

## **Package leaflet: Information for the user**

### **Amlodipine Upjohn® 5 mg and 10 mg tablets**

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

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

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

Amlodipine Upjohn 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 Upjohn 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 Upjohn**

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

- 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 Upjohn.

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 Upjohn has not been studied in children under the age of 6 years. Amlodipine Upjohn 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 Upjohn**

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

Amlodipine Upjohn 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, sirolimus, temsirolimus, and everolimus (medicines used to alter the way your immune system works)
- simvastatin (cholesterol lowering medicine)
- cyclosporine (an immunosuppressant)

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

### **Amlodipine Upjohn with food and drink**

Grapefruit juice and grapefruit should not be consumed by people who are taking Amlodipine Upjohn. 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 Upjohn.

### **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 Upjohn.

#### Breast-feeding

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

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

#### **Driving and using machines**

Amlodipine Upjohn 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.

#### **Amlodipine Upjohn contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take Amlodipine Upjohn**

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 Upjohn 5 mg once daily. The dose can be increased to Amlodipine Upjohn 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 Upjohn 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 Upjohn 5 mg tablets can be divided into halves to provide a 2.5 mg dose.

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 Upjohn 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 Upjohn tablets.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

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

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 Upjohn**

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.

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 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, bleeding 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

**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 Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Amlodipine Upjohn**

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.

### Tablets

Do not store above 25°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 protect the environment.

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

### **What Amlodipine Upjohn contains**

The active substance in Amlodipine Upjohn 5 mg tablets is amlodipine (as besilate).  
The active substance in Amlodipine Upjohn 10 mg tablets is amlodipine (as besilate).

The other ingredients are calcium hydrogen phosphate anhydrous, magnesium stearate, microcrystalline cellulose and sodium starch glycolate Type A.

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

5 mg tablets: White to off-white, emerald-shaped tablets engraved AML 5 and breaker score on one side and VLE on the other side.

10 mg tablets: White to off-white, emerald-shaped tablets engraved AML-10 on one side and VLE on the other side.

Amlodipine Upjohn 5 mg tablets are available in blisters containing 4, 10, 14, 20, 28, 30, 50, 60, 98, 100, 300, 500 tablets, calendar packs containing 28 and 98 tablets and in unit dose blister strips containing 50x1 and 500x1 tablets.

Amlodipine Upjohn 10 mg tablets are available in blisters containing 4, 10, 14, 20, 28, 30, 50, 60, 90, 98, 100, 300, 500 tablets, calendar packs containing 28 and 98 tablets and in unit dose blister strips containing 50x1 and 500x1 tablets.

Not all pack sizes may be marketed.

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

#### **Marketing Authorisation Holder**

Upjohn EESV  
Rivium Westlaan 142  
2909 LD Capelle aan den IJssel

Netherlands

**Manufacturer**

Pfizer Manufacturing Deutschland GmbH  
Betriebsstätte Freiburg  
Mooswaldallee 1  
79090 Freiburg,  
Germany

or

Mylan Hungary Kft.  
Mylan utca 1  
Komárom, 2900  
Hungary

or

MEDIS INTERNATIONAL a.s., výrobní závod Bolatice  
Průmyslová 961/16  
747 23 Bolatice  
Czech Republic

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

Tablets:

Austria, Bulgaria, Denmark, Estonia, Finland, Germany, Hungary, Iceland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Sweden: Norvasc  
Czech Republic: Zorem  
Ireland, Malta, United Kingdom: Istin  
Ireland: Amlodipine Upjohn  
Italy: Amlodipina Pfizer Italia  
Spain: Norvas 5 mg comprimidos, Norvas 10 mg comprimidos  
United Kingdom: Amlodipine

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**Other sources of information**

Detailed information on this medicinal product is available on the website of the Health Products Regulatory Authority.