

LISINOPRIL 5 mg, 10 mg and 20 mg Tablets

lisinopril dihydrate

Package leaflet: Information for the user

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

1 What lisinopril is and what it is used for

- Lisinopril belongs to a group of drugs called angiotensin-converting enzyme (ACE) inhibitors. These tablets are vasodilators (drugs which widen the blood vessels), making it easier for the heart to pump blood around the body. This helps lower blood pressure.
- Lisinopril is used:
 - to treat a condition known as symptomatic heart failure where the heart no longer pumps blood as effectively as it should
 - to treat high blood pressure
 - to help prevent any more heart problems in patients who have recently had a heart attack
 - to treat kidney disease resulting from diabetes and high blood pressure.

Lisinopril is recommended in children (above 6 years old) only for the treatment of high blood pressure (hypertension). Lisinopril should not be used in children with severe kidney impairment.

2 What you need to know before you take Lisinopril

Do not take Lisinopril if you:

- are allergic (hypersensitive) to lisinopril (as dihydrate) or any of the other ingredients of this medicine (listed in section 6), have suffered an allergic reaction to any other ACE inhibitors e.g. captopril, enalapril, which led to swelling of the face, lips, tongue and/or throat or a member of your close family have a history of face or body swelling (angioneurotic oedema) which may be unrelated to the use of medicines
- are more than 3 months pregnant. (It is also better to avoid Lisinopril in early pregnancy – see “Pregnancy and breast-feeding” section.)
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lisinopril if you:

- have narrowing of the arteries leading to the kidneys, any other kidney problems or are undergoing dialysis
- recently suffered from diarrhoea or vomiting
- have been on a low-salt diet
- have low blood pressure (you may notice this as dizziness or light-headedness especially when standing)
- have liver disease
- have insufficient blood supply to your heart (ischaemic heart disease)
- have insufficient blood supply to your brain (cerebrovascular disease)
- have aortic stenosis or outflow tract obstruction (a narrowing of the main artery leading from your heart), a narrowing of the heart valves (mitral valve stenosis) or an increase in the thickness of the heart muscle (hypertrophic cardiomyopathy)
- have a collagen vascular disease e.g. systemic lupus erythematosus, an allergic condition which causes joint pain, skin rashes and fever
- are to undergo desensitisation treatment (e.g. to reduce the effects of an allergy to wasp or bee stings)
- are to undergo LDL apheresis (removal of cholesterol from the blood by machine)
- recently had a heart attack and are suffering from low blood pressure or kidney problems
- have been told you have severe congestive heart failure
- 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.
 - aliskiren.
- have lower level of aldosterone hormone.
- have high blood potassium level (hyperkalemia) and taking co-trimoxazole.
- are taking any of the following medicines, the risk of angioedema may be increased:
 - racecadotril, a medicine used to treat diarrhoea;
 - medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus);
 - vildagliptin, a medicine used to treat diabetes.

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”

You must tell your doctor if you think you are (or might become) pregnant. Lisinopril 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 and breast-feeding” section).

If you are to have an operation requiring an anaesthetic (including treatment at the dentist), tell the doctor or dentist that you are taking Lisinopril tablets.

Other medicines and Lisinopril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially if you are taking any of the following:

- other drugs to reduce blood pressure such as diuretics (“water tablets”) e.g., amiloride as your blood pressure may become too low
- anti-psychotics e.g., chlorpromazine (to treat mental disorders) or tricyclic antidepressants e.g. amitriptyline, which may cause low blood pressure
- lithium, as lithium levels may be increased
- insulin or tablets for diabetes as the risk of hypoglycaemia (low blood sugar) may be increased
- 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; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots)
- medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors), may cause swelling of the airways or tongue, with or without respiratory impairment.
- medicines that contain gold e.g., sodium aurothiomalate, given as an injection. The possible side effects of feeling flushed, sick, dizzy or having low blood pressure may occur more frequently if you are also taking an ACE inhibitor such as lisinopril.

Tell your doctor before taking Lisinopril in combination with any of the following as they may reduce the effectiveness of Lisinopril:

- non-steroidal anti-inflammatory agents (a type of painkiller, e.g., indomethacin); kidney function may also be affected
- sympathomimetic drugs e.g., ephedrine, adrenaline or isoprenaline. Ephedrine may be present in medicines for colds and nasal stuffiness

Tell your doctor before taking Lisinopril in combination with any of the following as they may increase the risk of the blood disorder leucopenia (a reduction in the number of white blood cells) occurring:

- procainamide (to treat abnormal heart rhythms)
- allopurinol (to treat gout)
- immunosuppressive drugs (used following organ transplant)

Your doctor may need to change your dose and/or take other precautions:

- If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Lisinopril” and “Warnings and precautions”)

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.

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 before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lisinopril. Lisinopril 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 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

Lisinopril may cause dizziness or make you feel light headed especially if you are taking Lisinopril tablets for the first time. If affected do not drive or operate machinery.

3 How to take Lisinopril

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

The tablets should be swallowed preferably with a glass of water at approximately the same time each day. Lisinopril can be taken with or without food.

The recommended dose is:

Adults and the elderly

• High blood pressure

Treatment is generally started with one 10 mg tablet daily. Some patients, such as those with kidney problems may require a lower starting dose. The dose will then be gradually increased every 2 – 4 weeks until your blood pressure is controlled. The usual long-term dosage is 20 mg once daily.

• **Heart failure**

Treatment is generally started in hospital with one 2.5 mg tablet daily. The dose will then be gradually increased until your symptoms are controlled. The usual long-term dosage is 5–35 mg once daily. The dose of any diuretics ("water tablets") that you are taking may be reduced before starting treatment with Lisinopril.

• **After a heart attack**

The usual dosage is 5 mg on the first and second days, then 10 mg taken once daily which would normally continue for six weeks. Patients that have a low blood pressure (hypotension) are usually given a lower dose of 2.5 mg with a maintenance dose of 5 mg with temporary reductions to 2.5 mg if needed. If prolonged low blood pressure occurs your doctor may withdraw your Lisinopril treatment.

• **Kidney disease resulting from diabetes and high blood pressure**

Treatment is generally started with one 10 mg tablet daily. The dose will then be gradually adjusted according to your needs. The usual long-term dosage is 10–20 mg once daily.

Some Afro-Caribbean patients may require higher doses of Lisinopril to obtain adequate control of symptoms.

Use in children under 6 years

The use of Lisinopril is not recommended.

Use in children and adolescents aged 6 to 16 years

The dose depends on your weight. The usual starting dose is between 2.5 mg and 5 mg once daily, which can be increased to a maximum of 20 mg to 40 mg once daily. Patients with kidney problems should take a lower dose. Your doctor will decide the correct dose for you.

If you take more Lisinopril than you should

If you (or someone else) swallow a lot of the 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. An overdose is likely to cause severe lowering of blood pressure, changes in heart rate, dizziness, anxiety, cough, disturbances in the salt balance of the blood and failure of the kidneys to function, symptoms of which are drowsiness, nausea, vomiting, breathlessness and fainting. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Lisinopril

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lisinopril

Do not stop taking your medicine without talking to your doctor first even if you feel better.

If you have any further question 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.

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if any of the following happens:

- a severe allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).
- severe blistering, bleeding of the lips, eyes, mouth, nose and genital areas
- severe sudden chest pain which may spread to the neck, shoulders and arms with shortness of breath and a clammy feeling (these may be signs of a heart attack) or weakness or numbness down one side of the body, confusion, difficulty speaking or loss of coordination (these may be signs of a stroke). These may occur due to a large drop in blood pressure especially if you have symptoms such as severe dizziness, light-headedness at the start of the treatment, when the dose has increased or when you stand up.
- yellowing of your skin or whites of the eyes (jaundice), dark urine, pale stools, tiredness, fever, feeling sick (nausea), stomach pain and weakness. These may be signs of serious liver problems such as inflammation of the liver or blockage in the bile duct, which can lead to liver failure.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

If you are taking Lisinopril tablets for the first time you may feel dizzy or light-headed for a short time afterwards. This is unlikely to happen if you are taking the tablets regularly. Tell your doctor if you are worried.

The following side effects have been reported at the approximate frequencies shown:

Common (may affect up to 1 in 10 people):

- headache
- dizziness or light headedness, especially on standing up
- vomiting, diarrhoea
- dry cough
- problems with kidney function.

Uncommon (may affect up to 1 in 100 people):

- palpitations (awareness of overactivity of the heart), fast heart rate,
- heart attacks or stroke in susceptible patients (possibly due to an excessive drop in blood pressure)
- poor circulation which makes the fingers and toes pale, cold and numb
- pins-and-needles
- vertigo (a sensation that your surroundings are spinning, either up and down or from side to side)
- mood swings, changes in your sense of taste
- feeling sleepy or other sleeping problems such as inability to sleep
- runny nose
- abdominal pain, indigestion, feeling sick
- skin rash including hives, itching
- tiredness, loss of muscle strength (asthenia)
- high potassium levels in the blood

- increased levels of liver enzymes in the blood
- impotence (an inability to get or keep an erection)
- seen and/or heard hallucinations.

Rare (may affect up to 1 in 1,000 people):

- anaemia which is a reduction in red blood cells
- acute kidney failure resulting in nausea, vomiting, lethargy, drowsiness
- confusion
- dry mouth
- hair loss
- psoriasis (condition causing red, flaky, crusty patches on the skin)
- development of breasts in men
- changes in the way things smell
- changes to some of the cells or other parts of your blood. Your doctor may occasionally take blood samples to check if Lisinopril has had any effect on your blood
- feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH)

Very rare (may affect up to 1 in 10,000 people):

- blood disorders (which may be characterised by unusual bleeding or unexplained bruising, fever or chills, sore throat, ulcers in the mouth or throat)
- low blood sugar levels (hypoglycaemia). The signs may include feeling hungry or weak, sweating and a fast heartbeat
- passing less urine than usual or none at all
- wheezing, bronchitis, sinus problems, inflammation of the lungs (symptoms include cough, feeling short of breath and high temperature)
- jaundice (symptoms of which are yellowing of the skin and whites of the eyes)
- inflammation of the liver, this can cause loss of appetite, yellowing of the skin and eyes, and dark coloured urine
- inflammation of pancreas, this causes moderate to severe pain in the stomach
- sweating
- liver failure
- lumps
- inflamed gut
- blisters which may burst easily becoming raw and painful or may bleed, red itchy spots, or peeling skin leaving red, raw patches over the body
- a combination of symptoms including fever, blood disorders or pain in the muscles and joints, sensitivity to sunlight and a severe reduction in white blood cells making infection more likely.

Not known (frequency cannot be estimated from the available data):

- symptoms of depression
- fainting.

A higher incidence of angioedema (facial or body swelling) has been reported in the Afro-Caribbean population.

While taking Lisinopril there may be changes in the chemistry of your blood and urine. Your treatment may therefore be monitored by regular tests.

Side effects in children and adolescents

Safety data from clinical studies done on hypertensive children and adolescents taking Lisinopril, show that side effects were generally similar to those seen in adults (see above).

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 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 Lisinopril

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

Do not store above 25°C. Store in the original container. Do not transfer to another container. Do not use this medicine after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater. 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 Tablets contain:

- The active ingredient is lisinopril (as dihydrate), 5mg, 10 mg, or 20 mg.
- The other ingredients are pregelatinised starch, maize starch, calcium hydrogen phosphate, mannitol and magnesium stearate.

What Lisinopril Tablets look like and contents of the pack:

- Lisinopril 20 mg Tablets are white oval tablets marked "LSN 20" on one side and a breakline on the other
 - Lisinopril 10 mg Tablets are white oval tablets, marked "LSN 10" on one side and a breakline on the other.
 - Lisinopril 5 mg Tablets are white oval tablets, marked "LSN 5" on one side and a breakline on the other
- The product is available in blister packs of 28, 30, 50 and 100 tablets and hospital packs of 50 (EAV) and 100. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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