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PACKAGE LEAFLET: INFORMATION FOR THE USER

LISINOPRIL 2.5 mg, 5 mg, 10 mg & 20 mg TABLETS

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. **Content of the pack and other information**

1. WHAT LISINOPRIL IS AND WHAT IT IS USED FOR

Lisinopril belongs to a group of medicines called ACE inhibitors. These work by causing your blood vessels to relax, making it easier for your heart to pump blood around your body.

Lisinopril tablets can be used to treat:
- high blood pressure, also called hypertension
- heart failure, where the heart has difficulty pumping blood around your body
- patients who are stable but have had a heart attack within the last 24 hours (short term treatment)
- kidney disease in diabetic patients with 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.
If you are not sure why you have been prescribed this medicine then please ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LISINOPRIL

Do not take Lisinopril if you:
- are allergic to Lisinopril or any of the other ingredients of this medicine (listed in section 6).
- have ever had an allergic reaction to other ACE inhibitors medicines. The signs of an allergic reaction can include rash, swelling of the hands, feet, ankle, lips, face, throat or tongue, and difficulty in swallowing or breathing(angioedema).
- 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.
- a member of your family had a severe allergic reaction (angioedema) to an ACE inhibitor or you have had severe allergic reaction (angioedema) without a known cause.
- are more than 3 months pregnant, (it is also better to avoid Lisinopril in early pregnancy - see pregnancy section).
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.
If you develop a dry cough which is persistent for a long time after starting treatment with Lisinopril, talk to your doctor.

Warning and precautions
Talk to your doctor or pharmacist **before** taking Lisinopril if:
- you have a narrowing (stenosis) of the aorta (an artery in your heart), or a narrowing of the heart valves (mitral valves).
- you have a narrowing (stenosis) of the kidney artery.
- you have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- you have problems with your blood vessels (collagen vascular disease).
- you have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up.
- you have kidney problems or you are having kidney dialysis.
- you have liver problems.
- you have diabetes.
- 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:
  - temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer).
  - racecadotril, a medicine used to treat diarrhoea.
  - vildagliptin, a medicine used to treat diabetes.
- 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.
- Swelling of the head, neck, or hands and feet (angioedema)

If you experience swelling of the face, hands, feet, lips, tongue or throat (angioedema) during treatment with Lisinopril, stop taking the medicine and contact your doctor or nearest hospital immediately. This can occur at any time during treatment.

Your doctor may check your kidney function, blood pressure, and the amount of electrolyte (e.g. potassium) in your blood at regular intervals. See also information under the heading “Do not take Lisinopril”.
- 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. 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 section).
- if you are of black origin as Lisinopril may be less effective. You may also more readily get the side effect ‘angioedema’ (a severe allergic reactions).

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

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

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

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 heading “Do not take Lisinopril” and “Warning and precautions”)
- water tablets (diuretic medicines)
- beta-blocker medicines, such as atenolol and propranolol
- nitrate medicines (for heart problems)
- Non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and arthritis
- aspirin (acetylsalicylic acid), if you are taking more than 3 grams 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)
- medicines to suppress the body’s immune response (immunosuppressants)
- allopurinol (for gout)
- procainamide (for heart beat 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 avoid rejection of transplanted organs (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section 2 “Warnings and precautions”
- racecadotril used to treat diarrhoea
- vildagliptin, a medicine used to treat diabetes.

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 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 they 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
You may feel tired or dizzy while taking Lisinopril. If this happens, do not drive or use any tools or machines and tell your doctor.

3. HOW TO TAKE LISINOPRIL

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Once you have started taking Lisinopril your doctor may take blood tests. The dose of Lisinopril will depend on the condition being treated and any other medicines you are taking.

Taking your medicine
Swallow the tablets with a glass of water, with or without food. They should be taken at the same time each day. Keep taking Lisinopril for as long as your doctor tells you, it is a long-term treatment. It is important to keep taking Lisinopril every day.

Taking your first dose
The first Lisinopril tablets you take might make you feel dizzy or light-headed.
This is because the first dose may make your blood pressure fall by more than the doses you take after that. It may help to lie down until you feel better. If you are concerned, please talk to your doctor as soon as possible.

The recommended dose is:
Adults
Your dose depends on your medical condition and whether you are taking any other medicines. Your doctor will tell you

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how many tablets to take each day. Check with your doctor or pharmacist if you are unsure.

For high blood pressure
- The starting dose is usually 10 mg daily. This may be increased gradually to a maintenance dose of usually 20 mg each day. The maximum daily dose is 80 mg.
- The actual dose, decided by your doctor, will depend on your blood pressure and other medical conditions.
- If you are taking a high dose of water tablets (diuretics), your doctor may ask you to stop taking them for 2 to 3 days before you start taking Lisinopril.

For heart failure
- Lisinopril will usually be given with a diuretic (water tablet) and where necessary, medicines used to reduce heart function.
- The starting dose is usually 2.5 mg each day.
- It can be increased to as much as 35 mg once daily; your doctor will decide this depending on how your condition changes with Lisinopril. Any change will be done gradually over a number of weeks.

After a heart attack
- Treatment may be started within 24 hours of having a heart attack
- The usual starting dose of 5 mg each day for 2 days may be increased to 10 mg on the third day.
- Treatment may continue for about 6 weeks after your heart attack.

For kidney disease in diabetic patients with high blood pressure
- The usual maintenance dose is 10 mg - 20 mg once daily.

People with kidney problems
- If you have kidney problems, the doctor will alter the amount of Lisinopril you take depending on how well your kidneys are working
- If you are on kidney dialysis your dosage will vary day by day. Your doctor will let you know what your dose should be.
- Lisinopril should not be used in patients who have recently had a kidney transplant

Elderly
Your dose will be decided by your doctor. It will depend on how well your kidneys are working.

Use in children and adolescents
Aged 6 to 16 years with high blood pressure:
The dose depends on the child's bodyweight. 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. Patients with kidney problems should take a lower dose. Your doctor will decide the correct dose for you.

Children under 6 years:
Lisinopril is not recommended for use in children under 6 years.

If you take more Lisinopril than you should
Contact your doctor or go to the nearest hospital casualty department straight away. Take the medicine pack with you so the doctor knows what you have taken. The following effects are most likely to happen: Dizziness, palpitations.

If you forget to take Lisinopril
If you miss a dose do not worry. Take your normal dose when it is next due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lisinopril
Take your medicine until your doctor tells you to stop. If you feel better, do not stop taking the tablets. If you stop them, your condition may get worse.
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 get any of the following side effects, STOP TAKING Lisinopril and tell your doctor immediately or go to the nearest hospital emergency department:
- Severe allergic reaction (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 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).

Tell your doctor or pharmacist if you notice any of the following side effects:
Common (may affect up to 1 in 10 people)
- Headache
- Feeling dizzy, faint or light-headed when standing up quickly, this could be due to low blood pressure
- Diarrhoea, being sick (vomiting)
- Dry cough that does not go away.
- Impaired kidney function, (shown in a blood test).

Uncommon (may affect up to 1 in 100 people)
- Mood changes
- a feeling of dizziness or "spinning" (vertigo)
- change in the way things taste
- sleep problems
- unusual skin sensations such as numbness, tingling, pricking, burning, or creeping on the skin (paraesthesia)
- Heart problems including increased heart rate, uneven heart beat, chest pain and more serious conditions including heart attack and stroke
- Raynaud's phenomenon. Symptoms include toes or fingers that change colour when exposed to the cold or when pressure is put on them, pain in the fingers or toes when cold, tingling or pain on warming
- Runny nose, itching, sneezing and stuffy nose (rhinitis)
- Itchy, lumpy rash
- Difficulty in getting an erection or ejaculating (impotence)
- Tiredness, lack or loss of strength (weakness)
- Feeling sick (nausea)
- Stomach pain or indigestion
- Skin rash or itching
- 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
- Seen and/or heard hallucinations

Rare side effects (may affect up to 1 in 1,000 people)
- Feeling confused
- Dry mouth
- Hair loss or balding
- Breast enlargement in men
- Pale or red irregular raised patches with severe itching (hives)
- Psoriasis (itchy scaly pink patches on the elbows, knees, scalp and other parts of the body)
- High levels of urea and other waste products in the blood due to kidney failure, acute kidney failure
- Changes in the way things smell
- 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 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)
- Syndrome of inappropriate antidiuretic hormone secretion (SIADH)

Very rare side effects (may affect up to 1 in 10,000 people)
- Low blood sugar levels (hypoglycaemia). You may feel hungry or weak, a fast heart beat, a sense of nervousness, shaky or sweaty
- Narrowing of the airways, blocked or runny nose (sinusitis)
- Inflammation or infection of the lungs due to an allergy (allergic alveolitis or eosinophilic pneumonia) The signs include cough, feeling short of breath and high temperature (fever)
- Swelling of the intestines (intestinal angioedema), symptoms are stomach pain with or without feeling sick or being sick (vomiting)
- Excessive sweating
- Passing less urine than usual over the day
- Severe difficulty breathing, wheezing, tightness in the chest
- Yellowing of the skin or the whites of the eyes (jaundice)
- Inflammation of the liver. 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
- Liver failure
- Lumps
- Bone marrow depression, anaemia, thrombocytopenia, leucopenia, neutropenia, agranulocytosis, haemolytic anaemia, lymphadenopathy, autoimmune disease

Not known (frequency cannot be estimated from the available data)
- Anaphylactic/anaphylactoid reaction
- Depressive symptoms, syncope(fainting)

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

If any of the side effects become 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

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

Do not use this medicine after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lisiopril tablets contain
The active substance (the ingredient that makes the tablets work) is Lisinopril dihydrate.

The other ingredients are calcium hydrogen phosphate dehydrate (E341), magnesium stearate, maize starch, mannitol (E421), and croscarmellose sodium.

The 10 mg and 20 mg tablets also contain iron oxide (E172).

What Lisinopril tablets look like and contents of the pack
The 2.5 mg tablets are circular white tablets.

The 5 mg tablets are circular white tablets.

The 10 mg tablets are circular light pink tablets.

The 20 mg tablets are circular pink tablets.

All four strengths of Lisinopril tablets come in blister packs of 28, 30, 50, 84 and 100 tablets. Not all pack sizes may be marketed.

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For more information about this product, please contact the Marketing Authorisation Holder.

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