

Patient information leaflet

(For All Products not subject to Medical Prescription)

AMLOSIN 5 (Amlodipine Tablets 5 mg).

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Amlodipine tablets are and what they are used for
2. What you need to know before you take Amlodipine tablets
3. How to take Amlodipine tablets
4. Possible side effects
5. How to store Amlodipine tablets
6. Contents of the pack and other information

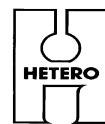
1. What amlodipine tablets are and what they are used for

Amlodipine tablets belongs to a group of medicines called calcium antagonists.

Amlodipine tablets are used to treat:

- high blood pressure (hypertension)
- chest pain due to narrowing of the blood vessels of the heart muscle (angina pectoris) or the more rare form of chest pain caused by cramping of the blood vessels of the heart muscle called Prinzmetal or variant angina.

If you suffer from high blood pressure, Amlodipine works by relaxing blood vessels, so that blood passes through them more easily.



If you suffer from angina, Amlodipine works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Amlodipine 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 (hypersensitive) to amlodipine or any of the other ingredients of this medicine listed in section 6, or to any other calcium antagonists (the so-called dihydropyridine derivatives like felodipine, nifedipine, nimodipine). This may be itching, reddening of the skin or difficulty in breathing.
- are suffering from cardiogenic shock. This is a condition where the heart is unable to pump sufficient blood around the body. The symptoms of cardiogenic shock are low blood pressure, low pulse and fast heartbeat.
- are suffering from 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) or if you suffer from heart failure after a heart attack.
- suffer from chest pain at rest or with minimal effort (unstable angina pectoris).
- are pregnant or breast-feeding.
- have severe low blood pressure (hypotension).

Warnings and precautions

Before taking Amlodipine tablets, tell your doctor if you

- have heart failure or have suffered a heart attack during the past month.
- Heart failure
- Severe increase in blood pressure (Hypertensive crisis)
- have liver problems
- are giving this medicine to a child under 18 years of age
- are elderly, your doctor may monitor you closely.

Children and adolescents



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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.

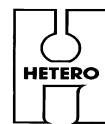
Other medicines and Amlodipine tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines (including medicines obtained without prescription, herbal medications or natural products) may interact with Amlodipine. This means that the action of both medicines can be changed.

In particular, tell your doctor if you are taking any of the following medicines:

- Medicines that can lower blood pressure (e.g. verapamil, diltiazem)
- Ketoconazole and itraconazole (antifungal medicines used to treat skin and fungal infections)
- HIV-protease-inhibitors (antiviral medicines used to treat HIV infections, e.g. ritonavir)
- Clarithromycin, erythromycin and telithromycin, rifampicin, rifabutin (antibiotics)
- Nefazodone (medicine to treat depression)
- St. John's wort (*Hypericum perforatum*; herbal medicine for depression)
- Dexamethasone (corticosteroid used to treat inflammatory and autoimmune conditions such as rheumatoid arthritis)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus (medicine used to alter the way your immune system works)
- simvastatin (cholesterol lowering medicine)
- cyclosporine (an immunosuppressant)
- Phenobarbital, phenytoin and carbamazepin (medicines for epilepsy)
- Ritonavir, Indinavir, Nelfinavir, Nevirapine (antiviral medicine used to treat HIV and AIDS)
- Sildenafil (medicine for impotence)



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

Taking Amlodipine tablets with food and drink

Amlodipine tablets should be taken with a glass of liquid (e.g. a glass of water) with or without food.

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 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 tablets.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts. If you are breastfeeding or about to start breast-feeding you must tell your doctor before taking Amlodipine tablets.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

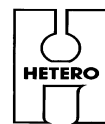
Amlodipine tablets may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Such side effects are more likely to occur at the start of treatment or following an increase in dose. If you suffer from these effects, you should not drive or perform other activities that require you to be alert.

3. How to take Amlodipine tablets

Dosage

Always take Amlodipine tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.



Methods and routes of administration

This medicine can be used 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.

Adults

The usual starting dose is 5 mg once daily. If necessary, your doctor may increase the dose to 10 mg once daily.

Use in 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.

Amlodipine 2.5 mg is not currently available and the 2.5 mg dose cannot be obtained with Amlodipine tablets 5 mg and 10 mg as these tablets are not manufactured to break into two equal halves.

Elderly patients

There is no special dosage for the elderly; however, care must be taken when the dose is increased.

If you have kidney problems

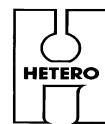
The normal dosage is recommended. Amlodipine cannot be removed from the blood by dialysis (artificial kidney). Amlodipine tablets should be administered with particular caution to patients undergoing dialysis.

If you have liver problems

Your doctor will decide if this medicine is suitable for you and the correct dose for you to take.

If you take more Amlodipine tablets than you should

If you or someone else has taken too much Amlodipine, contact your nearest hospital casualty department. Please carry with you the product leaflet or remaining tablets for better identification of the doctor. The person concerned should be made to lie down with their arms and legs up (resting on a couple of cushions, for example). Symptoms of an overdose are: extreme dizziness and/or feeling very light-headed, faint or weak, problems with breathing, having to urinate very



often. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness.

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. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amlodipine tablets

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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Amlodipine tablets can cause side effects, although not everybody gets them.

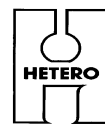
Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- 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.

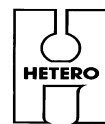
Common (may affect up to 1 in 10 people)

- 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
- Swollen ankles

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)

- Enlarged breasts or discomfort in men
- Sleep disorders, irritability, depression
- Pain, feeling unwell, dry mouth, uncontrolled shaking, pins and needles, increased Sweating
- Problems with your eye-sight (visual disturbances)
- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities
- Numbness or tingling sensation in your limbs, loss of pain sensation
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Ringing or buzzing in the ears
- Fainting, increased heart rate, chest pain, aggravation of angina may occur at the beginning of the treatment
- Low blood pressure, inflammation of the blood vessels
- Breathing difficulties, inflammation of the nasal mucosa, cough



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- Dry mouth, vomiting (being sick), diarrhoea, constipation, swollen gums
- Prickling and tingling sensation of the skin, itching, red patches on skin, nettle rash, hair loss, discolouration of the skin
- Muscle cramps, back pain, muscle and joint pain
- Increased need to urinate
- Impotence,
- Increase or decrease in weight

Rare (may affect up to 1 in 1,000 people)

- Confusion

Very rare (may affect up to 1 in 10,000 people)

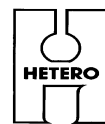
- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause weakness, tingling or numbness
- Swelling of the gums
- Abdominal bloating (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
- Disorders combining rigidity, tremor, and/or movement disorders

Reporting of side effects

If you get any side effects, talk to your doctor or 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 out of the reach and sight of children.

**Hetero**

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Do not use your tablets after the expiry date stated on the carton or label.

This medicine requires no special precautions for storage. Store tablets in the original package.

Medicinal should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Amlodipine tablet contains

- The active substance is amlodipine. Each tablet contains either 5 mg or 10 mg of amlodipine (as besilate).
- The other ingredients are microcrystalline cellulose (E460), sodium starch glycollate, sodium acid citrate (E331), magnesium stearate (E572), croscarmellose sodium and crospovidone.

What Amlodipine tablets look like and contents of the pack

Amlodipine 5 mg and 10 mg tablets are white, circular tablets, smooth on both sides.

Amlodipine tablets are available in blister pack of 28 tablets.

Bottle packs:

250,500 and 1000 tablets (for hospital or dose dispensing use only)

Not all pack sizes may be marketed.

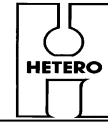
What AMLOSIN 5 (Amlodipine Tablets 5 mg) looks like and contents of the pack

White to off white round shaped, biconvex tablets, debossed with 'J' on one side and '20' on the other side.

AMLOSIN 5 (Amlodipine Tablets 5 mg) are available in:

Container pack: 3 x 10's Alu-PVC/PVdC Blister Pack

AMLOSIN 5 (Amlodipine Tablets 5 mg)



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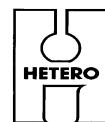
Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates,
Sanath Nagar,
Hyderabad-500 018
Telangana.

Country: INDIA



Hetero

AMLOSIN 5 (Amlodipine Tablets 5 mg)

Manufacturer:

(Company) Name : M/s. Hetero Labs Limited, Unit-V

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Telephone : +91 08542-238400

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