

Package Leaflet: Information for the User

Amlodipine 1 mg/ml Oral Solution

Amlodipine besilate

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.
- The name of this medicine is Amlodipine 1mg/ml Oral Solution but will be referred to as Amlodipine Oral Solution throughout this leaflet.

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

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

Amlodipine Oral Solution 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 Oral Solution 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 a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Amlodipine Oral Solution**Do not take Amlodipine Oral Solution**

- 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 Oral Solution

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 Oral Solution has not been studied in children under the age of 6 years. Amlodipine Oral Solution 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 Oral Solution

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

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

Amlodipine Oral Solution with food, drink and alcohol

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

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 Oral Solution.

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 Oral Solution.

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

Driving and using machines

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

Amlodipine Oral Solution contains liquid maltitol (E965), glycerol (E422) and ethanol absolute

- Amlodipine contains liquid maltitol (a type of sugar). If your doctor has told you that you cannot tolerate some sugars, talk to your doctor before taking this medicine.
- Amlodipine contains glycerol. This may cause headache, stomach upset and diarrhoea.
- This medicine contains 31.6 mg of alcohol (ethanol) in each ml of Oral Solution which is equivalent to 3.16% w/v. The amount in ml of this medicine is equivalent to less than 0.8 ml beer or 0.32 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Amlodipine Oral Solution

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 5mg (5ml measured in a 5 ml syringe) once daily. The dose can be increased to 10mg (10ml or 2 x 5ml syringes) once daily.

Use in children and adolescents

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

The maximum recommended dose is 5mg (5ml measured in a 5 ml syringe) a day.

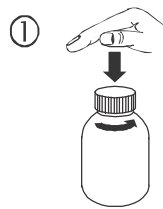
It is important to keep taking the dose. Do not wait until your medicine is finished before seeing your doctor.

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.

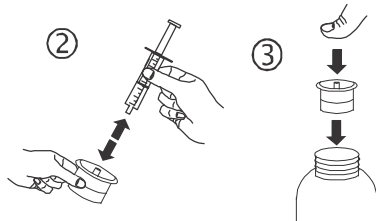
Do not take Amlodipine Oral Solution with grapefruit juice.

Instructions for use

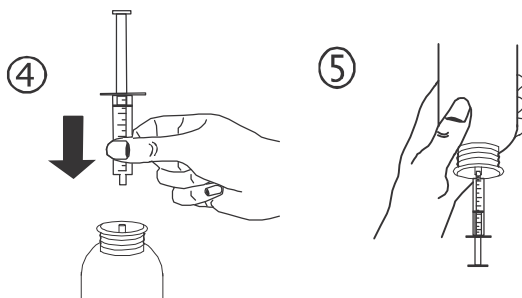
- Open the bottle: press the cap and turn it anticlockwise (figure 1).



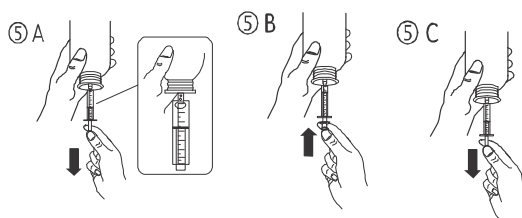
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.



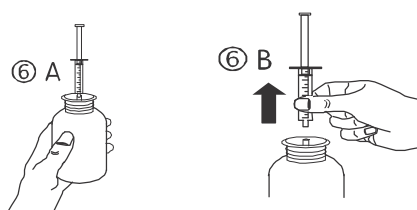
- Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).



- Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).

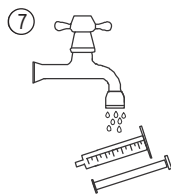


- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



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- Close the bottle with the plastic screw cap.
- Empty the contents of the syringe into your mouth
- After dosing, wash the syringe with water only (figure 7).



If you take more Amlodipine Oral Solution than you should

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

You may feel dizzy, light-headed, 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 much dose.

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 Oral Solution

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 forgotten dose.

If you stop taking Amlodipine Oral Solution

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Amlodipine Oral Solution

- Keep out of the sight and reach of children.
- No special storage condition required, Store in a tightly closed container protected from light.
- Do not store above 25°C after first opening of the bottle.
- Do not use after the expiry date stated on the carton and bottle label (EXP). The expiry date refers to the last day of that month
- Use within 60 days of first opening
- If your medicine becomes discoloured or shows any signs of deterioration, return it to your pharmacist
- 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. Contents of the pack and other information

What Amlodipine Oral Solution contains

The active substance is Amlodipine besilate. Each 1 ml of Oral Solution contains 1.385 mg of Amlodipine besilate. The other ingredients are glycerol (E422), liquid maltitol (E965), Butylated hydroxyanisole (E320), ethanol absolute, and frozen peppermint flavour (containing menthofuran, pulegone and estragole).

What Amlodipine Oral Solution looks like and contents of the pack

Amlodipine Oral Solution is a clear pale straw colored, viscous liquid.

Amlodipine 1mg/ml Oral Solution is packaged in amber colored glass bottle with white child resistant and tamper evident closure containing 150 ml of liquid product.

The package contains 5 ml oral syringe with graduation marking at every 0.5 ml and printed at 1.0, 2.0, 3.0, 4.0 and 5.0 ml markings together with an adaptor.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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Amlodipine 1 mg/ml Oral Solution; PL 40496/0035

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