

Package Leaflet: Information for the user
Amlodipine 5mg 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
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1. What Amlodipine is and what it is used for

Amlodipine tablets contain amlodipine, which belongs to a group of medicines called calcium antagonists.

Amlodipine is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

In patients with high blood pressure your medicine works by relaxing blood vessels, so that blood passes through them more easily.

In patients with angina, amlodipine works by improving blood supply to the heart muscle, which then receives more oxygen and as a result chest pain is prevented. Your medicine does not provide immediate relief of chest pain from angina.

You must talk to a doctor if you do not feel better or if you feel worse.

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.
- If you have severe low blood pressure (hypotension).
- If the blood flow from the left side of your heart is obstructed (e.g. if you have narrowing of the aortic heart valve (aortic stenosis)).
- If you suffer from heart failure after a heart attack.
- If you suffer from cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).

Warnings and precautions

Talk to your doctor or pharmacist before taking Amlodipine if you have, or have had, any of the following conditions:

- Heart failure.
- Severe increase in blood pressure (Hypertensive crisis).
- Liver disease.

During treatment

Talk to your doctor:

- If you are elderly and your dose needs to be increased as special care needs to be taken when dosage is increased in elderly patients.

Children and adolescents

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

Other medicines and Amlodipine

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

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

- anti-fungal medicines (e.g. ketoconazole, itraconazole)
- so called protease inhibitors used to treat HIV (e.g. ritonavir, indinavir, nelfinavir)
- rifampicin or macrolide antibiotics (e.g. erythromycin, clarithromycin) used to treat bacterial infections
- hypericum perforatum (St. John's wort)
- verapamil, diltiazem (heart medicines)

- dantrolene (infusion for severe body temperature abnormalities)
- simvastatin (a medicine to reduce blood cholesterol levels)
- tacrolimus (medicine used to control your body's immune response, enabling your body to accept the transplanted organ). Amlodipine may increase the levels of this medicine in your blood.
- ciclosporin (if you have had a kidney transplant and are taking ciclosporin) as amlodipine may alter the amount of this medicine in your blood

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.

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 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.

The safety of amlodipine in human pregnancy has not been established.

It is not known whether amlodipine is passed into breast milk. Your doctor may recommend that you take amlodipine if the benefits of treatment outweigh any risks to the baby.

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. These side effects may occur especially at the beginning of the treatment.

3. How to take Amlodipine

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended initial dose is Amlodipine 5 mg once daily. The dose can be increased to Amlodipine 10 mg once daily. Your medicine can be taken before or after food and drinks. You should take your medicine at the same time each day with a drink of water.

Patients with liver problems

Your doctor may ask you to take a lower dose and carry out frequent checks, if you are suffering from liver problems.

Use in children and adolescents

For children and adolescents (6-17 years old), the recommended usual starting dose is 2.5 mg a day.

The maximum recommended dose is 5 mg a day.

The tablet can be divided into equal doses.

It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor.

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 or have a rapid heart beat. 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

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

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your 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.

If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:

- Swelling of eyelids, face lips, tongue and throat which causes great difficulty in breathing or swallowing
- 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) or other allergic reactions
- Heart attack, abnormal or irregular heart beat, faster heart rhythm
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell
- Yellowing of the skin or eyes, pale stools, dark urine or stomach pain (these may be signs of liver problems such as inflammation of the liver (hepatitis) or jaundice).

Other possible side effects:

Very common (may affect more than 1 in 10 people):

- Swelling which may be due to retention of fluid in the tissues

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 which includes diarrhoea and constipation, indigestion
- Ankle swelling, tiredness, unusual weakness
- Visual disturbances including double vision
- Shortness of breath, muscle cramps

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

- Mood changes (including feeling anxious), feeling depressed, sleeplessness
- Trembling, taste abnormalities, fainting
- Numbness or tingling sensation in your limbs; decreased sensation
- Ringing in the ears
- Decreased heart rate
- 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, rash and hives, purple patches on the skin
- 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, chest 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):

- An increase in infections or fever eg. sore throat, mouth ulcers that you get (due to decreased number of white blood cells), or if you notice that you bruise or bleed more easily or without explanation (due to decrease in the number of blood platelets)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause weakness, tingling or numbness
- Swelling of the gums
- Abdominal bloating (gastritis)
- Liver enzyme increase which may be due to liver problems such as blockage in the bile duct
- 'Measles' like skin rash. This may be associated with a high fever and joint pains (erythema multiforme)
- Peeling of the skin over large areas of the body
- Inflammation of blood vessels, often with skin rash
- Skin sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

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

- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amlodipine

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

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

Store in the original package in order to protect from light.

Do not use this medicine if you notice any discolouration of the tablets.

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

The active substance is amlodipine.

Each tablet contains 5mg of amlodipine (as besilate).

The other ingredients are anhydrous calcium hydrogen phosphate, cellulose microcrystalline, sodium starch glycolate (type A), magnesium stearate.

What Amlodipine looks like and contents of the pack

Amlodipine 5 mg tablets are white coloured, round biconvex tablets debossed with "5" on one side and scored on the other side. The tablet can be divided into equal doses.

Amlodipine tablets are packed in a bottle containing 500 tablets.

Manufacturers

McDermott Laboratories Ltd, t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland or Generics UK Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom or Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary or Mylan B.V., Dieselweg 25, 3752 LB Bunschoten, The Netherlands.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Parallel Product Authorisation Number PPA 465/439/1

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	Name of medicinal product
Austria	Amlodipin Mylan 5 mg Tabletten
Belgium	Amlodipine besilate Mylan 5 mg tabletten
Bulgaria	Amlogem
Czech Republic	Amlodipin Mylan 5 mg, tablety
Denmark	Amlodipin Mylan 5mg tabletter
Germany	Amlodipin dura B 5 mg Tabletten
Greece	Amlodipine/Mylan Generics 5 mg tablet
Hungary	Amlodipin Mylan 5 mg tableta
Ireland	Amlodipine Mylan 5 mg tablets
Italy	Amlodipina Mylan 5 mg compresse
Poland	Amlomyl
Romania	Amlodipina Mylan 5 mg comprimate
Slovak Republic	Amlodipin Mylan 5 mg
Spain	Amlodipino MYLAN Pharmaceuticals 5 mg comprimidos EFG
Sweden	Amlodipin Mylan 5 mg tablett
The Netherlands	Amlodipine (als besilaat) Mylan 5 mg tabletten
United Kingdom	Amlodipine 5 mg tablets

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