165x594

Package leaflet: Information for the patient

Amlode 5 mg tablets
Amlode 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 Amlode is and what it is used for

Amlode belongs to a group of medicines called calcium antagonists.

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

2 What you need to know before you take Amlode

Do not take Amlode
- 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
Amlode has not been studied in children under the age of 6 years. Amlode 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 Amlode
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Amlode 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).

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

Amlode with food and drink
Grapefruit juice and grapefruit should not be consumed by people who are taking Amlode. 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 Amlode.

Pregnancy and breast-feeding
Pregnancy
The safety of Amlode 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 Amlode.

Driving and using machines
Amlode 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.

Amlode 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 Amlode

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 Amlode 5 mg once daily. The dose can be increased to Amlode 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 Amlode 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 Amlode 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 Amlode 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 Amlode
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 Amlode
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 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 heartbeat
- 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 heartbeat), 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.

Continued on the next page ››

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 national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Amlode

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 Amlode contains
- 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 starch glycolate (type A) and magnesium stearate.

What Amlode looks like and contents of the pack

Amlode 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.

Amlode 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, 98, 100, 120 tablets
HDPE container: 20, 30, 50, 60, 100, 120, 200, 250 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek S.A., ul. Domaniewska 50 C, PL-02-672 Warszawa, Poland.
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.
Salutas Pharma GmbH, Otto-von-Guericke Allee 1, D-39179 Barleben, Germany.
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
S.C. Sandoz S.R.L., Str. Livezeni nr. 7A, 540472 Targu-Mures, Romania.
Lek S.A., ul. Podlipie 16, 95-010 Stryków, Poland.
Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

This medicine is authorized in the Member States of the European Economic Area under the following names:

Austria:	Amlodipin Hexal 5 mg – Tabletten
	Amlodipin Hexal 7,5 mg – Tabletten
	Amlodipin Hexal 10 mg – Tabletten
Denmark:	Amlohexal
Germany:	Amlodipin HEXAL 5 mg Tabletten
	Amlodipin HEXAL 7,5 mg Tabletten
	Amlodipin HEXAL 10 mg Tabletten
Hungary:	Amlodipin Sandoz 5 mg tabletta
	Amlodipin Sandoz 10 mg tabletta
Ireland:	Amlode 5 mg tablets
	Amlode 10 mg tablets
Italy:	AMLODIPINA HEXAL AG
Poland:	Amlopin 5 mg
	Amlopin 10 mg

This leaflet was last revised in 06/2022.

I.M. L/308a+b 06-22