

## **PATIENT INFORMATION LEAFLET**

### **AMLOTAN 5mg TABLETS AMLOTAN 10mg TABLETS Amlodipine (as mesilate monohydrate)**

**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 more questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to anyone else. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects that are not listed in the leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Amlotan Tablets are and what they are used for
2. Before you take Amlotan Tablets
3. How to take Amlotan Tablets
4. Possible side effects
5. How to store Amlotan Tablets
6. Further information

The name of your medicine is Amlotan 5mg Tablets or Amlotan 10mg Tablets. We refer to them as Amlotan Tablets or amlodipine throughout this leaflet.

#### **1. WHAT AMLOTAN TABLETS ARE AND WHAT THEY ARE USED FOR**

Amlotan Tablets contain the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

Amlotan Tablets may be used to treat:

- high blood pressure (hypertension); and
- 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, these medicines work 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. Amlotan Tablets do not immediately relieve chest pain caused by angina.

#### **2. BEFORE YOU TAKE AMLOTAN TABLETS**

##### **Do not take Amlotan Tablets if you:**

- have ever had an allergic reaction to amlodipine or any of the ingredients in the tablet listed in section 6, or to any other calcium antagonist. An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue;
- have very low blood pressure (hypotension) so that you feel faint or dizzy;
- have cardiogenic shock (a condition where your heart cannot pump enough blood for your body's needs);
- have heart failure due to a heart attack;
- have narrowing of the heart valve of the aorta (aortic stenosis)

**Take special care with Amlotan Tablets**

You should inform your doctor if you have or have had any of the following conditions:

- Recent heart attack
- Heart failure
- Liver disease
- You are elderly and your dose needs to be increased
- Severe increase in blood pressure (Hypertensive crisis)

**Use in 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.

**Taking other medicines**

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

Amlodipine may affect or be affected by other medicines, such as:

- diltiazem, verapamil (heart medicines)
- ketoconazole, itraconazole (antifungal medicines used to treat thrush and ringworm)
- ritonavir, indinavir, nelfinavir (antivirals used in treatment of HIV infections)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- St John's wort (a herbal remedy for mild depression)
- dantrolene (infusion for severe body temperature abnormalities)
- simvastatin (a drug used to control elevated cholesterol)

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

If you see another doctor or go into hospital for any reason, tell them that you are taking Amlotan Tablets.

**Taking Amlotan Tablets with food and drink**

You should not drink grapefruit juice or eat grapefruit while taking this medicine. Grapefruit and grapefruit juice can lead to an increase in the blood levels of amlodipine, which can cause an unpredictable increase in its blood pressure lowering effect.

**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 Amlotan Tablets.

**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 taking Amlotan Tablets.

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

### **Driving and using machines**

Taking Amlotan Tablets may affect your ability to drive or use machinery because amlodipine could cause side effects such as dizziness, headaches, nausea or tiredness, all of which could affect your ability to concentrate.

### **3. HOW TO TAKE AMLOTAN TABLETS**

Swallow these tablets with a glass of water at the same time each day. You can take the tablets either before or after meals.

Follow your doctor's instructions. Check the pharmacy label to see how many tablets to take and how often to take them. If you are still not sure, ask your pharmacist or doctor. The usual doses are described below.

**Adults** - One 5mg tablet once a day. Your doctor may increase the dose to one 10mg tablet once a day.

**Children and adolescents** - For children and adolescents (6-17 years old), the recommended usual starting dose is 2.5mg a day. The maximum recommended dose is 5mg a day. Amlodipine 2.5mg is not currently available and the 2.5mg dose cannot be obtained with Amlotan 5mg or 10mg Tablets as these tablets are not manufactured to break into two equal halves.

**Elderly** - As for adults (one 5mg tablet a day). Your doctor will closely monitor your response to any increase in the dose.

#### **Patients with liver disease**

Your doctor may give you a different dose to normal.

#### **If you take more Amlotan Tablets than you should**

If you (or someone else) swallow a lot of tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Take your medication and the packaging with you to the doctor or casualty department. If you have taken an overdose, you may appear flushed (your skin will look red), or you may feel dizzy or faint. If blood pressure drop is severe enough shock can occur. Your skin could feel cool or clammy and you could lose consciousness.

#### **If you forget to take Amlotan Tablets**

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Never take two doses together. Take the remaining doses at the correct time.

#### **If you stop taking Amlotan Tablets**

Take this medicine for as long as your doctor tells you to, as you may become unwell if you stop.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Amlotan Tablets can cause side effects, although not everybody gets them.

**If any of the following reactions happen, stop taking Amlotan Tablets and tell your doctor immediately or contact the casualty department at your nearest hospital: -**

- swelling of the eyelids, face, lips
- swelling of the tongue and throat which causes great difficulty breathing
- sudden wheeziness, chest pain, difficulty breathing or swallowing

- severe skin reactions including itching, rash, peeling of the skin and extensive reddening, blistering or 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

Other known side effects are as follows. Tell your doctor if you notice or are worried by any of the side effects listed.

- **Common** (affects 1 to 10 users in 100)
  - Headache, drowsiness, dizziness (especially at the start of treatment)
  - flushing of the face and feeling hot
  - feeling sick, stomach ache
  - tiredness
  - palpitations (irregular or forceful heart beat)
  - swollen ankles
  
- **Uncommon** (affects 1 to 10 users in 1,000)
  - enlargement or discomfort of the breasts in men
  - a general feeling of being unwell, weakness
  - change in taste, dry mouth
  - involuntary shakiness, numbness, tingling or pins and needles
  - loss of pain sensation
  - increased sweating
  - sight problems, double vision
  - problems sleeping, irritability, depression, mood changes
  - fainting
  - low blood pressure
  - sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
  - being sick, diarrhoea, constipation, indigestion
  - itchy skin, red patches on skin, skin discolouration
  - hair loss
  - muscle cramps, back, muscle or joint pain
  - passing urine more often, night time urinating
  - inability to obtain an erection
  - weight loss or gain
  - ringing in the ears
  
- **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
  - raised blood sugar levels (hyperglycaemia)
  - problems feeling through fingers and toes due to nerve problems (peripheral neuropathy)
  - inflammation of the blood vessels, often with skin rash
  - abdominal bloating (gastritis)
  - cough

- swollen gums
- raised liver enzymes (detected in a blood test), yellowing of the skin or whites of the eyes (jaundice, hepatitis)
- increased muscle tension
- sensitivity to light
- disorders combining rigidity, tremor and/or movement disorders

Tell your doctor or pharmacist if you notice any other effects not listed.

## **5. HOW TO STORE AMLOTAN TABLETS**

Do not use the tablets after the end of the expiry month (use-by date) shown on the product packaging.

Do not store the tablets above 30°C.

Store in the original package.

**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**

Medicines 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 Amlotan Tablets contain**

- The active substance is amlodipine as amlodipine mesilate monohydrate. Each tablet contains 5mg or 10mg of amlodipine.
- The other ingredients are microcrystalline cellulose, anhydrous calcium hydrogen phosphate, sodium starch glycolate type A and magnesium stearate.

### **What Amlotan Tablets look like and the contents of the pack**

Amlotan Tablets are white to off-white, round and biconvex and come in two strengths: 5mg and 10mg. The 5mg tablets have the number '5' embossed on one side and the 10mg tablets have the number '10' embossed on one side, together with a breakline.

Amlotan Tablets are available in blister packs containing 28 tablets.

### **Product Authorisation holder and manufacturer:**

Athlone Laboratories, Ballymurray, Co. Roscommon, Ireland

### **Distributor:**

Clonmel Healthcare Ltd., Waterford Road, Clonmel, Co. Tipperary, Ireland.

This medicinal product is authorised in the member states of the EEA under the following names.

United Kingdom:	Amlodipine 5mg Tablets Amlodipine 10mg Tablets
Ireland:	Amlotan 5mg Tablets Amlotan 10mg Tablets

**This leaflet was last revised: June 2013**