

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lisinopril 2.5 mg Tablets Lisinopril 5 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.

In this leaflet:

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

Lisinopril Tablets belong to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme inhibitors). It acts by widening the blood vessels, which helps reduce your blood pressure and makes it easier for the heart to pump blood to all parts of your body.

Lisinopril Tablets are used for the treatment of:

- High blood pressure (hypertension).
- Symptomatic heart failure, a condition where the heart does not pump the blood through your body as well as it should.
- Heart attack (acute myocardial infarction) that may lead to a weakening of your heart.
- Kidney problems related to diabetes and high blood pressure.

Lisinopril is recommended in children and adolescents (6 to 16 years old) only for the treatment of high blood pressure (hypertension).

2. What you need to know before you take Lisinopril Tablets

Do not take Lisinopril Tablets

- If you are allergic to lisinopril or any of the other ingredients of this medicine (listed in Section 6) or any other medicine in the same group of drugs as Lisinopril Tablets (ACE inhibitors)
- If you have previously been treated with a medicine in the same group of drugs as Lisinopril Tablets (ACE inhibitors) and have had an allergic reaction which caused swelling of the hands, feet or ankles, the face, lips, tongue and/or throat with difficulty in swallowing or breathing (angioedema)
- If you know of angioedema in your family or you have had angioedema in any other circumstances.
- If you are more than 3 months pregnant. (It is also better to avoid Lisinopril 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.

Warnings and precautions

Tell your doctor or pharmacist before taking Lisinopril Tablets:

- If you are dehydrated due to treatment with diuretics (or 'water tablets'), dialysis, a low salt diet or because you have had diarrhoea or you have been sick. You are more likely to suffer from a drop in your blood pressure (hypotension) when you start to take the tablets and may feel faint or light headed.
- 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
- if you have a narrowing of the aorta (aortic stenosis) or the heart valves (mitral valve stenosis), or an increase in the thickness of the heart muscle (hypertrophic cardiomyopathy).
- If you have kidney disease or narrowing of the blood vessels to the kidney
- If you need haemodialysis treatment
- If you have liver disease
- If you have diabetes (metabolic disorder where sugar is not used properly in the body)

- If you have blood vessel disease (collagen vascular disease e.g. scleroderma, SLE (lupus))
- If you are taking potassium supplements
- If you are undergoing or will undergo desensitisation treatment for an allergy, for example, to insect stings. The desensitization treatment reduces the effect of the allergy (e.g. bee or wasp stings) but sometimes it can cause a more severe allergic reaction if you are taking ACE inhibitors during the desensitization treatment.
- If you are going into hospital for an operation. Tell your doctor or dentist that you are taking Lisinopril Tablets before you are given a local or general anaesthetic. Lisinopril Tablets, combined with some anaesthetics, may cause a short term drop in blood pressure soon after taking the tablets.

You must tell your doctor if you think you are (or might become) pregnant. Lisinopril Tablets are 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 section Pregnancy and breastfeeding section).

Stop taking Lisinopril Tablets and seek medical attention immediately

If any of the following situations occur (an allergic reaction):

- If you develop difficulty in breathing with or without swelling of the face, lips, tongue and/or throat If you develop swelling of the face, lips, tongue and/or throat which may cause difficulty in swallowing
- If you develop severe itching of the skin (with raised lumps)
- If you develop swelling of the hands, feet or ankles with itching in the same area.

Note: Take special care when taking the first dose of Lisinopril Tablets. It may cause a greater fall in blood pressure than will occur following continued treatment. You may notice this as dizziness or light-headedness and it may help to lie down. If you are concerned, please consult your doctor.

Contact your doctor if you have high temperature, sore throat or mouth ulcers (these may be the symptoms of infection caused by the lowering of the number of white blood cells) or if you notice yellowing of the skin and whites of the eyes (jaundiced) that may be a sign of liver disease.

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".

Other medicines and Lisinopril Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may affect the actions of other medicines.

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 tablets" and "Warnings and precautions").

Talk to your doctor if you are taking any of the following medicines:

- Diuretics (water tablets including those which conserve potassium)
- Other medicines for your high blood pressure (antihypertensives)
- Non-steroidal anti-inflammatory medicines (NSAIDs) such as indomethacin and high doses of acetylsalicylic acid (more than 3 grams per day), which are used to treat arthritis or muscle pain.
- Medicines containing gold and which are administered as injection (for example sodium aurothiomalate; used to treat arthritis).
- Medicines for mental disorders such as lithium, antipsychotics or tricyclic antidepressants.
- Potassium tablets or potassium containing salt substitutes
- Medicines for the treatment of diabetes, such as insulin or those taken orally, to lower blood sugar.
- Medicines that stimulate the central nervous system (sympathomimetics). These include ephedrine, pseudoephedrine and salbutamol and may be found in some decongestants, cough/cold remedies and asthma medication.
- Medicines that suppress the body's immune response (immunosuppressants), treatment with allopurinol (for gout) or procainamide (for abnormal heartbeats).

Lisinopril Tablets with food and drink

Lisinopril Tablets can be taken with food and drink.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 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 Tablets are 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 Tablets are 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 are unlikely to affect your ability to drive a car or to operate machinery. However, you should not perform tasks that require special attention until you know how your medicine will affect you.

3. How to take Lisinopril Tablets

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

The dosage is individual and it is important that you take it as prescribed by your doctor. Your starting dose and long-term dose will depend on your medical condition and whether you are taking any other medicines.

High blood pressure:

The recommended starting dose is 10mg taken once a day. The usual long-term dose is 20mg taken once daily.

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

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 usual starting dose is 2.5 mg taken once a day, which can be increased to a maximum of 20 mg taken once a day.
- For children who weigh more than 50 kg, the usual starting dose is 5 mg taken once a day, which can be increased to a maximum of 40 mg taken once a day.

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

Symptomatic heart failure:

The recommended starting dose is 2.5mg taken once a day. The usual long-term dose is 5 to 35mg taken once daily.

After a heart attack:

The recommended starting dose is 5mg on day 1 and day 2, then 10mg taken once a day. **Kidney problems related to diabetes:**

The recommended dose is either 10mg or 20mg taken once daily

Kidney impairment:

Your doctor may prescribe you (or your child) a lower dose.

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.

If you have the impression that the effects of Lisinopril Tablets are too strong or too weak, talk to your doctor or pharmacist as soon as possible.

In the beginning of treatment and/or during dosage adjustment, more frequent medical checkups may be necessary. You should not skip these visits even if you feel well. Your doctor will determine the frequency of these visits.

If you take more Lisinopril Tablets than you should

Contact your doctor or nearest hospital immediately if you have taken more than you should (overdose)

An overdose can cause very low blood pressure which can lead to light headedness and dizziness. Symptoms may also include shortness of breath, a rapid or slow pulse, palpitations, anxiety or coughing.

If you forget to take Lisinopril Tablets

Do not take a double dose to make up for a forgotten tablet. Just resume your usual schedule.

If you stop taking Lisinopril Tablets

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.

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

Headache. Dizziness or light headedness especially when standing up quickly. Low blood pressure. Diarrhoea, vomiting. Cough. Reduced function of the kidneys.

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

Tiredness. Weakness (loss of strength). Mood changes. Sleep disturbances. Vertigo. Skin rash. Itching. Change of colour (pale blue followed by redness) and/or numbness or tingling in the fingers or toes. Running nose. Taste disturbances, nausea, stomach pain or indigestion. Impotence. Awareness of heart beat, rapid heartbeat. Heart attack or stroke, possibly secondary to very low blood pressure in high risk patients. Increased level of blood urea, serum creatinine or potassium in the blood. Increased level of liver enzymes.

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

Allergy/angioneurotic oedema with symptoms like swelling of the extremities, face, lips, tongue and/or throat which may cause difficulty in breathing and/or swallowing, this may be more frequent in black patients than in nonblack patients. Confusion. Dry mouth. Hair loss. Psoriasis. Development of breasts in men. Renal failure. Changes to some of the cells or other parts of the blood. Itchy skin rash (urticaria). Increases in serum bilirubin (orange-yellow pigment in the bile). Low sodium level. Acute renal failure. Uraemia (retention on the blood stream of waste products normally excreted in the urine). Inappropriate secretion of a hormone of the brain regulating the water balance of the body (syndrome of inappropriate anti-diuretic hormone secretion/SIADH).

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

Inflammation of the paranasal sinuses (sinusitis). Narrowing of the airways accompanied by shortness of breath (bronchospasm). Inflammation of the lungs. Yellow skin and/or eyes (jaundice). Inflammation of the liver or pancreas. Hepatic failure. Sweating. Serious blistering skin disease (pemphigus). Skin rash (erythema multiforme), severe form of skin flushing (Steven-johnson syndrome), severe rash involving reddening, peeling and swelling of skin equivalent to severe burns (toxic epidermal necrolysis). Pseudolymphoma in the skin. Intense inflammation. Abnormally low or no urination. Decrease in serum glucose.

Side effects of unknown frequency (frequency cannot be estimated from the available data):

Faint, depressive symptoms

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

Stop taking Lisinopril Tablets and seek attention immediately

if you develop difficulty in swallowing or breathing with or without swelling of the face, lips, tongue and/or throat or if you develop swelling of the hands, feet or ankles with itching in the same area, also if you have severe itching of the skin with raised lumps (allergy).

Rarely, as mentioned above there may be changes to some of the cells or other parts of your blood. It is possible that your doctor may occasionally take blood samples to check whether Lisinopril Tablets has had any effect on your blood. Sometimes these changes may show themselves as tiredness or a sore throat, or they may be accompanied by a fever, joint and muscle pains, swelling of the joints or glands, or sensitivity to sunlight. If you are uncertain you should consult with your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Lisinopril Tablets

- Do not store above 25°C.
- Store in the original package in order to protect from moisture.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date printed on the carton, label and blister foil.
- 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 contain

The active substance in Lisinopril 2.5mg and 5mg Tablets is Lisinopril as lisinopril dihydrate.

The other ingredients are: Mannitol (E421), Calcium hydrogen phosphate dihydrate (E341), Pregelatinised starch, Croscarmellose sodium, Magnesium stearate.

What Lisinopril looks like and contents of the pack

Lisinopril 2.5mg Tablets are White, round, biconvex tablets.

Lisinopril 5mg Tablets are White, round, flat tablets

Lisinopril 2.5mg and 5mg Tablets are presented in blister packs of 28 tablets contained in a cardboard carton

Manufacturer:

Actavis, Barnstaple, EX32 8NS, UK.

Product procured from within the EU by the Parallel Product**Authorisation Holder:**

WPR Healthcare Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Parallel Product Authorisation number: PPA 565/46/1-2**Product repackaged and distributed by: PCO Manufacturing, Unit 10,**

Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

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

Germany Lisinopril-Actavis 2.5 mg/ 5 mg/10 mg/20 mg Tabletten

Austria Lisinopril Actavis 5 mg/10 mg/20 mg Tabletten

Czech Republic Lisinopril +pharma 2.5 mg/ 5 mg/10 mg/20 mg

Estonia Lisinopril Actavis

Hungary Linipril

Ireland Lestace 2.5 mg/5 mg/10 mg/ 20 mg Tablets

Italy Lisinopril Actavis

Lithuania Lisinopril Actavis

Latvia Lisinopril Actavis

Poland Linipril

Romania Lisinopril Actavis 2.5 mg/ 5 mg/10 mg/20 mg tablets

Slovak Republic Lisinopril +pharma 2.5 mg/ 5 mg/10 mg/20 mg

Slovenia Lisinopril Actavis 2.5 mg/ 5 mg/10 mg/20 mg

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