

Package leaflet: Information for the patient

Lispril 20 mg Tablets

lisinopril

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

1. What Lispril is and what it is used for

Lispril is used to treat:

- **high blood pressure**
- **reduced heart pumping ability (heart failure)**
- **patients recovering from a heart attack**
- **kidney disease** resulting from diabetes and high blood pressure.

Lispril is recommended in children (above 6 years old) only for the treatment of high blood pressure (hypertension).

Lispril contains a medicine called lisinopril. This belongs to the ACE inhibitor medicine group (angiotensin-converting enzyme inhibitors). Lisinopril expands your blood vessels. This reduces your blood pressure and makes it easier for your heart to pump blood to all body parts.

2. What you need to know before you take Lispril

Do not take Lispril

- if you are **allergic** to lisinopril or to any of the other ingredients of this medicine (listed in section 6) or to other ACE inhibitors
- if during earlier ACE inhibitor use you had **swelling of the face, lips, tongue** and/or **throat** with difficulty swallowing, breathing or with joints

Do not take Lispril if you had any of these reactions

- without a known cause or
- if it has been confirmed that you have a hereditary or
- other form of fluid accumulation (angioedema).

- 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
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you are more than 3 months **pregnant**. (It is also better to avoid Lispril in early pregnancy – see pregnancy section.)

Warnings and precautions

Talk to your doctor before taking Lispril

- if you have a **low blood pressure**. You may notice this as feeling dizzy or light-headed, especially when standing up. This may happen on starting medication if you suffer from **dehydration** due to treatment with “water tablets” (diuretics), dialysis, a low salt diet, vomiting or diarrhoea
- if you suffer from **heart disorders** such as heart failure, a narrowing (stenosis) of the aorta (an artery in your heart) or a narrowing of the heart valves (mitral valves), or an increase in the thickness of the heart muscle (hypertrophic cardiomyopathy or ‘HOCM’)
- if you have a condition involving the **blood vessels in the brain**
- if you have **kidney problems**, including a narrowing (stenosis) of the kidney artery
- if you are undergoing:
 - **dialysis treatment** with high flux membranes
 - a treatment called ‘LDL apheresis’, a blood separation treatment **to remove cholesterol** from your blood by machine with dextran sulphate
 - **desensitisation treatment** to reduce the effects of an allergy to a **bee or wasp sting**.

In these cases, tell your doctor that you are taking Lispril. Your doctor may wish to interrupt your Lispril treatment to prevent a possible allergic reaction.

- if you have **liver problems**
If you develop jaundice during use of Lispril stop taking it and consult your doctor
- if you have **blood vessel disease**, known as collagen vascular disease
- if you are **Black of Afro Caribbean origin** as Lispril may be less effective. You may also have a higher risk of having a severe allergic reaction (angioedema):
 - sudden fluid accumulation in the skin and mucous membranes such as throat or tongue
 - breathing difficulties
 - itching and rash.
- if you have a **cough**
Inform your doctor if this becomes worse
- if you need to **have surgery** (including dental surgery) **or an anaesthetic**, remind your doctor or dentist that you are taking Lispril. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking Lispril.
- if **taking other medicines**, such as potassium supplements, lithium (for mental disorders) or medicines against 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.
 - aliskiren.

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 Lispril”.

- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) 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 and other medicines belonging to the class of mTOR inhibitors)
- vildagliptin, a medicine used to treat diabetes
- medicines to break up blood clots (tissue plasminogen activator), usually given in hospital.
- if you experience 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 you should see your doctor immediately.

If you are unsure if any of the above apply to you, please discuss this with your doctor.

You must tell your doctor if you think that you are (or might become) pregnant. Lispril 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).

Children and adolescents

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

Other medicines and Lispril

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

This particularly applies to:

- **Diuretics** (“water tablets”) which are used to treat high blood pressure.
- Other **medicines used to treat high blood pressure**.

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 Lispril” and “Warnings and precautions”).

- Medicines that reduce inflammation and treat pain or arthritis, such as **acetylsalicylic acid** (if you are taking more than 3 grams each day), **ibuprofen**, **indomethacin** or **selective cyclooxygenase-2 inhibitors** (COX-2 inhibitors)
- Medicines for mental disorders or depressions such as
 - **lithium**
 - **medicines to treat psychoses**
 - **tricyclic antidepressants**, such as amitriptyline
- **Potassium** supplements (including salt substitutes), potassium-sparing diuretics (such as spironolactone, triamterene or amiloride) and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole, also known as trimethoprim/sulfamethoxazole, 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** (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section “Warnings and precautions”.
- **Racecadotril** used to treat diarrhoea. See section “Warnings and precautions”.
- **Blood sugar lowering medicines**, such as insulin or those taken orally (including vildagliptin). The antidiabetic medicine dose may need adjusting. See also section “Warnings and precautions”.
- **Sacubitril/valsartan** (used to treat long-term heart failure). See section “Do not take Lispril”.

- **Medicines to break up blood clots** (tissue plasminogen activators), usually given in hospital. See section “Warnings and precautions”.
- Central nervous system stimulative medicines, such as
 - **ephedrine** or **pseudoephedrine**, which could be included in medicines for treating nose or sinus congestion or in other cough/cold remedies
 - **salbutamol**, a medicine for treating asthma.
- **Medicines to suppress the body’s immune system**
- **Allopurinol**, a medicine to treat gout
- **Procainamide**, used to treat abnormal heartbeats
- **Beta-blocker medicines** (such as atenolol and propranolol), used to regulate heart rhythm
- **Nitrate medicines**, used for heart problems (such as angina pectoris)
- **Gold injections (sodium aurothiomalate)**, a medicine to injection against rheumatic arthritis.

Pregnancy and breast-feeding

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

Pregnancy

You must tell your doctor if you think that you are (or might become) pregnant.

Your doctor will normally advise you to stop taking Lispril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lispril. Lispril 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. Lispril 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.

Lispril contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Lispril

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

Lispril should be taken once daily preferably every morning. Take the tablets with a glass of water. Try to take your tablets at the same time each day. It does not matter if you take this medicine before or after food.

Keep taking this medicine for as long as your doctor tells you to, it is a long-term treatment. It is important to keep taking this medicine every day.

The tablets can be divided into equal doses.

Taking your first dose

- Take special care when you have your first dose of this medicine 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. Once you have started taking this medicine your doctor may take blood tests. Your doctor will tell you how many tablets to take each day. Check with your doctor or pharmacist if you are unsure.

- **For high blood pressure**

The recommended starting dose is 10 mg once a day.

For severe conditions your doctor may decide to start you on between 2.5 mg and 5 mg once a day.

Once optimal control of blood pressure has been reached, the usual long-term dose is 20 mg once a day.

Diuretic-treated patients

If possible, the diuretic should be discontinued 2 to 3 days before beginning therapy with lisinopril. Patients with high blood pressure who cannot discontinue the diuretic therapy, should begin Lispril treatment with 5 mg once a day.

- **For heart failure**

The recommended starting dose is 2.5 mg once a day.

The usual long-term dose is 5 to 35 mg once a day.

- **After a heart attack**

The recommended starting dose is 5 mg within 24 hours of your attack and 5 mg one day later.

The usual long-term dose is 10 mg once a day.

- **Diabetic patients with kidney problems**

The recommended dose is either 10 mg or 20 mg once a day.

Use in children and adolescents (6 to 16 years old) with high blood pressure

- This medicine is not recommended for children under 6 years or in any children with severe kidney problems.
- The doctor will work out the correct dose for your child. The dose depends on the child's body weight.
- For children who weigh between 20 kg and 50 kg, the recommended starting dose is 2.5 mg once a day. The dose can be increased to a maximum of 20 mg once daily.
- For children who weigh more than 50 kg, the recommended starting dose is 5 mg once a day. The dose can be increased to a maximum of 40 mg once daily.

Patients with reduced kidney function

If you suffer from a kidney disorder, the doctor should prescribe the lowest possible dose and monitor your kidney function.

Patients following recent kidney transplant

The use of Lispril tablets is not recommended.

Elderly, over 65 years

No special dose adjustment is necessary. In case of reduced kidney function, the dose should be adjusted carefully.

If you take more Lispril than you should

Contact your doctor or the nearest hospital casualty department immediately.

Take this leaflet or some tablets with you so that people will know what you have taken. The following effects are most likely to happen: dizziness and a forceful heartbeat that may be rapid.

If you forget to take Lispril

Take the missed dose as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Lispril

Do not stop treatment before talking to your doctor, even if you are feeling well. This will reduce the treatment's effect.

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.

Stop taking Lispril and seek medical advice immediately, if you develop any of the following reactions:

- Severe allergic reactions (rare, may affect up to 1 in 1,000 people). The signs may include sudden onset of:
 - swelling of the face, lips, tongue and/or throat
 - difficulties in breathing and swallowing, dizziness
 - severe or sudden swelling of hands, feet and ankles
 - severe itching skin (with raised lumps).
- Severe skin disorders including Stevens-Johnson Syndrome and pemphigus (the symptoms include a sudden, unexpected rash or burning, red skin, blistering of the lips, eyes or mouth, genitals, skin peeling, fever) and aggregate of mature or abnormal looking lymphocytes in the dermis (cutaneous pseudo lymphoma) (very rare, may affect up to 1 in 10,000 people).
- Inhibition of the formation of blood in the bone marrow which can cause weakness, bruising or make infections more likely. Other symptoms may include sudden sore throat, fever, tiredness, paleness, mouth sores (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, abnormalities of the lymph glands or urinary problems (very rare, may affect up to 1 in 10,000 people).
- Inflammation of the liver (hepatitis) or liver failure. This can cause loss of appetite, yellowing of the skin and eyes, fever, chills, tiredness, stomach pain, feeling sick, and dark coloured urine (very rare, may affect up to 1 in 10,000 people).
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach (very rare, may affect up to 1 in 10,000 people).
- Possible heart attack (chest pressure or ache) or stroke (weakness or paralysis of limbs or face, difficulty speaking) in high-risk patients (with heart disease caused by narrowing or blockage of blood vessels supplying the heart muscle or with disease of the blood vessels supplying the brain), increased

heart rate and quick and irregular heartbeat (palpitations) (uncommon, may affect up to 1 in 100 people).

- Not going to the toilet (low urine output) which can also occur with a high temperature (fever), nausea, tiredness, pain in your sides, swelling of your legs, ankles, feet, face and hands or blood in your urine. These are due to a severe kidney problem (sudden kidney failure) (rare, may affect up to 1 in 1,000 people).
- Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion (rare, may affect up to 1 in 1,000 people).

Other possible side effects:

Common: may affect up to 1 in 10 people

- dizziness
- headache
- fall in blood pressure as a result e.g. of standing up rapidly from a sitting or lying position, sometimes accompanied by dizziness
- a dry cough that does not go away
- diarrhoea
- being sick (vomiting)
- kidney problems (shown in a blood test).

Uncommon: may affect up to 1 in 100 people

- mood changes
- spinning sensation (vertigo)
- changes in the way things taste (taste abnormalities)
- difficulty in sleeping
- seeing, feeling or hearing things that are not there (hallucinations)
- change of colour in your fingers or toes (pale blue followed by redness) or numbness or tingling in your fingers or toes
- runny nose
- feeling sick (nausea)
- abdominal pain
- indigestion
- skin rash and/or itching
- inability to maintain an erection (impotence)
- tiredness
- general weakness
- changes in blood tests that show how well your liver and kidneys are working
- too much potassium in the blood, sometimes manifesting itself as muscle cramps, diarrhoea, nausea, dizziness, headache (hyperkalaemia).

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

- decrease of the red blood pigment haemoglobin and number of red blood cells (haematocrit)
- mental confusion
- dry mouth
- nettle rash
- hair loss
- psoriasis, a skin disorder

- kidney failure leading to excessive urea in the blood
- enlargement of one or both breasts in men
- increase of bilirubin, a substance produced in the liver
- low sodium level in the blood (signs are tiredness, confusion and muscle twitching)
- changes in the way things smell.

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

- low blood sugar levels. The signs may include feeling hungry or weak, sweating and a fast heartbeat.
- inflammation of nasal sinuses (a feeling of pain and fullness behind your cheeks and eyes)
- difficulty in breathing or wheezing
- certain forms of inflammation of the lungs. The signs include cough, feeling short of breath and high temperature (fever).
- allergic reaction in the small intestine (intestinal angioedema)
- changes in your lymph glands
- autoimmune disease, a condition when your immune system attacks your own healthy tissues
- yellowing of the skin and/or the whites of the eyes (jaundice)
- excessive sweating
- passing less water (urine) than normal or passing no water.

Not known: frequency cannot be estimated from the available data

- symptoms of depression
- fainting.

A complex of symptoms has been reported, whereby one or more of the following symptoms may occur: fever, inflamed blood vessels (vasculitis) with skin rash, purplish-red spots and itching, muscle and joint pains, swelling of the joints or glands, certain blood abnormalities (including increased quantity of antibodies (ANA), increased sedimentation of red blood cells (ESR), increased number of white blood cells (eosinophilia and leukocytosis)), skin rash, sensitivity to light or other skin disorders.

Children

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 the national reporting system: HPRC Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lispril

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 blister and on the carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicine 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 Lispril contains

The active substance is lisinopril.

Each tablet contains 20 mg of lisinopril (as lisinopril dihydrate).

The other ingredients are calcium hydrogen phosphate dihydrate, mannitol (E421), maize starch, croscarmellose sodium and magnesium stearate, iron oxide red (E172).

What Lispril looks like and contents of the pack

Lispril 20 mg tablets are round, biconvex with a score notch on one side.

The tablets are uniformly red, mottled with a smooth surface packed in blisters.

Polyvinylchloride/aluminium blisters packed in cardboard boxes containing 10, 14, 28, 30, 50, 56, 98, 100 and 100x1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co. Cork, Ireland.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

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

Austria	Lisinopril 1A Pharma 20 mg – Tabletten
Belgium	Lisinopril Sandoz 20 mg tabletten
Ireland	Lispril 20 mg Tablets
Italy	LISINOPRIL SANDOZ
Netherlands	LISINOPRIL SANDOZ 20 MG, TABLETTEN
UK	Lisinopril 20 mg Tablets

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