor or pharmacist.

Use in children and adolescents

It is not recommended for children or adolescents to use this medicine.

If you take more [Invented name] than you should

If you take too many [Invented name] tablets (more than the normal daily dose), the most likely side effect is very low blood pressure (hypotension). Contact your doctor or go to the nearest hospital. Take along with you the remaining tablets, the packaging and the whole box, so that hospital staff can easily tell what type of medicine have been taking.

If you forget to take [Invented name]

If you miss a dose, you should 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 [Invented name]

Don't stop taking [Invented name] without the doctor's advice.

If you have any further questions on the use of this medicine or wish to stop the treatment, ask your doctor or pharmacist.

4. Possible side effects

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

Visit your doctor immediately if you experience any of the following side effects after taking this medicine:

- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions.

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

- an allergic reaction - symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat (which can cause considerable difficulty in breathing), collapse.
- unexplained muscle weakness, muscle tenderness, muscle pain or rupture, red-brown discolouration of urine and if at the same time, you feel unwell or have a high temperature. Very rarely, this combination of symptoms transforms into a serious, life-threatening condition called rhabdomyolysis (breakdown of muscle cells).
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Common side effects (may affect up to 1 in 10 people):

- allergic reaction;
- headache (especially at the beginning of treatment), dizziness, fatigue, drowsiness;
- palpitations (sensation of irregular heart beat);
- flushing;
- inflammation of the nasal passages, pain in the throat, bleeding from the nose;
- nausea, stomach pain, indigestion, altered bowel habits (including diarrhoea, constipation and winds);
- muscle and joint pain, muscle cramps and spasms, back pain, leg pain, swelling in the arms, hands, legs;
- increase in blood sugar levels (patients with diabetes should continue to monitor their blood glucose levels closely), increase in blood creatine kinase, blood test results that show your liver function can become abnormal.

Uncommon side effects (may affect up to 1 in 100 people):

- inflammation of the liver (hepatitis);
- catarrh, loss of appetite, decrease in blood sugar levels (patients with diabetes should continue to monitor their blood glucose levels closely), increase or decrease in body weight;
- sleep disturbances, nightmares, mood changes (including anxiety), depression, tremor, sensory nerve damage (reduced sensation) in the extremities, loss of memory;
- visual disturbances (including double vision), blurred vision, buzzing or humming in the ears;
- shortness of breath, fainting, excessive sweating, low blood pressure (hypotension);
- dry mouth, taste disorder, vomiting;
- hair loss, bruising or small haemorrhagic spots under the skin (purpura), skin discolouration, reductions of sensation to touch or pain, skin rash or itching, hives;
- disorders of the urinary tract (including passing of large amounts of urine at night and increased frequency of urination), impotence, breast enlargement in men;
- feeling weak, feeling unwell, fever, muscle weakness, inflammation of the pancreas (causing abdominal pain), neck pain, chest pain, pain;
- swelling of the ankles, feet or fingers;
- the presence of white blood cells in urine.

Rare side effects (may affect up to 1 in 1,000 people):

- numbness or tingling in the fingers and toes

- severe muscle inflammation, severe pain or muscle spasms that may very rarely lead to rhabdomyolysis (breakdown of muscle cells);
- reduction in the number of blood platelets;
- yellowing of the skin and whites of the eyes (cholestasis);
- serious allergic reactions with fever, red patches, joint pain and/or eye problems (*Stevens-Johnson syndrome*, toxic epidermal necrolysis);
- skin rash with irregular red patches (*dermatitis bullous*, including *erythema multiforme*);
- inflammation of the tendons, damage to the tendons;
- confusion.

Very rare side effects (may affect up to 1 in 10,000 people):

- sudden swelling of the face, tongue or pharynx with difficulty breathing and swallowing and hives (Quincke's oedema);
- extreme redness and scaling of the skin (*exfoliative dermatitis*);
- increased sensitivity to sunlight (photosensitivity);
- reduction in the number of white blood cells;
- stiffness or excessive muscle tone;
- irregular heart rate, heart attack, inflammation of the small blood vessels, stomach pain (inflammation of the stomach);
- swollen gums (gingival hyperplasia), cough;
- yellowing of the skin (jaundice);
- hearing loss, liver failure.

Side effects of unknown frequency:

- muscle weakness that is constant;
- trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

Other possible side effect:

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Do not store above 25°C.

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

Do not use this medicine after the expiry date stated on the carton and blister. 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 to protect the environment.

6. Contents of the pack and other information

What [Invented name] contains

- The active substances of the medicine are amlodipine and atorvastatin.
[Invented name] 5 mg / 10 mg contains 5 mg of amlodipine as amlodipine besilate and 10 mg of atorvastatin as atorvastatin calcium trihydrate.
[Invented name] 10 mg / 10 mg contains 10 mg of amlodipine as amlodipine besilate and 10 mg of atorvastatin as atorvastatin calcium trihydrate.
- The other ingredients are: pregelatinised starch, microcrystalline cellulose, magnesium carbonate heavy, polysorbate 80, hydroxypropyl cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate;
The film-coating of [Invented name] 5 mg / 10 mg tablets contains poly(vinyl alcohol), titanium dioxide (E171), macrogol, talc.
The film-coating of [Invented name] 10 mg / 10 mg tablets contains poly(vinyl alcohol), titanium dioxide (E171), indigo carmine aluminium lake (E132), macrogol, talc.

What [Invented name] looks like and contents of the pack

[Invented name] 5 mg / 10 mg are white, or almost white, oval, biconvex film-coated tablets, with dimensions 4.6 mm × 9.2 mm.

[Invented name] 10 mg / 10 mg are light-blue, oval, biconvex, film-coated tablets, scored on one side, with dimensions 4.6 mm × 9.1 mm. The scoreline is not intended for the breaking of the tablets.

[Invented name] is available in Aluminium//OPA/Aluminium/PVC blister of 30 tablets each.

Marketing Authorisation Holder and Manufacturer

Pharmaceutical Works POLPHARMA SA
19 Pelplińska Street, 83-200 Starogard Gdański, Poland

In order to obtain more detailed information concerning the medicine and its name in a member state of the European Economic Community, please contact the representative of the Marketing Authorisation Holder:

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This leaflet was last revised in: