

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.

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. 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, to any other calcium antagonists, or any of the other ingredients of this medicine (listed in section 6). This may be itching, reddening of the skin or difficulty in breathing.
- if you have severe low blood pressure (hypotension)
- if you have narrowing of the aortic 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 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

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 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 (antifungal 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)
- simvastatin (used to lower elevated cholesterol levels in blood)
- tacrolimus, sirolimus, everolimus, and ciclosporin (used to prevent organ transplant rejection and for cancer)
- temsirolimus (used for cancer)

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 substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Amlodipine.

Pregnancy and breast-feeding**Pregnancy**

The safety of amlodipine in human pregnancy has not been established. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

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.

Amlodipine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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.

The usual initial dose is Amlodipine 5 mg once daily. The dose can be increased to Amlodipine 10 mg once daily.

Your medicine can be used before or after food and drinks. You should take your medicine at the same time each day with a drink of water. Do not take Amlodipine with grapefruit juice.

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.

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

The tablet can be divided into equal doses.

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.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

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 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.

Continued on the next page >>

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 tightness, 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, flu-like symptoms followed by blistering, peeling and swelling of the skin, mouth, eyes and genitals (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
- Inflammation of the liver (hepatitis) which may result in yellowing of your skin and the whites of your eyes (jaundice), fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, dark urine

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
- Difficulty breathing
- Abdominal pain, feeling sick (nausea)
- Altered bowel habits, diarrhoea, constipation, indigestion
- Ankle swelling
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps

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, 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, rash, 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
- Chest pain
- 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, 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

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: 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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on carton and blister or container after “EXP”. The expiry date refers to the last day of that month.

Blister: Store in the original package in order to protect from light. Do not store above 30°C.

HDPE container: Store in the original package in order to protect from light.

Do not throw away any medicine 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 contain

The active substance is amlodipine.

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

Each tablet contains 10 mg of amlodipine (as besylate).

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

What Amlodipine looks like and contents of the pack

5 mg Tablets:

White or almost white, oblong tablet with bevelled edges, score line on one side and marked with a “5” on the other side.

10 mg Tablets

White or almost white, oblong tablet with bevelled edges, score line on one side and marked with a “10” on the other side.

The tablets are packed in Alu/PVC blister or in Alu/OPA/Alu/PVC blister which are inserted in a carton or packed in a HDPE container with a screw cap (tamper evident).

Pack sizes:

Blister (Alu/PVC)/Blister (Alu/OPA/Alu/PVC): 10, 14, 20, 28, 30, 50, 50x1, 60, 100, 120 tablets

HDPE container: 20, 30, 50, 60, 90, 100, 105, 120, 200, 250 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Sandoz Limited

Park View, Riverside Way

Watchmoor Park

Camberley, Surrey

GU15 3YL

United Kingdom

Manufacturer:

Hexal Polska Sp.z o.o, ul. Domaniewska 50 C, PL-02-672 Warsaw, Poland, **or** Lek S.A., Ul. Podlipie 16, 95 010 Strykow, Poland, **or** Tillomed Laboratories Ltd., 3 Howard Road, Eaton Socon, St Neots, Cambs PE19 8ET, United Kingdom, **or** Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland, **or** Salutas Pharma GmbH, Otto-Von-Guericke-Allee 1, D-39179 Barleben, Germany, **or** LEK Pharmaceuticals d.d, Verovskova 57, 1526 Ljubljana, Slovenia. **or** S.C. Sandoz SRL, 7A Livezeni Street, Mures District, RO-540472 Targu-Mures, Romania or Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia

This leaflet was last revised in 06/2022.

SZ00105LT04C

Artwork Proof Box:

Variation:	V114: Align PI with CMDh - SPC, PL	Technical Colours:	
Proof no:	019.0	<div></div>	Legend:
Date prepared:	20/06/2022	<div></div>	Cutting:
Font size:	9pt		
Fonts:	Helvetica		
Dimensions:	165 x 594 mm		
Technical data:			
SKUs:	44085023, 44085025, 44084995, 44085024		
SZ codes:	SZ00105LT04C		
Item codes:	0000000	Colours:	
Pharma codes:	0000000	<div></div>	Black
Novartis data if applicable:			
Version:	0000000		
Print Proof date:	0000000		
AQWA#:	0000000		
Production site:	0000000		
Technical num:	0000000		
Old Comp num:	0000000	<div><div></div>SANDOZ</div>	

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Artwork	Signature
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