Package leaflet: information for the user

Amlodipine 2.5 mg, 5 mg, 7.5 mg and 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, 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, which belongs to the group of medicines called calcium anatagonists.

Amlodipine is used to treat high blood pressure (hypertension) or a type of chest pain called angina, a rare form of which is Prinzmetal's angina or variant angina.

In patients with high blood pressure, this 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. This medicine does not provide immediate relief from 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 or any of the other ingredients of this medicine (listed in section 6) or to any other calcium antagonists. The symptoms of an allergy reaction are itching, reddening of the skin or difficulty breathing.
- You have very severe low blood pressure (hypotension).
- You have a 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).
- You suffer from heart failure after a heart attack.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medication.
Tell 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

Children and adolescents
Amlodipine has not been studied in children under the age of 6 years. Amlodipine should only be used for hypertenton 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, have recently taken or might take any other medicines, including medicines obrained 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)
- tacrolimus, sirolimus, temsirolimus and everolimus (medicines used to alter the way your immune system works)
- simvastatin (cholesterol lowering medicine)
- cyclosporine (an immunosuppressant).

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

Amlodipine with food, drink and alcohol
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.

Pregnancy and breast-feeding
Pregnancy
The safety of amlodipine in humans during pregnancy has not been established. If you think you may 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, tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

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.

The recommended starting dose is Amlodipine 5 mg once daily. The dose may be increased to Amlodipine 10 mg once daily.

This medicine can be taken before or after food and drinks. You should take this 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 to 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.

If you take too much amlodipine then 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 the 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.

4. Possible Side Effects

Like all medicine, this medicine can cause side effects, although not everybody gets them.

See your doctor **immediately** if you experience any of the following side effects after taking this medicine.

- Sudden wheezing, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of 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 rate
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

The following **very common adverse event** has been reported. If this causes you problems or if **it lasts for more than a 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: Affects up to 1 in 1000 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, bleeding 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 adverse events
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 national reporting system listed in Appendix V*
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 use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pahramcist 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).
The other ingredients are Microcrystalline cellulose, sodium starch glycollate and magnesium stearate.

What Amlodipine Tablets look like and contents of the pack

Amlodipine 2.5mg Tablets: White, round tablet.

Amlodipine 5mg Tablets: White round tablet, scored A5 on one side and marked with "—" score on the other side.

Amlodipine 7.5mg Tablets: White, round tablet, engraved with "7.5" on one side and plain on the other side.

Amlodipine 10 mg Tablets: White, round tablet, engraved with "10" on one side and plain on the other side.

The tablets are available in blister packs containing 10, 14, 20, 28, 30, 40, 50, 56, 60, 90, 98, 100, 105, 112, 120, 250 and 500 tablets.

Not all pack sizes may be placed on the market.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder:
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