

Package leaflet: Information for the patient

Lisinopril 5 mg, 10 mg & 20 mg Tablets

Lisinopril dihydrate

Read all of this leaflet carefully before you start using 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.

What is in this leaflet:

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

1. What Lisinopril tablets are and what they are used for

Lisinopril tablets belong to a group of medicines called ACE inhibitors. ACE is short for *Angiotensin-Converting Enzyme*. ACE inhibitors cause the body to produce less angiotensin (a hormone which tightens blood vessels and increases blood pressure), resulting in a reduction in pressure inside blood vessels and an improvement in heart function.

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.

Lisinopril tablets are used:

- in the treatment of high blood pressure (hypertension),
- in patients whose heart is unable to pump properly (heart failure),
- after an acute heart attack (myocardial infarction),
- to treat kidney problems due to Type II diabetes in people with high blood pressure (hypertensive patients).

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 tablets

Do not take Lisinopril tablets:

- if you are **allergic** (hypersensitive) to lisinopril or any of the other ingredients of this medicine (see section 6: “Further information”) or to any other angiotensin converting enzyme (ACE) inhibitor.
- if you have ever had an allergic reaction during previous treatment with ACE inhibitors. Symptoms of an allergic reaction are: a sudden build-up of fluid in the skin and mucous membranes (e.g. throat or tongue), swelling of hands, feet, ankles, face, lips, tongue or throat. It may also cause breathing difficulties and/or itching and skin rash (**angioedema**). Similarly, do not take Lisinopril tablets if someone in your family has had a similar reaction.
- if you have ever had an severe allergic reactions (**angioedema**) of unknown cause.
- If you are more than 3 months pregnant. (It is also better to avoid Lisinopril Tablets in early pregnancy – see pregnancy section)
- if you are **breast-feeding** or wish to breastfeed.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Lisinopril tablets.

If you develop a dry cough which is persistant for a long time after starting treatment with Lisinopril Tablets, talk to your doctor

Warning and precautions

Talk to your doctor, pharmacist or nurse before taking Lisinopril tablets

- If you are prone to fainting and suffer from dizziness (occasional **low blood pressure**). The risk of low blood pressure is greater if you are using a diuretic (water pill), if you are on a low-salt diet, if you receive dialysis, or if you have vomiting or diarrhoea (being sick).
- If you have a **narrowing (stenosis) of the aorta (an artery in your heart), renal artery or mitral valve** in the heart, or **thickening of the heart muscle (known as hypertrophic cardiomyopathy)**.
- If you have 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 recently had diarrhoea or vomiting (being sick).
- If your doctor has told you to control the amount of salt in your diet.
- If you are of black origin as Lisinopril tablets may be less effective. Patients with dark skin are at greater risk of angioedema than other patients. If symptoms of angioedema occur, you must stop taking Lisinopril tablets and consult a doctor immediately.
- If you are receiving **dialysis** with a ‘high-flux’ membrane (e.g. AN 69).
- If you have high levels of cholesterol and are receiving **LDL apheresis treatment** a procedure that removes the LDL cholesterol from the blood.
- if you experience a **persistent dry cough**.
- if you are at greater risk of **too much potassium in the blood** as a result of reduced kidney function, diabetes or using potassium-sparing medicines such as spironolactone or medicines containing potassium. Having too much potassium in the blood can cause symptoms such as muscle cramps, diarrhoea, nausea, dizziness and headache.
- you must tell your doctor if you think you are (or might become) pregnant. Lisinopril Tablet 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 **breast-feeding** or wish to breastfeed.
- 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.
 - If you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as throat) is increased:
 - Sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs).

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 Tablets”.

Please consult your doctor if any of the above-mentioned situations applies to you, or has ever applied to you in the past.

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 tablets 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 tablets). This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking Lisinopril tablets.

Children and adolescents

Lisinopril tablets have been studied in children. For more information, talk to your doctor. Lisinopril is not recommended in children under 6 years of age or in any child with severe kidney problems.

Other medicines and Lisinopril tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Lisinopril tablets can affect the way some medicines work and some medicines can have an effect on Lisinopril tablets.

Your doctor may need to change your dose and/or to 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 Tablets” and “Warnings and precautions”).

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

- Aliskiren containing medicines (for treatment of high blood pressure)
- **medicines containing potassium or salt substitutes**. Taking these at the same time as Lisinopril tablets may lead to excessive levels of potassium in the blood or other drugs that may increase serum potassium in your body (such as heparin, and co-trimoxazole also known as trimethoprim/sulfamethoxazole).
- **diuretics (water pills)** including potassium-sparing diuretics such as *spironolactone*, *triamterene* or *amiloride* (used to treat high blood pressure). If taken at the same time as Lisinopril tablets, the blood pressure-lowering effect may be enhanced.
- Medicines to break up blood clots (usually given in hospital)
- Medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section 2 “Warnings and Precautions”.
- Beta-blocker medicines, such as atenolol and propranolol.
- Nitrate medicines (for heart problems)
- **lithium** (a drug used to treat manic depression). If taken at the same time as Lisinopril tablets, the amount of lithium may increase in the blood.
- **painkillers** with an anti-inflammatory and fever-reducing effect (NSAIDs (non-steroidal anti-inflammatory drugs), used to treat pain and arthritis, and if you take more than 3 grams of aspirin (Acetylsalicylic acid) a day). If taken at the same time, the blood pressure-lowering effect of Lisinopril tablets may be reduced.
- Medicines used to treat asthma.
- other medicines to treat **high blood pressure** (*antihypertensives*). If taken at the same time, the

- blood pressure-lowering effect of Lisinopril tablets may be enhanced.
- Procainamide (for heart beat problems)
 - medicines used to treat **depression** (*tricyclic antidepressants*), **psychosis** (*antipsychotics*) and **narcotics** (*anaesthetics*). If taken/ administered at the same time as Lisinopril tablets, the blood pressure may be lowered even further.
 - medicines that have a **stimulating effect on a certain part of the central nervous system** (*sympathomimetics*). If taken at the same time, the blood pressure-lowering effect of Lisinopril tablets may be reduced.
 - medicines that suppress your immune system (immunosuppressants).
 - Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
 - Medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.
 - allopurinol, a medicine used in the treatment for gout.
 - Insulin or medicines taken orally used in the treatment of **diabetes** (*antidiabetics*). If taken at the same time, the blood glucose-lowering effect of antidiabetics may be enhanced.

Lisinopril can be used at the same time as **blood-thinners** (*thrombolytic agents*).

Pregnancy and breast-feeding

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

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Lisinopril Tablet 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 tablets may cause dizziness and tiredness. If you should experience dizziness or tiredness, do not drive any vehicles and/or use machinery that requires alertness. You must wait to see how your medicine affects you before trying these activities.

3. How to take Lisinopril tablets

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Once you have started taking Lisinopril tablets your doctor may take blood tests. Your doctor may then adjust your dose so you take the right amount of medicine for you.

Taking your medicine

- Swallow the tablet with a drink of water
- Try to take your tablets at the same time each day. It does not matter if you take Lisinopril tablets before or after food.
- Keep taking Lisinopril tablets for as long as your doctor tells you to, it is a long term treatment. It is important to keep taking Lisinopril tablets every day.

Taking your first dose

- Take special care when you have your first dose of Lisinopril tablets 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 many tablets to take each day. Check with your doctor or pharmacist if you are unsure.

Usual dosages are as follows:

1. High blood pressure (hypertension)

Lisinopril tablets can be used alone or in combination with other medicines that lower blood pressure.

Starting dose: take **10 mg** of Lisinopril tablets **once a day**.

Maintenance dose: take **20 mg** of Lisinopril tablets **once a day**.

- * Patients on diuretics (water pills): consult your doctor before you start using Lisinopril tablets.
- * Patients with reduced kidney function: consult your doctor. Your dosage will probably have to be adjusted.

2. Patients whose heart is unable to pump properly (heart failure)

Lisinopril tablets are generally used alongside treatment with diuretics (water pills), digitalis or beta-blockers.

Starting dose: take **2.5 mg** of Lisinopril tablets **once a day** (one half Lisinopril tablets 5 mg tablet).

Long term dose: take **5 to 35 mg** once a day.

Dosage will be adjusted depending on how your body responds to treatment.

3. After an acute heart attack

Lisinopril tablets treatment should begin within 24 hours after onset of heart attack.

Starting dose (for the first 3 days after the heart attack): 5 mg Lisinopril tablets, followed by another 5 mg Lisinopril tablets 24 hours later, followed by 10 mg Lisinopril tablets after a further 24 hours and then 10 mg Lisinopril tablets once a day. Your dose will be adjusted if you suffer from low blood pressure or impaired kidney function.

Maintenance dose: take **10 mg** Lisinopril tablets **once a day**. If your blood pressure drops too low, your dosage will be lowered or discontinued. After 6 weeks, you will be checked to see whether you can stop taking Lisinopril tablets or whether treatment must be continued.

4. Kidney problems due to diabetes (Type 2 diabetes mellitus) in hypertensive patients

(Starting) dose: take **10 mg** Lisinopril tablets **once a day**. If necessary, your dose can be increased to **20 mg** Lisinopril tablets **once a day**.

* Patients with reduced kidney function: consult your doctor. Your dosage will probably have to be adjusted.

Use in Children (Under 6 years)

The use of Lisinopril is not recommended for children under 6 years or in any children with severe kidney problems.

Use in Children and adolescents aged 6 to 16 years

Lisinopril tablets are not recommended for children with severe kidney problems. The dose depends on the child's weight. The usual starting dose is between 2.5mg and 5mg once daily, which can be increased to a maximum of 20mg to 40mg once daily.

For children who weigh between 20kg and 50kg, the recommended start dose is 2.5mg once a day.

For children who weigh more than 50kg, the recommended starting dose is 5mg once a day. Patients with kidney problems should take a lower dose. Your doctor will decide the correct dose for you.

Elderly

In the elderly, Lisinopril tablets can be used as above. However, it must be remembered that kidney function may be impaired in the elderly therefore if you have kidney problems or are taking diuretic medicines your doctor may give you a lower dose than the usual dose.

Kidney transplant patients

Use of Lisinopril tablets in kidney transplant patients is not recommended, as there is no experience in this patient group.

Directions for use

Take Lisinopril tablets every day at around the same time. Choose a time that is easy to remember;

before a meal, for example.

The easiest way to break the tablet is illustrated below:

- place the tablet so that the break line is facing towards you
- then, using your index finger and thumb of the same hand, press downwards and outwards on either side of the break line, as shown in the diagram.



If you have the impression that Lisinopril tablets have an effect which is too strong or too weak, talk to your doctor or pharmacist.

If you take more Lisinopril tablets than you should

contact your doctor or pharmacist immediately

Symptoms

The following effects are most likely to happen: Dizziness, palpitations.

What you must do

If you have used or taken too much Lisinopril tablets try to find out how much Lisinopril tablets have been taken. Keep the Lisinopril tablets carton close at hand.

If you forget to take Lisinopril tablets:

You can still take Lisinopril tablets for up to 12 hours after the usual time. If more than 12 hours have passed, skip the forgotten dose and take your next tablet at the usual time. Do not take a double dose of Lisinopril tablets to make up for a forgotten dose.

If you stop using Lisinopril tablets

There is a risk that the symptoms - for which Lisinopril tablets had originally been prescribed - will return. Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following reactions, **stop taking Lisinopril and see your doctor immediately:**

- Severe allergic reactions (rare, may affect up to 1 in 1,000 people). The signs may include sudden onset of:
 - Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
 - Severe or sudden swelling of your hands, feet and ankles.
 - Difficulty breathing.
 - Severe itching of the skin (with raised lumps).
- Severe skin disorders, like a sudden, unexpected rash or burning, red or peeling skin (very rare, may affect up to 1 in 10,000 people).
- An infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems (very rare, may affect up to 1 in 10,000 people).

Rarely patients may experience a sudden build-up of fluid in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and skin rash, often as an allergic reaction (**angioedema**). If this happens, you should stop taking this treatment and see your doctor.

Very rarely patients may experience **liver problems, with jaundice**. If this happens you should stop taking this treatment and see your doctor.

Very rarely patient may develop a certain serious **blood disorder** (a lack of white blood cells) accompanied by an increased susceptibility to infections (neutropenia) or by sudden high fever, severe sore throat and mouth ulcers (agranulocytosis). Contact your doctor immediately if you develop such symptoms.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Headache
- Feeling dizzy or light-headed, especially if you stand up quickly
- Diarrhoea
- A dry cough that does not go away
- Being sick (vomiting)
- Kidney problems (shown in a blood test)

Uncommon (may affect up to 1 in 100 people)

- Mood changes
- Change of colour in your fingers or toes (pale blue followed by redness) or numbness or tingling in your fingers or toes.
- Changes in the way things taste.
- Feeling Sleepy
- Spinning feeling (vertigo)
- Having difficulty sleeping
- Stroke

- Fast heart beat
- Inflammation of the nose lining, characterized by a blocked or runny nose and sneezing (rhinitis)
- Feeling sick (nausea)
- Stomach pain or indigestion
- Skin rash or itching
- Being unable to get an erection (impotence)
- Feeling tired or feeling weak (loss of strength)
- A very big drop in blood pressure may happen in people with the following conditions: Coronary heart disease; narrowing of the aorta (a heart artery), kidney artery or heart valves; an increase in the thickness of the heart muscle. If this happens to you, you may feel dizzy or light headed, especially if you stand up quickly.
- Changes in blood tests results regarding urea, serum creatinine and liver enzymes that show how well your liver and kidneys are working
- Heart attack
- Seen and/or heard hallucinations

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

- 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
- Blood disorders (e.g. a drop in blood haemoglobin levels, reduction in haematocrit).
- 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 tablets 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
- Mental confusion

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

- Tight-chestedness caused by muscle spasms in the airways, inflammation of the paranasal sinuses, a feeling of pain and fullness behind your cheeks and eyes (sinusitis), pneumonia.
- Wheezing
- Low levels of sugar in your blood (hyperglycaemia). The signs may include feeling hungry or weak, sweating, dizziness and a fast heart beat (hypoglycaemia).
- Inflammation of the liver. This can cause loss of appetite, yellowing of the skin and eyes, and a dark

coloured urine.

- Inflammation of the pancreas. This causes moderate to severe pain in the upper stomach radiating to the back, as well as nausea and vomiting, fluid build-up in the intestinal wall (recognisable by such symptoms as abdominal pain), inflammation of the liver (hepatitis) accompanied by jaundice (yellow discolouration of the skin).
- Blood and lymphatic system disorders accompanied by an increased susceptibility to infections, anaemia, haemolytic anaemia.
- 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

Combinations of the following side effects have also been reported: inflamed blood vessels, muscle pain, painful joints, inflamed joints, certain blood disorders, hypersensitivity to sunlight and other skin reactions.

Side effects in children appear to be comparable to those seen in adults.

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 via the Yellow card scheme at 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 tablets

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

Do not store above 30°C

Do not use this medicine after the expiry date which is stated on the carton after “do not use after” or “exp”. The expiry date refers to the last day of that month.

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 tablets contains

- The active substance is lisinopril dihydrate. Each Lisinopril tablets 5 mg, 10 mg and 20 mg contains lisinopril dihydrate, equivalent to 5 mg, 10 mg and 20 mg of anhydrous lisinopril, respectively.
- The other ingredients are mannitol, calcium hydrogen phosphate dihydrate, maize starch, pregelatinised starch, magnesium stearate and colloidal anhydrous silica (*see Section 2 'Important information about some of the ingredients of Lisinopril Tablets'*).

What Lisinopril tablets looks like and contents of the pack

- 5 mg tablets are white, round biconvex tablets with embossing “5” on one side and breakline on the other side.
- 10 mg tablets are white, round biconvex tablets with embossing “10” on one side and breakline on the other side.
- 20 mg tablets are white, round biconvex tablets with embossing “20” on one side and breakline on the other side.

Packed in boxes containing strips of 14, 28, 30 or 98 tablets

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

For any information about this medicinal product, please contact the Marketing Authorisation Holder: Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, UK

Manufacturer

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