PACKAGE LEAFLET: INFORMATION FOR THE USER

Amlodipine 5 mg tablets

Amlodipine 7.5 mg tablets

Amlodipine 10 mg tablets

Amlodipine

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, 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT AMLODIPINE IS AND WHAT IT IS USED FOR

Amlodipine belongs to a group of medicines called calcium antagonists.

Amlodipine 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 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. BEFORE YOU TAKE AMLODIPINE

Do not take Amlodipine

- if you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of your medicine listed in section 6, or to any other calcium antagonists. 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

Take special care with 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

Use in children and adolescents

Amlodipine has not been studied in children under the age of 6 years. Amlodipine should only 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.

Taking other medicines

Please 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 (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)

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

Taking 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

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

It is not known whether amlodipine is passed into breast milk. If you are breast-feeding or about to start breast-feeding you must tell your doctor before takingAmlodipine.

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 feel you sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

3. HOW TO TAKE AMLODIPINE

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

The usual initial dose is Amlodipine 5 mg once daily. The dose can be increased to Amlodipine 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 Amlodipine 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.

If you take more Amlodipine 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. Do not take a double dose to make up for a missed dose.

If you stop taking Amlodipine tablets

Your doctor will advise you how long to take Amlodipine. Your condition may return if you stopusing your 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 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) 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 **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: affects 1 to 10 users in 100

- 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: affects 1 to 10 users in 1,000

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
- 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: affects 1 to 10 users in 10,000

- Confusion

Very rare: affects less than 1 user in 10,000

- 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
- Cough, 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,
- Inflammation of blood vessels, often with skin rash Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

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.

5. HOW TO STORE AMLODIPINE

Keep out of the reach and sight of children.

Do not use Amlodipine after the expiry date „EXP“ which is stated on the packaging. 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.

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. FURTHER INFORMATION

What Amlodipine contains

Amlodipine 5 mg tablets

- The active substance is amlodipine. Each tablet contains 5 mg of amlodipine (as besilate).
- The other ingredients are microcrystalline cellulose, anhydrous calcium hydrogen phosphate, sodium starch glycolate (type A) and magnesium stearate.

Amlodipine 7.5 mg tablets

- The active substance is amlodipine. Each tablet contains 7.5 mg of amlodipine (as besilate).
- The other ingredients are microcrystalline cellulose, anhydrous calcium hydrogen phosphate, sodium starch glycolate (type A) and magnesium stearate.

Amlodipine 10 mg tablets

- The active substance is amlodipine. Each tablet contains 10 mg of amlodipine (as besilate).
- The other ingredients are microcrystalline cellulose, anhydrous calcium hydrogen phosphate, sodium starch glycolate (type A) and magnesium stearate.

What Amlodipine looks like and contents of the pack

Amlodipine 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.

The tablet can be divided into equal halves.

Amlodipine 7.5 mg tablets

A white or almost white, oblong tablet with bevelled edges, double score line on one side and marked with a "7.5" on the other side.

The tablet can be divided into three equal parts.

Amlodipine 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.

The tablet can be divided into equal halves.

Your tablets come in:

- Blister packs of 10, 14, 20, 28, 30, 50, 60, 98 (only for DK/H/0960/001+003),100, 120 tablets and 50 x
- 1 tablets in perforated unit dose blisters
- Plastic containers of 20, 30, 50, 60, 100, 120, 200 and 250 tablets

Not all pack sizes and pack types may be marketed.

Marketing Authorisation Holder

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This medicinal product is authorized in the Member States of the EEA under the following names:

Amlodipine 5 mg tablets

Amlodipine 7.5 mg tablets

Amlodipine 10 mg tablets

This leaflet was last approved in June 2013