

10 mm

10 mm

30mm

FLAT DIMENSION =

160 x 480mm

FOLDED DIMENSION =

160 x 30mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

AMLODIPINE 5 MG TABLETS
AMLODIPINE 10 MG TABLETS
Amlodipine Besilate

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, please ask your doctor or pharmacist.
- The medicine has been prescribed for you only and 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-channel blockers. 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 amlodipine 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. This medicine 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 other calcium channel blockers or any other ingredients of this medicine (these are listed in section 6). This may include itching, reddening of the skin or difficulty in breathing.
- have severe low blood pressure (hypotension).
- 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).
- 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

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)
- simvastatin (a cholesterol lowering medicine)
- tacrolimus, sirolimus, temsirolimus, and everolimus (medicines used to alter the way your immune system works)
- cyclosporine (an immunosuppressant)

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

Use in 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.

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**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.

Important information about the ingredients of Amlodipine

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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Amlodipine tablets should be swallowed whole with a glass of water.
- 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.

Adults and the elderly:

- The recommended initial dose is 5mg amlodipine tablet once daily which may be increased to a maximum dose of 10mg depending on the individual patient's response.

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.

For tablets without a break-line: Amlodipine 2.5 mg is not currently available and the 2.5 mg dose cannot be obtained with Amlodipine tablets 5 mg as these tablets are not manufactured to break into two equal halves. 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 Tablets 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 Tablets

- Do not worry and take the next dose at the right time. Do not take a double dose tomake up for the forgotten dose. xxxxxx

5mm

sam size artwork
160 x 480 mm
front

If you stop taking Amlodipine Tablets

Your doctor will advise you how long to take your 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.

STOP TAKING this medicine and see your doctor **immediately** if you experience any of the following severe 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 (red blood cell damage)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause muscular weakness, tingling or numbness
- Bleeding gums
- 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

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. You can also report side effects directly via the Yellow Card Scheme Website: 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 expiry date stated on the pack after 'EXP'. The expiry date refers to the last day of that month.
- Blister Packs: Do not store above 25°C. Store in the original package.
Containers: Do not store above 25°C. Keep the container tightly closed.
- 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 tablets contain

The active substance is Amlodipine (as besilate). Each tablet contains 5mg or 10mg of Amlodipine.

The other ingredients are calcium hydrogen phosphate dihydrate, microcrystalline cellulose, sodium starch glycolate, silica colloidal anhydrous and magnesium stearate.

What Amlodipine tablets look like and contents of pack

Amlodipine 5 mg tablets are white to off white, round, biconvex, uncoated tablets with '5' debossed on one side.

Amlodipine 10 mg tablets are white to off white, round, biconvex, uncoated tablets with '10' debossed on one side.

Amlodipine tablets come in blister packs of 28, 56, 84 tablets and containers of 100, 250, 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Amlodipine 5mg tablets; PL 17907/0085

Amlodipine 10mg tablets; PL 17907/0086

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To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.