

Package leaflet: Information for the user
Amlodipine Thame 5mg/5ml Oral Solution
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, pharmacist or nurse.
- ▶ 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.

The name of your medicine is Amlodipine Thame 5mg/5ml Oral Solution but it will be referred to as Amlodipine throughout this leaflet.

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.

You must talk to your doctor if you do not feel better or if you feel worse.

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 section 6) or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- ▶ You have severe low blood pressure (hypotension).
- ▶ 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).
- ▶ 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 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, sirolimus, temsirolimus, and everolimus (medicines 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, breast-feeding and fertility

Pregnancy

The safety of amlodipine in human pregnancy has not been established. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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

Fertility

The data on the effect of amlodipine on human fertility is not sufficient. In rats, amlodipine has shown adverse effects on male fertility.

Driving and using machines

Amlodipine may affect your ability to drive or use machines. If this medicine makes you feel sick, dizzy or tired, or gives you a headache, do not drive or use machines and contact your doctor immediately.

Amlodipine contains:

Methyl parahydroxybenzoate (E218): May cause an allergic reaction (possibly delayed).

Propylene Glycol (E1520): This medicine contains 390mg propylene glycol in each 5ml.

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

Glycerol (E422): May cause headache, stomach upset and diarrhoea.

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.

Doses (For lower strength 5mg/5ml oral solution)

Your doctor will determine what dose is appropriate for you.

For Adults:

- ▶ The recommended initial dose is 5mg (5ml) once daily.
- ▶ The dose can be increased to 10mg (10ml) once daily.

'It is recommended to use the lower strength (5mg/5ml) of Amlodipine when a lower dose (<5mg) is required.'

'It is recommended to use the higher strength (10mg/5ml) of Amlodipine when a higher dose is required.'

For children and adolescents (6-17 years old):

- ▶ The recommended usual initial dose is 2.5mg (2.5ml) once daily.
- ▶ The dose can be increased to 5mg (5ml) once daily.
- ▶ The maximum recommended dose is 5mg (5ml) a day.

'It is recommended to use the lower strength (5mg/5ml) of Amlodipine when a lower dose (<5mg) is required.'

'It is recommended to use the higher strength (10mg/5ml) of Amlodipine when a higher dose is required.'

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

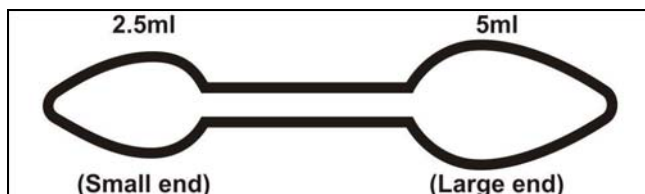
Amlodipine is not recommended for use in children under 6 years.

Your medicine can be used before or after food and drinks. You should take your medicine at the same time each day with a drink of water. **Do not take Amlodipine with grapefruit juice.**

Method of administration

- ▶ Use the 2.5-5ml double-ended spoon supplied in the pack to measure the required dose (see figure below).
- ▶ Swallow the solution.
- ▶ Wash the spoon with clean water after taking every dose.

2.5-5ml double-ended Spoon



If you take more Amlodipine than you should

Overdose may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If your blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness.

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

Seek immediate medical attention if you take too much Amlodipine.

If you forget to take Amlodipine

Do not worry. If you forget a dose, 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.

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
- ▶ 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. 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 carton and bottle label after 'EXP:'. The expiry date refers to the last day of that month.
- ▶ Store in a refrigerator (2°C - 8°C).
- ▶ For 100ml and 150ml packs: Discard 30 days after first opening.
- ▶ For 300ml pack: Discard 60 days after first opening.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ 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 contains

The active substance is amlodipine (as besilate).

Each 5ml of oral solution contains 5mg amlodipine (as besilate).

Each ml of oral solution contains 1mg amlodipine (as besilate).

The other ingredients are methyl parahydroxybenzoate (E218), propylene glycol (E1520), disodium phosphate anhydrous (E339), sodium dihydrogen phosphate dihydrate, purified water and glycerol (E422).

What Amlodipine looks like and contents of the pack

Amlodipine is a clear, greenish yellow coloured oral solution. It comes in an amber glass bottle with a child-resistant plastic cap. The pack also contains a 2.5-5ml double ended spoon.

Amlodipine is supplied in bottles containing 100ml, 150ml and 300ml of oral solution.

Not all pack sizes may be marketed.

POM

Marketing Authorisation Holder:

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