

**Package leaflet: Information for the user**
**Lisinopril 1mg/ml Oral Solution**

Lisinopril dihydrate

**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 Lisinopril 1mg/ml Oral Solution is and what it is used for
2. What you need to know before you take Lisinopril 1mg/ml Oral Solution
3. How to take Lisinopril 1mg/ml Oral Solution
4. Possible side effects
5. How to store Lisinopril 1mg/ml Oral Solution
6. Contents of the pack and other information


**1. What Lisinopril 1mg/ml Oral Solution is and what it is used for**

Lisinopril 1mg/ml Oral Solution contains a medicine called Lisinopril. This belongs to a group of medicines called ACE inhibitors.

Lisinopril 1mg/ml Oral Solution can be used for the following conditions:

- To treat high blood pressure (hypertension).
- To treat heart failure.
- If you have recently had a heart attack (myocardial infarction).

- To treat kidney problems caused by Type II diabetes in people with high blood pressure.

Lisinopril works by making your blood vessels widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

**2. What you need to know before you take Lisinopril 1mg/ml Oral Solution**
**Do not take Lisinopril 1mg/ml Oral Solution if:**

- You are allergic (hypersensitive) to lisinopril or any of the other ingredients of Lisinopril 1mg/ml Oral Solution (listed in section 6).
- You have ever had an allergic reaction to another ACE inhibitor medicine. The allergic reaction may have caused swelling of the hands, feet, ankles, face, lips, tongue or throat. It may also have made it difficult to swallow or breathe (angioedema).
- You have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.
- A member of your family has had severe allergic reactions (angioedema) to an ACE inhibitor or you have had severe allergic reactions (angioedema) without a known cause.
- You are more than 3 months pregnant. (It is also better to avoid Lisinopril 1mg/ml Oral Solution in early pregnancy - see Pregnancy section).
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing ailsikren.

Do not take Lisinopril 1mg/ml Oral Solution if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

If you develop a dry cough which is persistent for a long time after starting treatment with Lisinopril 1mg/ml Oral Solution, talk to your doctor.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Lisinopril 1mg/ml Oral Solution:

- If you have a narrowing (stenosis) of the aorta (an artery in your heart) or a narrowing of the heart valves (mitral valves).
- If you have a narrowing (stenosis) of the kidney artery.
- If you have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- If you have problems with your blood vessels (collagen vascular disease).
- If you have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up.
- If you have kidney problems or you are having kidney dialysis.
- If you have liver problems.
- If you have diabetes.
- If you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
  - temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer);
  - racecadotril, a medicine used to treat diarrhoea;
  - vildagliptin, a medicine used to treat diabetes;

- If you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems - ailsikren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading "Do not take Lisinopril 1mg/ml Oral Solution".

- If you have recently had diarrhoea or vomiting (being sick).

- If your doctor has told you to control the amount of salt in your diet.

- If you have high levels of cholesterol and you are having a treatment called 'LDL apheresis'.

- You must tell your doctor if you think you are (or might become) pregnant. Lisinopril 1mg/ml Oral Solution is not recommended in early pregnancy and must not be taken if

you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

- If you are of black origin as Lisinopril 1mg/ml Oral Solution may be less effective. You may also more readily get the side effect 'angioedema' (a severe allergic reaction).
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Lisinopril 1mg/ml Oral Solution.

**Treatment for allergies such as insect stings**

Tell your doctor if you are having or are going to have treatment to lower the effects of an allergy such as insect stings (desensitisation treatment). If you take Lisinopril 1mg/ml Oral Solution while you are having this treatment, it may cause a severe allergic reaction.

**Operations**

If you are going to have an operation (including dental surgery) tell your doctor or dentist that you are taking Lisinopril 1mg/ml Oral Solution. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking Lisinopril 1mg/ml Oral Solution.

**Children and adolescents**

Lisinopril 1mg/ml Oral Solution has been studied in children. For more information, talk to your doctor. Lisinopril 1mg/ml Oral Solution is not recommended in children under 6 years of age or in any child with severe kidney problems.

**Other medicines and Lisinopril 1mg/ml Oral Solution**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because Lisinopril 1mg/ml Oral Solution can affect the way some medicines work and some medicines can have an effect on Lisinopril 1mg/ml Oral Solution. Your doctor may need to change your dose and/or to take other precautions.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines to help lower your blood pressure.
- An angiotensin II receptor blocker (ARB) or ailsikren, (see also information under the headings "Do not take Lisinopril 1mg/ml Oral Solution" and "Warnings and precautions").
- Water tablets (diuretic medicines).
- Beta-blocker medicines, such as atenolol and propranolol.
- Nitrate medicines (for heart problems).
- Non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and arthritis.
- Aspirin (Acetylsalicylic acid), if you are taking more than 3 grams each day.
- Medicines for depression and for mental problems, including lithium.
- Potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclesporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).
- Insulin or medicines that you take by mouth for diabetes.
- Medicines used to treat asthma.
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- Medicines to suppress the body's immune response (immunosuppressants).
- Allopurinol (for gout).
- Procainamide (for heartbeast problems).
- Medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.

The following medicines may increase the risk of angioedema (signs of angioedema include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing):

- Medicines to break up blood clots (tissue plasminogen activator), usually given in hospital.
- Medicines which are most often used to avoid rejection of transplanted organs (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section 2 "Warnings and precautions".
- Racemicatril used to treat diarrhoea.
- Vildagliptin, a medicine used to treat diabetes.

**Pregnancy and breastfeeding**
**Pregnancy:**

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Lisinopril 1mg/ml Oral Solution before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lisinopril 1mg/ml Oral Solution. Lisinopril 1mg/ml Oral Solution is not recommended in early pregnancy and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

**Breast-feeding:**

Tell your doctor if you are breast-feeding or about to start breast-feeding. Lisinopril 1mg/ml Oral Solution is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

**Driving and using machines**

- Some people feel dizzy or tired when taking this medicine. If this happens to you, do not drive or use any tools or machines.
- You must wait to see how your medicine affects you before trying these activities.

**Lisinopril 1mg/ml Oral Solution contains sodium benzoate**

This medicine contains less than 1mmol sodium (23 mg) per ml oral solution, that is to say essential 'sodium-free'.

This medicine contains 1.5 mg benzote salt in each ml oral solution. Benzote salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

**3. How to take Lisinopril 1mg/ml Oral Solution**

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Once you have started taking Lisinopril 1mg/ml Oral Solution your doctor may take blood tests. Your doctor may then adjust your dose so you take the right amount of medicine for you.

Your carton contains a measuring cup with multiple graduations. Use the measuring cup provided in the carton to deliver the required dose. The cup should be cleaned after use.

**Taking this medicine**

- Try to take your medicine at the same time each day. It does not matter if you take Lisinopril 1mg/ml Oral Solution before or after food.
- Mixing with food or drinks has not been studied, and any mixing with food and drinks is therefore the responsibility of the health care professional or the user.
- Keep taking Lisinopril 1mg/ml Oral Solution for as long as your doctor tells you to, it is a long-term treatment. It is important to keep taking Lisinopril 1mg/ml Oral Solution every day.

**Taking your first dose**

- Take special care when you have your first dose of Lisinopril 1mg/ml Oral Solution or if your dose is increased. It may cause a greater fall in blood pressure than later doses.
- This may make you feel dizzy or light-headed. If this happens, it may help to lie down. If you are concerned, please talk to your doctor as soon as possible.

**Adults**

Your dose depends on your medical condition and whether you are taking any other medicines. Your doctor will tell you how much Lisinopril 1mg/ml Oral Solution has had any effect on your blood. The signs may include feeling tired, pale skin, a sore throat, high temperature (fever), joint and muscle pains, swelling of the joints or glands, or sensitivity to sunlight.

- Low levels of sodium in your blood (the symptoms may be tiredness, headache, nausea, vomiting).
- Sudden renal failure.

**Rare (affects 1 to 10 users in 10,000)**

- Feeling confused.
- A lumpy rash (hives).
- Dry mouth.
- Hair loss.
- Psoriasis (a skin problem).
- Changes in the way things smell.
- Development of breasts in men.
- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples from time to time to check whether Lisinopril 1mg/ml Oral Solution has had any effect on your blood. The signs may include feeling tired, pale skin, a sore throat, high temperature (fever), joint and muscle pains, swelling of the joints or glands, or sensitivity to sunlight.

- Severe pain in the legs.
- Headache.
- Nausea.
- Diarrhoea.
- Rash.
- Itching.
- Changes in the way things smell.
- Development of breasts in men.
- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples from time to time to check whether Lisinopril 1mg/ml Oral Solution has had any effect on your blood. The signs may include feeling tired, pale skin, a sore throat, high temperature (fever), joint and muscle pains, swelling of the joints or glands, or sensitivity to sunlight.

**Very rare (affects less than 1 user in 10,000)**

- Sinusitis (a feeling of pain and fullness behind your cheeks and eyes).
- Wheezing.
- Low levels of sugar in your blood (hypoglycaemia). The signs may include feeling hungry or weak, sweating and a fast heartbeat.
- Inflammation of the lungs. The signs include cough, feeling short of breath and high temperature (fever).
- Yellowing of the skin or the whites of the eyes (jaundice).
- Inflammation of the liver. This can cause loss of appetite, yellowing of the skin and eyes, and dark coloured urine.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Severe skin disorders. The symptoms include redness, blistering and peeling.
- Sweating.
- Passing less water (urine) than normal or passing no water.
- Liver failure.
- Lumps.
- Inflamed gut.

**Not known (frequency cannot be estimated from available data)**

- Symptoms of depression.
- Fainting.
- Side effects in children appear to be comparable to those seen in adults.

**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 via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 Lisinopril 1mg/ml Oral Solution**

- 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. The expiry date refers to the last day of that month.
- Do not use your medicine if you notice that the container is damaged.
- After first opening: Use within 60 days.
- 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 Lisinopril 1mg/ml Oral Solution contains**

- The active substance is lisinopril dihydrate equivalent to 1 mg lisinopril. Each 1 ml oral solution contains 1 mg of lisinopril.
- The other ingredients are glycerol (E422), hydroxyethyl cellulose, sodium benzoate (E211) and citric acid (E330).

**What Lisinopril 1mg/ml Oral Solution looks like and contents of the pack**

Lisinopril 1mg/ml Oral Solution is a clear and colourless solution.

Lisinopril 1mg/ml Oral Solution is available in 150ml amber glass bottles with a child-resistant, tamper evident screw cap and a measuring cup with multiple gradations.

**Marketing Authorisation Holder and Manufacturer**
**Marketing Authorisation Holder**

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This leaflet was last revised in April 2024

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