

Package leaflet: Information for the user

Lisopress Tablets 2.5 mg, 5 mg, 10 mg and 20 mg

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

1. What Lisopress is and what it is used for

Lisopress tablet contains an active substance called lisinopril. This belongs to a group of medicines called ACE inhibitors (angiotensin converting enzyme inhibitors).

Lisopress tablet 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.

Lisopress tablet works by making your blood vessels widen. This helps 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 Lisopress

Do not take Lisopress

- if you are allergic to lisinopril or any of the other ingredients of this medicine (listed in section 6).
- if 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).
- if 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.
- if you are more than 3 months pregnant. (It is also better to avoid taking Lisopress tablets in early pregnancy - see Pregnancy 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.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Lisopress tablet.

If you develop a dry cough which is persistent for a long time after starting treatment with Lisopress tablet, talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lisopress tablet:

- if you have 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 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 Lisopress”.

- 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. Lisopress 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 Lisopress may be less effective. You may also more readily get the side effect ‘angioedema’ (a severe allergic reaction).
- 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:
 - sirolimus, everolimus, temsirolimus and other medicines belonging to the class of so-called mTOR inhibitors (used to prevent rejection of transplanted organs and for cancer).
 - tissue plasminogen activator (medicines to break up blood clots), usually given in hospital;
 - vildagliptin, a medicine used to treat diabetes;
 - racecadotril used to treat diarrhoea.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Lisopress.

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

Children and adolescents

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

Other medicines and Lisopress

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

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 aliskiren (see also information under the headings “Do not take Lisopress tablets” and “Warnings and precautions”).
- Water tablets (diuretic medicines to increase the volume of urine).
- Medicines to break up blood clots (usually given in hospital).
- Beta-blocker medicines, such as atenolol and propranolol.
- Nitrate medicines (for heart problems).
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat pain and arthritis.
- Aspirin (acetylsalicylic acid), if you are taking 3 grams or more 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; ciclosporin, 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 without prescription).
- Medicines to suppress the body’s immune response (immunosuppressants).
- Allopurinol (for gout).
- Procainamide (for heart rhythm 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 prevent rejection of transplanted organs and for cancer (sirolimus, everolimus, temsirolimus and other medicines belonging to the class of so-called mTOR inhibitors). See section “Warnings and precautions”.
- Vildagliptin, a medicine used to treat diabetes.
- Racecadotril used to treat diarrhoea.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 Lisopress before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lisopress tablet. Lisopress 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.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Lisopress 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

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.

3. How to take Lisopress

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

Once you have started taking Lisopress 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 Lisopress before or after food.

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

Taking your first dose

Take special care when you have your first dose of Lisopress 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.

For high blood pressure

The recommended starting dose is 10 mg once a day.

The usual long-term dose is 20 mg once a day.

For heart failure

The recommended starting dose is 2.5 mg once a day.

The 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.

For kidney problems caused by diabetes

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

If you are elderly, have kidney problems or are taking diuretic medicines your doctor may give you a lower dose than the usual dose.

Use in children and adolescents

Children and adolescents (6 to 16 years old) with high blood pressure

Lisopress tablet 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.

For children who weigh more than 50 kg, the recommended starting dose is 5 mg once a day.

If you take more Lisopress than you should

If you take more Lisopress tablets than prescribed by your doctor, talk to a doctor or go to a hospital immediately. The following effects are most likely to happen: dizziness, palpitations (feeling of strong heartbeats).

If you forget to take Lisopress

If you forget to take a dose, take it 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 Lisopress

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 medicine, 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 Lisopress and see your doctor immediately:

- Severe allergic reactions (rare, may affect up to 1 in 1000 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).

Other possible side effects:

Common side effects (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 side effects (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.
- Runny nose.
- 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 that show how well your liver and kidneys are working.
- Heart attack.
- Seen and/or heard hallucinations.

Rare side effects (may affect up to 1 in 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.
- 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 Lisopress 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.

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

- 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 (pneumonia). 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 (hepatitis). 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.
- Severe allergic hypersensitivity reactions (anaphylactic/anaphylactoid reactions).

Additional side effects in 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lisopress

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

Do not use Lisopress after the expiry date which is stated on the blister foil and on the outer carton {MM YYYY}. 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 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 Lisopress contains**

The active substance in Lisopress is lisinopril (as lisinopril dihydrate).

The other ingredients are magnesium stearate, talc, mannitol, maize starch, calcium hydrogen phosphate dihydrate.

What Lisopress looks like and contents of the pack

Lisopress tablets are supplied in 4 strengths: 2.5 mg, 5 mg, 10 mg and 20 mg.

The 2.5 mg tablets are white, round, debossed with 2.5 on one side and a breakline on the other.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The 5 mg tablets are white, round, debossed with 5 on one side and a breakline on the other.

The tablet can be divided into equal doses.

The 10 mg tablets are white, square, debossed with 10 on one side and a breakline on the other.

The tablet can be divided into equal doses.

The 20 mg tablets are white, pentagonal, debossed with 20 on one side and a breakline on the other.

The tablet can be divided into equal doses.

They are supplied in boxes containing blister packs of 28, 30, 50 or 100 tablets for Lisopress 2.5 and 10 mg tablets.

They are supplied in boxes containing blister packs of 28, 30, 50, 60 or 100 tablets for Lisopress 5 and 20 mg tablets.

Not all pack size may be marketed.

Marketing Authorisation Holder

Gedeon Richter Plc.
19-21 Gyömrői út
1103 Budapest
Hungary

Manufacturer

Gedeon Richter Plc.
19-21 Gyömrői út
1103 Budapest
Hungary

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