Package leaflet: Information for the user

Amlodipine 5 mg tablets
Amlodipine 10 mg tablets

Amlodipine (as besilate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep thisleaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Amlodipine tabletis and what it is used for

Amlodipine tablets contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

Amlodipine tablet 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 patient 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 works by improving blood supply to the heart muscle, which then receive 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 tablet

- if you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of this medicine (listed in section 6) or any other calcium antagonists. e.g. felodipinenifedipine or nicardipine. 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 (acondition where your heart is unable to supply enough blood to the body).

- If you suffer from heart failure after a heart attack.

Warning and Precautions
Talk to your doctor or pharmacist or nurse before taking Amlodipine tablets

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

Children and adolescents
Amlodipine tablet has not been studied in children under the age of 6 years. Amlodipine tablet 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
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Amlodipine tablets 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)
- hypericumperforatum (St. John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- simvastatin (a cholesterol lowering medicine)
- cyclosporine (an immunosuppressant)

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

Amlodipine tabletswith 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
<u>Pregnancy</u>
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.

<u>Breast-feeding</u>
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 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.

3. How to take Amlodipine tablets

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

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 5 mg tabletas 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.

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 your medicine. Your condition may return if you stop using your medicine before you are advised.

If you have any further questions on the use of this medicine, ask your doctor or 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 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 yourwhole body, severe itching, blistering, peeling and swelling of the skin, inflammation ofmucous membranes (Stevens Johnson Syndrome) or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied withfeeling very unwell

The following very **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.**

Very common: may affect more than 1 in 10 people

- Ankle swelling (oedema)

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 to 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 habit, diarrhoea, constipation, indigestion
- Weakness, tiredness
- shortness of breath
- Muscle cramps

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 affects up to 1 to 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, , ringing in the ears
- Irregular heart beatLow blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Cough
- Dry mouth, vomiting (beingsick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discoloration
- 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 to 1,0 00 people
- Confusion

Very rare: may affects up to 1 in 10,000 people
- Decreased numbers of white blood cells, decrease in blood platelets which may result inunusual 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
- Heart attack

- inflammation of the pancreas causing pain in the upper abdomenSwelling 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, 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
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971, Fax: +353 1 6762517
Website:www.hpra.ie
e-mail: medsafety@hpra.ie
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 after "EXP". The expiry date refers to the last day of that month.

Store below 25°C. Keep the blister in the outer carton in order to protect from light.

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. Content of the pack and other information

What Amlodipine tablets contain
- The active substance is amlodipine (as besilate).

The other ingredients of the tablet are microcrystalline cellulose, dibasic calcium phosphate (dehydrate), sodium starch glycolate Type A, colloidal anhydrous silica and magnesium stearate.

The tablets are available in two strengths. Each Amlodipine tablet contains either 5 milligrams or 10 milligrams of amlodipine added as amlodipine besilate.

Each 5mg tablet contains 6.94 mg amlodipine besilate equivalent to 5 mg amlodipine

Each 10mg tablet contains 13.87 mg amlodipine besilate equivalent to 10 mg amlodipine

What Amlodipine tablets look like and contents of the pack

- Amlodipine 5 mg tablets are white to off white, round, tablets with "5" debossed on one side and plain on the other side.

- Amlodipine 10 mg tablets are white to off white, round, tablets with "10" debossed on one side and plain on the other side.

Amlodipine tablets are available in clear PVC /aluminium blister. Available in pack of 28 tablets, 14 tablets/strip, 2 strips in a carton box.

Marketing Authorisation Holder
Cipla (EU) Limited
Hillbrow House
Hillbrow Road
Esher, Surrey
KT10 9NW
United Kingdom

Manufacturer
Cipla (EU) Limited
4th Floor
1 Kingdom Street
London
W2 6BY
United Kingdom

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

Greece	Amlodipine Cipla 5 mg και 10 mg δισκία
Ireland	Amlodipine 5 mg and 10 mg Tablets
United Kingdom	Amlodipine 5 mg and 10 mg Tablets

This leaflet was last revised in **05/2015.**