

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
2. What you need to know before you take Amlode
3. How to take Amlode
4. Possible side effects
5. How to store Amlode
6. Contents of the pack and other information

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, ciclosporin (used to control your body's immune response, enabling your body to accept the transplanted organ).

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.

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.

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 Amlode. 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, Amlode 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 heartbeat
- 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 heartbeat), flushing
- 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, 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.

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 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.

Continued on the next page >>

5 How to store Amlode

Keep out of the sight and reach of children.

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

Blister: Keep the blister in the outer carton in order to protect from light. Do not store above 30°C.

Tablet 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 or 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

A 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

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

Your tablets come in:

- Blister packs of 10, 14, 20, 28, 30, 50, 60, 98, 100, 120 tablets and 50x1 tablets in perforated unit dose blisters
- HDPE tablet container of 20, 30, 50, 60, 100, 120, 200 and 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.

Salutas Pharma GmbH, Dieselstr. 5, 70839 Gerlingen, Germany.

S.C. Sandoz S.R.L., Str. Livezeni nr. 7A, 540472 Targu-Mures, Romania.

Lek S.A., ul. Podlipie 16, 95-010 Stryków, Poland.

This medicinal product is authorized in the Member States of the EEA 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 tableta
Amlodipin Sandoz 10 mg tableta

Ireland: Amlode 5 mg Tablets
Amlode 10 mg Tablets

Italy: AMLODIPINA HEXAL AG

Poland: Amlopin 5 mg
Amlopin 10 mg

Spain: Amlodipino BEXAL 5 mg comprimidos EFG
Amlodipino BEXAL 10 mg comprimidos EFG

This leaflet was last revised in 01/2018.

I.M. L/308a+b 01-18

46210792