

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# AMLODIPINE 5 mg TABLETS AMLODIPINE 10 mg TABLETS

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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is 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 contains 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 to amlodipine or any of the other ingredients of this medicine (listed in the 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)
- 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 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, have recently taken or might take any other medicines. 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 (for infections caused by bacteria)
- hypericum perforatum (St. John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ)
- 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

It is not known whether amlodipine passed into breast milk. 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 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 has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one Amlodipine 5 mg Tablet once daily. The dose can be increased to one Amlodipine Tablet 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. The 2.5mg dose can be obtained with Amlodipine 5 mg Tablets as these tablets can be divided into two equal doses.

Amlodipine 10mg tablets can also be divided into equal doses.

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

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

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

Stop taking the medicine and/or seek urgent medical advice if you experience any of the following side effects after taking this medicine:

**Common:** may affect up to 1 in 10 people

- Shortness of breath or difficulty in breathing

**Uncommon:** may affect up to 1 in 100 people

- Chest pain
- Abnormal heart beat

**Very rare:** may affect up to 1 in 10, 000 people

- Sudden wheeziness
- 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
- 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
- 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 muscular 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
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**Not known:** frequency cannot be estimated from the available data

- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk

#### 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 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 store above 25°C. Store in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month. Do not use this medicine if you notice any signs of discolouration or deterioration of the tablets.

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 contains:**

- The active substance is amlodipine (as besilate). Each tablet contains amlodipine besilate equivalent to 5 mg amlodipine. Each tablet contains amlodipine besilate equivalent to 10 mg amlodipine.
- The other ingredients are microcrystalline cellulose, calcium hydrogen phosphate, sodium starch glycolate and magnesium stearate.

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

- Amlodipine 5 mg Tablets are white, round, slightly concave with a breakline and debossed A 5 on one side. The other side is plain and slightly convex and are available in pack sizes of 28 tablets.
- Amlodipine 10 mg Tablets are white, round, slightly concave with a breakline and debossed A10 on one side. The other side is plain and slightly convex and are available in pack sizes of 28 tablets.

**Product procured from within the EU by the Parallel Product Authorisation Holder:**

WPR Healthcare Limited, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

**Product repackaged and distributed by:**

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

**Parallel Product Authorisation Numbers:**

Amlodipine 5mg Tablets      PPA 565/59/1  
Amlodipine 10mg Tablets    PPA 565/59/2

**Manufacturer**

TEVA UK Limited, Eastbourne, BN22 9AG, UK or TEVA Pharmaceutical Works Private Limited Company, H-4042 Debrecen, Pallagi ut 13, Hungary.

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

Austria: Amlodipin Teva 5 mg & 10 mg Tabletten  
Belgium: Amlodipine Teva 5 mg & 10 mg Tabletten  
Bulgaria: Amloteron 5 mg & 10 mg tablets  
Czech Republic: Amlodipin -Teva 5 mg & 10 mg  
Denmark: Amlodipin Teva  
Estonia: Amlodipine Teva  
Greece: Amlodipine besilate Teva 5 mg & 10 mg δισκία  
Hungary: Amlodipin-Teva 5 mg & 10 mg tableta  
Ireland: Amlodipine Teva 5 mg & 10 mg Tablets  
Italy: Amlodipina Teva Italia 5 mg & 10 mg compresse  
Latvia: Amlodipine Teva  
Lithuania: Amlodipine Teva 5 mg & 10 mg tabletės

The Netherlands: Amlodipine (als besilaat) 5 mg & 10 mg PCH, tabletten  
Poland: Amlodipinum 123ratio, 5mg & 10mg tabletki  
Portugal: Amlodipina Teva 5 mg & 10 mg comprimidos  
Sweden: Amlodipine Teva 5 mg & 10 mg tablett  
Slovenia: Amlodipin Teva 5 mg & 10 mg tablete  
United Kingdom: Amlodipine 5 mg & 10 mg tablets

**This leaflet was prepared by WPR Healthcare Limited: November 2016**