

Package Leaflet: Information for the user

Amlodipine 2mg/ml Oral Solution

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

1. What Amlodipine Oral Solution is and what it is used for

The name of your medicine is Amlodipine 2mg/ml Oral Solution (called Amlodipine in this leaflet). Amlodipine 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 your 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. Your medicine does not provide immediate relief of chest pain from angina.

2. What you need to know before you take Amlodipine Oral Solution**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

Please 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 (medicine used to alter the way your immune system works)
- simvastatin (a cholesterol lowering medicine)
- ciclosporine (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

- 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

- 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 any medicine.

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 Oral Solution contains liquid maltitol and glycerol.

- Amlodipine contains liquid maltitol (E965) (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Amlodipine contains glycerol (E422). This may cause headache, stomach upset and diarrhoea.

3. How to take Amlodipine Oral Solution

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

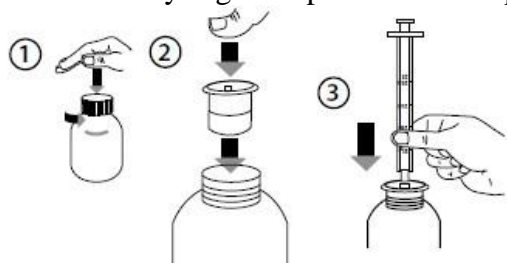
Taking this medicine

- This medicine contains 2 milligram (2mg) of Amlodipine in each 1 millilitre (1ml) of solution.
- Take this medicine by mouth.
- This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. See “Taking this medicine via NG or PEG tubes”. Do not use with a tube which is made of latex. There is further information in the SmPC, ask your doctor, pharmacist or nurse for this information.
- Do NOT shake the bottle before use.
- 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

Measuring your dose using the oral syringe provided

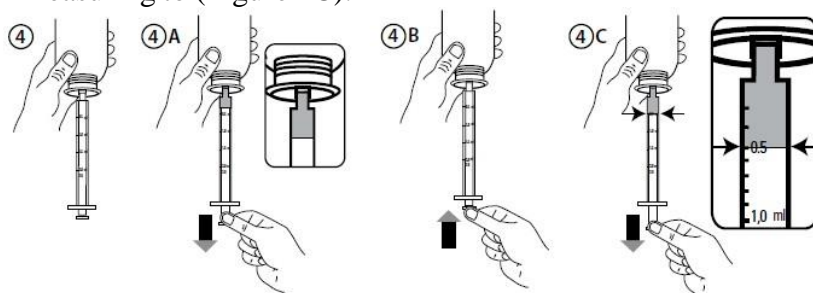
Instructions for use

- Open the bottle: press the cap and turn it anticlockwise (Figure 1).
- Separate the syringe adaptor from the syringe and insert the adaptor securely into the bottle neck (Figure 2).
- Take the syringe and put it in the adaptor opening (Figure 3).

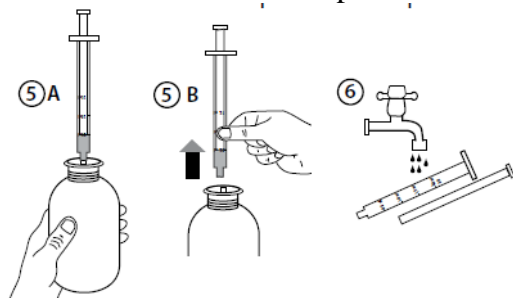


- Turn the bottle upside down (Figure 4).
- Fill the syringe with a small amount of solution by pulling the plunger down (Figure 4A). Then push the plunger upward in order to remove any possible bubbles (Figure 4B). Finally, pull the plunger down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor. The top

flat edge of the plunger should be in line with the graduation mark you are measuring to (Figure 4C).



- Turn the bottle the right way up (Figure 5A).
- Remove the syringe from the adaptor (Figure 5B).
- Put the end of the syringe into your mouth and push the plunger slowly back in to take the medicine.
- Wash the syringe with water and let it dry before you use it again (Figure 6).
- Close the bottle with the plastic screw cap - leave the syringe adaptor in the bottle.



Taking this medicine via NG or PEG tubes

- The minimum volume of water that is required to flush tube sizes 8 Fr is 10mL and for tube sizes 10 Fr and above it is 20mL.
 1. Ensure the tube is clear before taking the medicine
 2. Flush the tube with the minimum volume of water required.
 3. Administer the medicine with a suitable measuring device, which will be provided by your doctor, pharmacist or nurse. Do not use the oral syringe provided in the pack.
 4. Flush the tube again with the minimum volume of water.

Adults

The usual initial dose of Amlodipine is 5mg (2.5ml) once daily. The dose can be increased to 10mg (5ml) once daily.

Use in children and adolescents

For children and adolescents (6-17 years old), the recommended usual starting dose is 2.5mg (1.25ml) a day. The maximum recommended dose is 5mg (2.5ml) a day.

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

If you take more Amlodipine than you should

Taking too much medicine may cause your blood pressure to become low or even dangerously low.

You may feel dizzy, lightheaded, faint or weak. If the 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 much medicine.

If you forget to take Amlodipine

- Do not worry. If you forget to take 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 missed dose.

If you stop taking Amlodipine

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your 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, Amlodipine can cause side effects although not everybody gets them.

Visit your doctor **immediately** if you experience any of the following very rare, severe 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: affects 1 to 10 users in 100

- 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: affects 1 to 10 users in 1,000

- 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 discoloration
- 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: 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 (red blood cell damage)
- excess sugar in blood (hyperglycaemia)
- a disorder of the nerves which can cause 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.iee-mail: medsafety@hpra.ie**5. How to store Amlodipine Oral Solution**

- Keep out of the sight and reach of children.
- Store in a refrigerator (2-8°C). Keep the bottle stored upright.
- Do not use after the expiry date (month, year) stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Use within 30 days of opening.
- Do not use Amlodipine if you notice anything wrong with the medicine. Talk to 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 Oral Solution contains**

- The active substance is amlodipine besilate. This medicine contains 2mg of amlodipine (as besilate) in each 1ml of solution.
- The other ingredients are glycerol (E422), liquid maltitol (E965) and purified water.

What Amlodipine Oral Solution looks like and contents of the pack

Your medicine is a clear, pale straw coloured viscous liquid.

It comes in a brown glass bottle holding 150ml of solution with a 5ml purple oral syringe and adaptor.

Marketing Authorisation Holder:

Perrigo Pharma International DAC,
The Sharp Building,
Hogan Place,
Dublin 2,
Ireland

Manufacturer:

Jenson R+ (Ireland) Ltd, 2 Dublin Landing, N Wall Quay, North Dock, Dublin 1, D01 V4A3, Ireland.

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

UK, Ireland – Amlodipine 2mg/ml Oral Solution

France – Amlodipine Cevibra 2 mg/ml, solution buvable

This leaflet was last revised in 11/2020