

PATIENT INFORMATION LEAFLET

Amlotan 5mg AND 10mg 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 your 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 that are not listed in this leaflet. See section 4.**

What is in this leaflet:

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

The name of your medicine is Amlotan5mg Tablets or Amlotan10mg Tablets. We refer to them as Amlotan Tablets or Amlotan 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, Amlotan 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 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;
- if you have very low blood pressure (hypotension) so that you feel faint or dizzy;
- if you have cardiogenic shock (a condition where your heart cannot pump enough blood for your body's needs);
- if you have heart failure due to a heart attack;
- if you have narrowing of the heart valve of the aorta (aortic stenosis)

Warnings and precautions

Talk to your doctor or pharmacist before taking Amlotan tablets if you 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).

Children and adolescents

Amlotan has not been studied in children under the age of 6 years. Amlotan 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 Amlotan

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

Amlotan 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)
- Hypericum perforatum* - 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)
- tacrolimus, sirolimus, temsirolimus, and everlimus (medicines used to alter the way your immune system works)
- cyclosporine (immunosuppressive drug)

Amlotan 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.

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 Amlotan, which can cause an unpredictable increase in its blood pressure lowering effect.

Pregnancy and Breast-feeding

Pregnancy

The safety of Amlotan 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

Amlotan 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 Amlotan Tablets.

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

Driving and using machines

Amlotan 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.

Amlotan contains Sodium

Amlotan 5mg and 10mg tablets contain sodium. This medicine contains less than 1 mmol sodium (23mg) per tablet, which means it is essentially 'sodium-free'.

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. Do not take Amlotan with grapefruit juice.

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 dose is:

Adults

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

Use in 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. Amlotan 2.5mg is not currently available and the 2.5mg dose cannot be obtained with Amlotan 5mg 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.

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

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, lightheaded, faint, or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool or clammy and you could lose consciousness. Seek immediate medical attention if you take too many Amlotan tablets.

If you forget to take Amlotan 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 forgotten dose.

If you stop taking Amlotan Tablets

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 or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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: -**

- sudden wheeziness, chest pain, shortness of breath, difficulty breathing or swallowing swelling of the eyelids, face, 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 can cause severe abdominal and back pain accompanied with feeling 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)

- 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 (irregular or forceful heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Altered bowel habits, diarrhea, 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/runny 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 the blood vessels, often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor and/or movement disorders

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace IRL - Dublin 2; Tel: +353 16764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail: medsafety@hpra.ie.

5. HOW TO STORE AMLOTAN TABLETS

Keep this medicine out of the sight and reach of children.

Do not take your medicine after the expiry date, which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Do not store the tablets above 30°C. Store in the original package.

Do not use this medicine if you notice any visible signs of deterioration.

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 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 10, 14, 20, 28, 30, 50, 98, 100 or 200 tablets. Not all pack sizes may be marketed.

Marketing authorisation holder:

Athlone Pharmaceuticals Limited Ballymurray, Co. Roscommon, 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: March 2022