

PACKAGE LEAFLET: INFORMATION FOR THE USER

Amlodipine 5 mg tablets Amlodipine 10 mg tablets

Amlodipine

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Amlodipine is and what it is used for.
2. Before you take Amlodipine.
3. How to take Amlodipine.
4. Possible side effects.
5. How to store Amlodipine.
6. Further information.

1. WHAT AMLODIPINE IS AND WHAT IT IS USED FOR

Amlodipine belongs to a group of medicines called calcium antagonists.

Amlodipine is used to treat:

- high blood pressure
- chest pain due to narrowing of the coronary arteries of the heart muscle (angina pectoris) or the more rare form of chest pain caused by cramping of the coronary arteries of the heart muscle (vasospastic angina).

If you suffer from high blood pressure, Amlodipine works by relaxing blood vessels, so that blood passes through them more easily.

If you suffer from angina, Amlodipine works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Amlodipine does not provide immediate relief of chest pain from angina.

2. BEFORE YOU TAKE AMLODIPINE

Do not take Amlodipine

- if you are **allergic** to Amlodipine or similar calcium channel blockers (the so-called dihydropyridine derivatives) or to any of the other ingredients (for a full list of ingredients, see section 6)
- if you have very **low blood pressure**
- if you are suffering from **insufficient blood supply** to your tissues with symptoms like e.g. low blood pressures, low pulse, fast heartbeat (shock, including cardiogenic shock). Cardiogenic shock means shock due to severe heart troubles.
- if you have **heart failure** after a heart attack within the last four weeks.
- if you are suffering from **narrowing of the aorta** (aortic stenosis)
- if you get heart-associated chest pain also at rest or with minimal effort (unstable angina pectoris)
- if you are pregnant or breast-feeding

Take special care with Amlodipine

Tell your doctor before you start treatment:

- if you have **heart failure**
- if you have reduced **liver function**
- if you have reduced **kidney function**

Elderly

The dose should be increased with caution.

Children

Safety and effectiveness have been studied in 6-17 year old boys and girls. Amlodipine has not been studied in children under the age of 6 years. For more information, talk to your doctor.

Taking other medicines

Some medicines (including medicines obtained without prescription, herbal medications or natural products) may interact with Amlodipine. This means that the action of both medicines can be changed.

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

- **Medicines that can lower blood pressure**, e.g. beta-blockers, ACE-inhibitors, alpha-1-blockers and diuretics. Amlodipine may enhance the blood pressure lowering effects of these medicines.
- **Diltiazem (cardiac medicine)** may intensify the effect of Amlodipine.
- **Ketoconazole and itraconazole (antifungal medicines)** may intensify the effect of Amlodipine.
- **HIV-protease-inhibitors (antiviral medicines to treat HIV infections, e.g. ritonavir)** may intensify the effect of Amlodipine.
- **Clarithromycin, erythromycin and telithromycin (antibiotics)** may intensify the effect of Amlodipine.
- **Nefazodone (medicine to treat depression)** may intensify the effect of Amlodipine.
- **Rifampicin and rifabutin (antibiotics)** may reduce the effect of Amlodipine.
- **St. John's Wort (Hypericum perforatum; herbal medicine for depression)** may reduce the effect of Amlodipine.
- **Dexamethasone (cortisone)** may reduce the effect of Amlodipine.
- **Phenobarbital, phenytoin and carbamazepine (medicines for epilepsy)** may reduce the effect of Amlodipine.
- **Nevirapine (antiviral medicine to treat HIV infection)** may reduce the effect of Amlodipine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Amlodipine with food and drink

Amlodipine should be taken with a glass of water, with or without food.

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

Pregnancy and breast-feeding

If you are pregnant or become pregnant during treatment, do not take Amlodipine unless specifically prescribed by your doctor.

There is insufficient data to evaluate the risk for the baby when you take Amlodipine during pregnancy.

If you are breast-feeding, do not take Amlodipine. Please contact your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Be careful if you drive or operate machinery if you take this medicine. Amlodipine may not directly affect your ability to drive or operate machinery. However, some patients experience side effects such as dizziness or sleepiness related to the fall in the blood pressure (see section 4 of this leaflet). Such side effects are more likely to occur after beginning to take Amlodipine or after dose increases. If you experience these side effects, you should refrain from driving and other activities requiring alertness.

3. HOW TO TAKE AMLODIPINE

Dosage

Always take Amlodipine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

The usual starting dose is 5 mg once daily. If necessary, your doctor may increase the dose to 10 mg once daily.

Children

For children (6-17 years old), the recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day. Amlodipine 2.5 mg is not currently available and the 2.5 mg dose cannot be obtained with Amlodipine tablets 5 mg or 10 mg as these tablets are not manufactured to break into two or four equal parts.

Elderly patients

There is no special dosage for the elderly; however, care must be taken when the dose is increased.

If you have kidney problems

The normal dosage is recommended. Amlodipine cannot be removed from the blood by dialysis (artificial kidney). Amlodipine should be administered with particular caution to patients undergoing dialysis.

If you have liver problems

The exact dose needed for patients with liver problems has not been

determined. If you have liver problems, Amlodipine should be used very carefully (see also the section "Take special care with Amlodipine").

Methods and routes of administration

Swallow the tablets with a glass of water. Do not chew. You can take them with or without food.

If you take more Amlodipine than you should

If you or someone else has taken too much Amlodipine, contact your doctor or pharmacist. If possible, take the tablets or the pack with you to show the doctor or pharmacist. The person concerned should be made to lie down with their arms and legs up (resting on a couple of cushions, for example). Symptoms of an overdose are: extreme dizziness and/or feeling very light-headed, problems with breathing, having to urinate very often.

If you forget to take Amlodipine tablets

If you have forgotten to take a tablet, you can still take it up to 12 hours after you usually take your tablet. If it is more than 12 hours after the time that you should have taken the tablet, you should not take the missed dose and you should take the next tablet at the usual time. Never take a double dose of Amlodipine tablets to make up for the dose that you have missed.

If you stop taking Amlodipine tablets

Your doctor has told you how long you should take Amlodipine for. If you stop the treatment suddenly, your symptoms may come back. Do not stop the treatment earlier than agreed without discussing this with your doctor.

Amlodipine is usually used for long-term treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor **immediately** if you experience any of the following symptoms after taking this medicine. Although they are very rare the symptoms can be severe.

- allergic skin rash with irregular red spots, caused by medicines (erythema exsudativum multiforme) or severe allergic reactions with blistering eruptions of the skin and mucous membranes (exfoliative dermatitis, Stevens-Johnson-Syndrome).
- allergic reaction with swelling of the skin of face or extremities, swelling of lips or tongue, swelling of the mucous membranes in the mouth and throat, resulting in shortness of breath and difficulty to swallow (angioedema).

The following side effects have been observed during treatment with Amlodipine:

Common side effects :

- headache (especially at the beginning of treatment), sleepiness, dizziness, weakness
- a quicker or irregular heart beat (palpitations)
- nausea, digestive problems, stomach pain
- facial redness and feeling hot (especially at the beginning of treatment)
- swollen ankles

Uncommon side effects:

- enlarged breasts in men
- sleep disorders, irritability, depression
- confusion, mood changes including anxiety
- feeling unwell, dry mouth, uncontrolled shaking (tremor), pins and needles (paraesthesia), increased sweating
- change in taste
- problems with your eye-sight (visual disturbances)
- ringing or buzzing in the ears (tinnitus)
- fainting, increased heart rate (tachycardia), chest pain, aggravation of angina may occur at the beginning of the treatment.
- low blood pressure, inflammation of the blood vessels
- breathing difficulties, inflammation of the nasal mucosa (rhinitis), cough
- vomiting, diarrhoea, constipation
- increase of certain liver enzymes; yellowing of the skin or whites of the eyes, this could be the result of abnormal liver function or inflammation of the liver
- prickling and tingling sensation of the skin (exanthema), itching, nettle rash, hair loss, discolouration of the skin
- muscle cramps, back pain, muscle and joint pain

- increased need to urinate (increased micturition frequency)
- impotence
- increase or decrease in weight

Very rare side effects:

- reduced number of white blood cells, which may cause unexplained fever, sore throat, and flu-like symptoms (leukopenia)
- reduced number of blood platelets in blood, which may cause easy bruising or nasal bleeding (thrombocytopenia)
- increase of the blood sugar level
- pain or numbness in hands and feet (peripheral neuropathy)
- heart attack (myocardial infarction), irregular heartbeat and chest pain (angina pectoris)
- inflammation of the stomach lining (gastritis), inflammation of the pancreas (pancreatitis)
- swelling and bleeding of the gums (Gingival hyperplasia)

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via The Yellow Card Scheme website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMLODIPINE

Keep out of the reach and sight of children.

Do not use Amlodipine after the expiry date "EXP" which is stated on the packaging. The expiry date refers to the last day of that month.

This medicine requires no special precautions for storage.

Keep the tablets in the original packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Amlodipine contains

Amlodipine 5 mg tablets

- The active substance is Amlodipine. Each tablet contains 5 mg of Amlodipine (as besilate).
- The other ingredients are microcrystalline cellulose (E460), sodium starch glycolate, sodium acid citrate (E331), magnesium stearate (E572), croscarmellose sodium, crospovidone.

Amlodipine 10 mg tablets

- The active substance is Amlodipine. Each tablet contains 10 mg of Amlodipine (as besilate).
- The other ingredients are microcrystalline cellulose (E460), sodium starch glycolate, sodium acid citrate (E331), magnesium stearate (E572), croscarmellose sodium, crospovidone.

What Amlodipine looks like and contents of the pack

Amlodipine 5 mg tablets

A white, circular tablet, plain on both sides.

Amlodipine 10 mg tablets

A white, circular tablet, plain on both sides.

Your tablets come in:

- Blister packs of 28 tablets.

Marketing Authorisation Holder

Somex Pharma

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Manufacturer

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High Road, Ilford, Essex, IG3 8RA

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