

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Amlodipine 5 mg & 10 mg Capsules 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 of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet, See section 4.

**In this leaflet:**

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

#### **1. What Amlodipine is and what it is used for**

Amlodipine capsules contain the active substance Amlodipine which belongs to a group of medicines called calcium antagonists.

Amlodipine 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 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 of chest pain from angina.

#### **2. What you need to know before you take Amlodipine**

##### **Do not take Amlodipine**

- 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. 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.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking 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)
- You are elderly and your dose needs to be increased
- Liver disease

### **Children and adolescents**

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**

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 (anti-fungal 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 (medicine 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 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 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.

#### Breast-feeding

Amlodipine has been shown to pass into breast milk in small amount. 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 capsules 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**

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 initial dose is Amlodipine 5 mg once daily. The dose could be increased to Amlodipine 10 mg once daily.

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.

### **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.

Amlodipine 2.5 mg is not currently available and the 2.5 mg dose cannot be obtained with Amlodipine Capsules.

It is important to keep taking the capsules. Do not wait until your capsules are finished before seeing your doctor.

### **If you take more Amlodipine than you should.**

Taking too many capsules 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 capsules.

### **If you forget to take Amlodipine.**

Do not worry. If you forget to take a capsule, 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 capsule.

### **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 product, ask your doctor or pharmacist.

#### 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 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 disturbance, 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: 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
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause muscles 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 HPRA Pharmacovigilance; Earlsfort; Terrace; IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine

**5. How to store Amlodipine**

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 pack after 'EXP'. The expiry date refers to the last day of that month

Capsules

Do not store 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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Amlodipine 5mg and 10 mg hard capsule contains**

The active substance is amlodipine (as besilate).

The other ingredients:

- **For Amlodipine 5mg hard capsules:**

Microcrystalline Cellulose  
Dried Maize Starch  
Magnesium Stearate

**Capsule:**

Gelatin,  
Titanium Dioxide E 171,  
Yellow Iron oxide E172,  
Black Iron Oxide E172,  
Red Iron Oxide E172,  
Indigo carmine E132,  
Quinoline Yellow E104

- **For Amlodipine 10mg hard capsules:**

Microcrystalline Cellulose  
Dried Maize Starch  
Magnesium Stearate

**Capsule:**

Gelatin,  
Titanium Dioxide E 171,  
Yellow Iron Oxide E 172,  
Erythrosin E127,  
Indigo carmine E132

### **What Amlodipine looks like and contents of the pack**

5 mg capsules: Buff opaque body and light green opaque cap.

10 mg capsules: Light yellow opaque body and light orange opaque cap.

Each strength of Amlodipine is supplied in blister packs of 28 and 56.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **The marketing authorisation holder**

Chanelle Medical, Loughrea, Co Galway, Ireland.

**The manufacturer**

Chanelle Medical, Loughrea, Co Galway, Ireland.

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