

Package leaflet: information for the user

AGEN 5 mg tablets AGEN 10 mg tablets amlodipine

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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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

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2. What you need to know before you take AGEN
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1. What AGEN is and what it is used for

AGEN contains the active substance amlodipine, which belongs to a group of medicines called calcium antagonists.

AGEN is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina (and also its rare form called Prinzmetal's or variant angina).

In patients with high blood pressure, this medicine works by relaxing the blood vessel walls, so that blood could pass through the vessels more easily. In patients with angina, AGEN works by improving blood supply to the heart muscle, which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain caused by angina.

2. What you need to know before you take AGEN

Do not take AGEN if

- You are allergic (hypersensitive) to Amlodipine or any of the other ingredients of this medicine (listed in section 6), or to any other calcium antagonists. Allergy symptoms may include itching, redness of the skin or difficulty breathing.
- You have very low blood pressure (hypotension).
- You have a narrowing of the aortic valve (aortic stenosis) or cardiogenic shock (condition in which your heart is unable to pump enough blood into your body).
- You suffer from heart failure as a result of a heart attack.

Warnings and precautions

Talk to your doctor or pharmacist before taking AGEN.

Tell your doctor if you have or have had any of the following conditions:

- Recent heart attack.
- Heart failure.

- Severe increase in blood pressure (hypertensive crisis).
- Liver disease.
- You are elderly and your dose needs to be increased.

Use in children and adolescents

AGEN has not been studied in children under 6 years of age. AGEN can only be used for hypertension in children and adolescents from the age of 6...17 (see section 3). For more information, ask your doctor.

Other medicines and AGEN

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

AGEN may affect or be affected by other medicines, such as:

- Ketoconazole, itraconazole (anti-fungal medicines).
- Ritonavir, indinavir, nelfinavir (so-called protease inhibitors used to treat HIV).
- Rifampicin, erythromycin, clarithromycin (antibiotics).
- St. John's Wort (*Hypericum perforatum*).
- Verapamil, diltiazem (heart medicines).
- Dantrolene (infusion for severe body temperature abnormalities).
- Tacrolimus (used for managing the body's immune response to lessen the rejection risk of an organ transplant).
- Simvastatin (used for lowering high cholesterol).
- Cyclosporine (immunosuppressant).

AGEN may lower your blood pressure even further if you are already taking other medicines to treat your high blood pressure.

AGEN with food, drink and alcohol

Grapefruit juice and grapefruit should not be consumed by people who are taking AGEN. This is because grapefruit and grapefruit juice can lead to an increase in the levels of the active ingredient amlodipine in the blood, which can in turn cause an unpredictable increase in the blood pressure lowering effect of AGEN.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

The safety of Amlodipine in human pregnancy has not been established. If you think you might be pregnant or are planning to have a baby, tell your doctor before taking AGEN.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts.. If you are breast-feeding or wish to begin breast-feeding, tell your doctor before taking AGEN.

Driving and using machines

AGEN may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines, and contact your doctor immediately.

3. How to take AGEN

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

The recommended starting dose of AGEN is 5 mg once a day. The dose of AGEN may be increased to 10 mg once a day.

This medicine may be taken before or after eating or drinking. It is recommended to take the medicine with a glass of water at the same time every day. Do not take AGEN with grapefruit juice.

Children and adolescents

For children (ages 6...17), the recommended starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day.

The 5 mg AGEN tablet may be split into two equal doses of 2.5 mg each.

It is important not to discontinue taking the tablets. You do not have to wait until your tablets are finished before seeing your doctor.

If you take more AGEN than you should

Taking too many tablets may cause low or even dangerously low blood pressure. You may experience dizziness, vertigo, feelings of faintness or light headedness. Severe lowering of blood pressure may lead to shock. In such cases, your skin may feel cool and clammy. Loss of consciousness may also occur.

Excess fluid may build up in your lungs (pulmonary oedema), causing shortness of breath, which may occur 24...48 hours after taking them.

Seek immediate medical attention if you take too many AGEN tablets.

If you forget to take AGEN

Do not worry. If you have forgotten to take a tablet, skip that dose completely. Take the next dose at the right time.

Do not use a double dose to make up for a forgotten dose.

If you stop taking AGEN

Your doctor will advise you on how long to take your medicine. Your condition may deteriorate if you stop using the medicine before you are advised to.

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.

Tell your doctor immediately if you get any of the following very rare but severe side effects after taking this medicine:

- Sudden dyspnoea, chest pain, shortness of breath or difficulty breathing.
- Swelling of eyelids, face or lips.
- Swelling of the tongue and throat, which may cause severe breathing difficulties;
- Severe skin reactions, including severe rash, hives, redness of the skin over the 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.
- Heart attack, arrhythmia.
- Pancreatitis which may cause severe abdominal and back pain accompanied with feeling very unwell.

The following **common side effects** have been reported. If any of these causes you problems or **lasts more than a week**, talk to your doctor.

Common side effects (affects 1 to 10 users in 100):

- headache, dizziness, drowsiness (especially at the beginning of the treatment) ;

- heart palpitations, flushing;
- abdominal pain, feeling unwell (nausea);
- swelling (oedema) of the ankles, fatigue.

Other known side effects are listed below. If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Uncommon side effects (affects 1 to 10 users in 1,000):

- mood changes, anxiety, depression, insomnia;
- trembling, taste abnormalities, fainting, feelings of faintness;
- numbness or tingling in your limbs, loss of pain sensation;
- visual disturbances, double vision, ringing in the ears;
- low blood pressure;
- sneezing / runny nose caused by the inflammation of the nasal mucous membrane (rhinitis);
- a change in bowel habits, diarrhoea, constipation, indigestion, dry mouth, vomiting (feeling unwell);
- hair loss, increased perspiration, itchy skin, red patches on the skin, skin discoloration;
- difficulty passing urine, increased need to urinate at night, increased frequency of urination;
- inability to obtain an erection, discomfort or enlargement of the mammary glands in men;
- weakness, pain, feeling unwell;
- joint or muscle pain, muscle cramps, back pain;
- weight gain or loss.

Rare side effects (affect 1 to 10 users in 10,000):

- confusion.

Very rare side effects (affect less than 1 user in 10,000):

- Decreased number of white blood cells, decrease in blood platelets (thrombocytes), which may result in unusual bruising or easy bleeding (red blood cell damage);
- increased blood sugar (hyperglycaemia);
- nerve damage, which may cause fatigue, tingling or numbness;
- cough, swelling of the gums;
- abdominal bloating (gastritis);
- abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), increase in liver enzyme activity, which may affect some medical tests;
- increased muscle tension;
- Inflammation of blood vessels, often accompanied with skin rash.
- sensitivity to light.

Unknown side effects (incidence cannot be estimated from available data):

- trembling, rigidity, masklike face, slow movements and shuffling of the feet, unbalanced gait.

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 www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store AGEN

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

Do not store above 25°C.

Store in the original package, protected from light.

Do not use this medicine after the expiry date stated on the carton. 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 AGEN contains

- The active substance is amlodipine. Each tablet contains 6.935 mg or 13.870 mg of amlodipine besylate, which is equivalent to 5 mg or 10 mg of amlodipine in one tablet.
- The excipients are: microcrystalline cellulose, sodium starch glycolate A, calcium hydrogen phosphate dihydrate, magnesium stearate.

What AGEN looks like and contents of the pack

AGEN comes as white or off-white oval tablets, with a score line and markings “A” and “5” or “A” and “10” on one side. The dimensions of the tablets are 9 x 4.5 mm and 12 x 6 mm, respectively. The tablet may be divided into equal doses.

The tablets are packaged into PVC/PVDC/Al blister (white) or PVC/Al blister (white) packs. The pack contains 10, 30 or 90 tablets.

Marketing Authorisation Holder and Manufacturer

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For any further information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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