

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 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 Amlodipine is and what it is used for.
2. What you need to know before you take Amlodipine.
3. How to take Amlodipine.
4. Possible side effects.
5. How to store Amlodipine.
6. Contents of the pack and other 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 (hypertension)
- a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant 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. What you need to know before you take Amlodipine

Do not take Amlodipine

- if you are allergic to amlodipine or any of the other ingredients of this medicine (listed in section 6), or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- if you have very low blood pressure (hypotension).
- if you are suffering from narrowing of the aorta heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack

Warnings and precautions

Talk to your doctor or pharmacist before taking Amlodipine

You should inform 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

Children and adolescents (below 18 years)

Amlodipine should not be used in children and adolescents because of insufficient experience.

Other medicines and Amlodipine

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

Amlodipine 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)
- hypericum perforatum (St. John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus, sirolimus, temsirolimus, and everolimus (medicines used to alter the way your immune system works)
- simvastatin (cholesterol lowering medicine)
- ciclosporin (an immunosuppressant)

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

Amlodipine with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking Amlodipine Tablets. 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 Tablets.

Pregnancy and breast-feeding

Pregnancy

The safety of amlodipine in human pregnancy has not been established. If you think you might be pregnant, or are planning to get pregnant, you must tell your doctor before you take Amlodipine.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking Amlodipine.

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

Driving and using machines

Amlodipine 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 Amlodipine

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

Dosage

Adults

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

Children and adolescents (younger than 18 years)

Amlodipine should not be given to children and adolescents.

Methods and routes of administration

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

If you take more Amlodipine than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many Amlodipine tablets.

If you forget to take Amlodipine tablets

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amlodipine tablets

Your doctor will advise you how long to take this medicine. Your condition may return if you stop using this medicine before you are advised.

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.

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

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing
- 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
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

The following **very common side effect** has been reported. If this causes you problems or if it **lasts for more than one week**, you should **contact your doctor**.

Very common: may affect more than 1 in 10 people

- Oedema (fluid retention)

The following **common side effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

Common: may affect up to 1 in 10 people

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Altered bowel habits, diarrhoea, constipation, indigestion,
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps
- Ankle swelling

Other side effects that have been reported include the following list. If any of these get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon: may affect up to 1 in 100 people

- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities, fainting
- Numbness or tingling sensation in your limbs, loss of pain sensation
- Ringing in the ears
- Low blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Cough
- Dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discolouration
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Inability to obtain an erection, discomfort or enlargement of the breasts in men
- Pain, feeling unwell
- Joint or muscle pain, back pain
- Weight increase or decrease

Rare: may affect up to 1 in 1,000 people

- Confusion

Very rare: may affect up to 1 in 10,000 people

- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause muscular weakness, tingling or numbness
- Swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

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 the Yellow Card Scheme at 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 sight and reach of children. Do not use this medicine after the expiry date "EXP" which is stated on the packaging. The expiry date refers to the last day of that month.

This medicinal product requires no special precautions for storage. Keep the tablets in the original packaging.

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 Amlodipine contains

Amlodipine 5 mg Tablet

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

Amlodipine 10 mg Tablet

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

What Amlodipine looks like and contents of the pack

Amlodipine 5 mg Tablet

A white, circular, biconvex, uncoated tablet with 5 on one side and plain on the other side.

Amlodipine 10 mg Tablet

A white, circular, biconvex, uncoated tablet with 10 on one side and plain on the other side.

Your tablets come in:

- Blister strips containing 28 or 30 tablets per carton.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Wockhardt UK Limited Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer

CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Amlodipine 5 mg Tablets	29831/0451
Amlodipine 10 mg Tablets	29831/0452

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 03/2018