

Amlodipine 5mg and 10mg tablets

Amlodipine mesilate monohydrate

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, pharmacist or nurse.
- This medicine has been prescribed for you. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Amlodipine tablets are and what they are used for

Amlodipine tablets contain the active substance amlodipine mesilate monohydrate. Amlodipine belongs to a group of medicines called calcium antagonists. It is used to treat:

- high blood pressure (hypertension).
- angina pectoris (pain in the chest caused by blockages in the arteries leading to the heart) or chest pain classed as vasospastic angina pectoris (or Prinzmetal's 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 tablets work 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.

2 What you need to know before you take Amlodipine Tablets

Do not take Amlodipine tablets if you:

- are **allergic** to amlodipine, dihydropyridine derivatives or any of the other ingredients of this medicine (listed section 6) or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- are in **shock** including shock caused by heart problems (a condition where your heart is unable to supply enough blood to the body)
- suffer from an obstruction in the heart caused by an extreme narrowing of the heart valves (**aortic stenosis**)
- suffer from heart failure after a heart attack
- have **severe low blood pressure (hypotension)**.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Amlodipine tablets if you:

- have **liver** problems
- have recent **heart attack**
- have heart failure
- are **elderly**, your doctor may monitor you closely.
- have/suffer from severe increase in blood pressure (**hypertensive crisis**)

Children and adolescents

Safety and effectiveness have been studied in 6-17 year old boys and in girls. Amlodipine should only used for hypertension in children and adolescents from 6 years to 17 years of age. Amlodipine has not been studied in children under the age of 6 years. For more information, talk to your doctor.

Other medicines and Amlodipine Tablets

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

- **ketoconazole** or **itraconazole** (antifungal drugs)
- **ritonavir**, **indinavir**, **nelfinavir** (so called protease inhibitors used to treat HIV)
- **rifampicin**, **erythromycin**, **clarithromycin** (antibiotic drug)
- **hypericum perforatum** (**St. John's wort** -used for depression)
- **diltiazem**, **verapamil** (to treat heart diseases)
- **dantrolene** (infusion for severe body temperature abnormalities)
- **trimethoprim and co-trimoxazole** (for infections caused by bacteria)
- **temsirolimus** (for cancer)
- **everolimus** (for prevention of graft rejection)
- **tacrolimus** (used to control your body's immune response, enabling your body to accept the transplanted organ)

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

Amlodipine tablets with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking Amlodipine tablets. 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 tablets.

Pregnancy and breast-feeding

Pregnancy The safety of Amlodipine in human pregnancy has not been established. If you are pregnant, think you might be pregnant, or are planning to get pregnant, you must tell your doctor before you take Amlodipine tablets.

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 tablets.

Driving and using machines

Amlodipine tablets may cause dizziness, headaches, tiredness or feeling sick. Any of these side effects would reduce your ability to react, do not drive or use machinery if you are affected.

3 How to take Amlodipine Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- **Adults (including the elderly and children 18 years or over):**
5mg once a day, up to a maximum of 10mg a day as a single dose depending on your response. If you are elderly, your doctor will closely monitor your response to any dose increase.

- **Use in Children and adolescents (6–17 years old):** the recommended usual starting dose is 2.5mg a day. The maximum recommended dose is 5mg a day. Amlodipine 2.5mg is not currently available and the 2.5mg dose cannot be obtained with Amlodipine tablets 5mg as **these tablets are not manufactured to break into two equal halves.**
- **Patients with impaired liver function:** your doctor may prescribe you a different dose.

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

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.

If you forget to take Amlodipine tablets

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amlodipine tablets

Do not interrupt or stop treatment with Amlodipine tablets without consulting your doctor, as your symptoms could return or 'flare-up'.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 very rare, 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 (severe chest pain) abnormal heart beat.
- inflamed pancreas, which may cause severe abdominal and back pain, accompanied with feeling very unwell.

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)
- Ankle swelling (oedema), tiredness

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, weakness
- Numbness or tingling sensation in your limbs; loss of pain sensation
- Visual disturbances, double vision, ringing in the ears (tinnitus)
- Low blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Altered bowel habits (diarrhoea, constipation, indigestion), 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
- Weakness, pain, feeling unwell
- Joint or muscle pain, muscle cramps, 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 (Leukocytopenia, thrombocytopenia) which increases the risk of infections, sore throats, nosebleeds, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage)
- Excess sugar in blood (thirst, excessive urinating, tiredness, hyperglycaemia)
- A disorder of the nerves which can cause weakness, tingling or numbness (peripheral neuropathy)
- Cough, swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis causing tiredness, pain in abdomen, joints or muscles), yellowing of the skin or whites of the eyes (jaundice), liver enzyme increase (detected in blood test) which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels (vasculitis), often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

Not known (cannot be established from the data)

- Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion. If you have these symptoms contact your doctor as soon as possible 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 the Yellow Card Scheme at:

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 Tablets

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

Do not take the tablets after the expiry date which is stated on the carton. The expiry date is also stated on the back of the strip after 'Exp'.

Do not store the tablets above 30°C.

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 amlodipine mesilate monohydrate). Each tablet contains either 5mg or 10mg of the active substance.
- The other ingredients are: microcrystalline cellulose, anhydrous calcium hydrogen phosphate, sodium starch glycolate type A, magnesium stearate

What Amlodipine tablets look like and the contents of the pack:

Amlodipine 5mg and 10mg tablets are white to off-white, round, biconvex tablets.
Pack size is 28.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

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