

and blueness of the fingers (Raynaud's phenomenon), running nose, feeling sick, stomach pain, indigestion, reduced sexual potency in men, tiredness, weakness or loss of strength, increases in blood urea, creatinine and potassium levels, rash, itching.

Rare (may affect 1 in 1,000 people):

Decreases in haemoglobin and haematocrit, mental confusion, dry mouth, pale or red irregular raised patches with severe itching (hives), hair loss, 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, enlarged breasts in men, increases in blood levels of bilirubin, decreases in blood levels of sodium, syndrome of inappropriate antidiuretic hormone secretion (SIADH).

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

Reduced production of blood cells by the bone marrow, lymph node disease – enlargement of lymph nodes, autoimmune disease, changes in the numbers and types of your blood cells (anaemia, thrombocytopenia, eosinophilia, leucocytosis, leucopenia, neutropenia, agranulocytosis, haemolytic anaemia). If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test, low blood sugar levels, narrowing of the airways, sinusitis, inflammation or infection of the lungs due to an allergy (allergic alveolitis or eosinophilic pneumonia), inflammation of the liver (hepatitis) or pancreas, swelling of the intestines (intestinal angioedema), liver failure, an abnormally low or non production of urine, sweating, serious blistering skin disease (pemphigus), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson Syndrome), widespread skin rash – circular, irregular red patches on the skin of the hands and arms (erythema multiforme), 'symptom complex' which may include one or more of the following: fever, blood vessel inflammation, muscle pain (myalgia), joint pain (arthralgia) or inflammation (arthritis), blood changes (such as positive antinuclear antibodies, elevated red blood cell sedimentation rate), sensitivity to sunlight or artificial light (e.g. sun beds), or other skin reactions.

Not known (frequency cannot be estimated from the available data): Fainting, depression.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store

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

Do not store above 25°C.

If you are using half tablets, be careful to keep them safely in the pack.

Do not use this medicine after the expiry date which is stated on the label/carton/bottle after 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 to protect the environment.

6 Contents of the pack and other information

What Lisinopril tablets contain

The active substance (the ingredient that makes the medicine work) is lisinopril as lisinopril dihydrate. Each tablet contains either 2.5mg, 5mg, 10mg or 20mg of the active ingredient.

The other ingredients are mannitol (E421), calcium hydrogen phosphate dihydrate (E341), pregelatinised maize starch, croscarmellose sodium and magnesium stearate. The 10mg and 20mg tablets also contain iron oxide (E172).

What Lisinopril tablets look like and contents of the pack

2.5mg tablets are white, round, biconvex tablets.

5mg tablets are white, round, flat tablets.

10mg tablets are light pink, round, biconvex tablets.

20mg tablets are pink, round, biconvex tablets.

Pack size is 28.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

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actavis

Actavis, Barnstaple, EX32 8NS, UK

actavis

Lisinopril 2.5mg, 5mg, 10mg and 20mg tablets

2 What you need to know before you take

Do not take Lisinopril tablets:

- if you are **allergic** to lisinopril, other ACE inhibitors (such as captopril, ramipril) or any of the other ingredients of this medicine (listed in section 6).
- if you have **previously had allergic reactions** with swollen legs, arms, face, mucous membranes and tongue with ACE inhibitors.
- if you or any of **your family have experienced allergic symptoms**, which may be unrelated to the use of medicines.
- 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

Talk to your doctor or pharmacist before taking Lisinopril tablets if you:

- are **dehydrated** due to sickness and diarrhoea, use of diuretics (water tablets), on a low salt diet or have severe renin-dependent hypertension.
- have **reduced blood flow** to the heart (ischaemic heart disease) or disease of the blood vessels in the brain (cerebrovascular disease).
- have any of the following **heart diseases**: heart failure, narrowing (stenosis) of the opening of the aortic or mitral valve or enlarged heart (hypertrophic cardiomyopathy).
- have had a **heart attack** and have low blood pressure or are in cardiogenic shock.
- have reduced **kidney** function, narrowing of the arteries supplying the kidneys or renovascular hypertension (high blood pressure due to a blockage in a blood vessel in the kidney).
- are having **dialysis** or have had a **kidney transplant**.
- are receiving treatment to lessen your reactions to **bee or wasp stings** or for so called **LDL apheresis**

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**
- 3 How to take**
- 4 Possible side effects**
- 5 How to store**
- 6 Contents of the pack and other information**

1 What Lisinopril tablets are and what they are used for

Lisinopril belongs to a group of medicines called ACE inhibitors. These cause the blood vessels to relax, making it easier for the blood to pass through them.

Lisinopril tablets are used to treat:

- high blood pressure.
- heart failure.
- diabetic kidney disease in patients with high blood pressure.
- patients who are stable but have had a heart attack within the last 24 hours (short term treatment).
- 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.

- have had **surgery** on your **airways**.
- have problems with your **immune system** due to some illness or medicines such as scleroderma, lupus erythematosus, allopurinol, procainamide or drugs to suppress the immune system (especially if you also have impaired kidney function). You should tell your doctor if you have any sign of infection.
- have **diabetes**.
- are **Afro-Caribbean**. If you are taking Lisinopril tablets as the only treatment for your high blood pressure, you may have a reduced response to this medicine. This may mean that you may need a higher dose than usually recommended.
- 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 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 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”

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 they may cause serious harm to your baby if used at that stage (see pregnancy section).

Other medicines and Lisinopril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- **Diuretics** (water tablets) - cause a large drop in blood pressure.
- **Potassium-sparing diuretics** (e.g. spironolactone, triamterene or amiloride), potassium supplements, potassium salts or any other medicines that can increase levels of potassium in the blood (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole). Frequent monitoring of the potassium levels in the blood is necessary.
- **Anaesthetics** - the blood pressure lowering effect of Lisinopril tablets is enhanced when taken with these medicines. Therefore, it is important that the doctor/hospital is informed

about your treatment with Lisinopril tablets.

- **Lithium** (used to treat depression) - when taken with Lisinopril tablets an increase of lithium levels may occur. Frequent monitoring of lithium levels in blood is necessary.
- **Non-steroidal anti-inflammatory drugs** (NSAIDs - pain killer and anti-inflammatory medicine) including **aspirin** (doses of greater than or equal to 3g a day) - may reduce the blood pressure lowering effect of Lisinopril tablets. These medicines also cause an increase in potassium levels in blood and reduce kidneys function.
- **Allopurinol** (used to treat gout), medicines used to suppress the **immune system** or **procainamide** (used to treat heart rhythm disorders).
- Tricyclic **antidepressants**, **muscle relaxants** or **antipsychotics** – may further reduce your blood pressure.
- **Sympathomimetics** (used in asthma) - may reduce the blood pressure lowering effect of Lisinopril tablets.
- **Antidiabetics** (tablets and insulin)- when taken with Lisinopril tablets blood glucose may be reduced further, particularly during the first weeks of treatment with Lisinopril tablets and in patients with reduced kidney function.
- Other **blood pressure lowering** medicines e.g. fosinopril – cause an increase in the blood pressure lowering effect when taken together with Lisinopril tablets.
- **Glycerol trinitrate**, other **nitrates** or **vasodilators** e.g. hydralazine – may lower your blood pressure further.
- **Gold** – may cause flushing, dizziness, blood pressure to drop too much or feeling sick.
- 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 “Warnings and precautions”.

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” and “Warnings and precautions”)

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 tablets are 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.

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Breast-feeding

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

Use of Lisinopril tablets may cause side effects such as dizziness, tiredness or confusion which may affect your ability to drive or operate machinery. Make sure you are not affected before driving or operating machinery.

Tests

Your doctor may want to carry out tests to monitor your kidney function and the amount of potassium in your blood.

Surgery

You should inform your doctor that you take Lisinopril tablets if you are having an operation or an anaesthetic.

3 How to take

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

Swallow the tablets with a glass of water **with or without food**. They should be taken at the same time each day.

The 5mg, 10mg and 20mg tablets can be cut in half.

Doses:

- **Adults** (occasionally some people start their treatment under medical supervision)
 - **High blood pressure**
Initial dose is 10mg once daily.
Your doctor may increase your dose to a maintenance dose of 20mg once daily, up to a maximum dose of 80mg once daily. If you are already taking diuretics, your doctor may tell you to stop taking the diuretic for several days before beginning treatment with Lisinopril tablets.
 - **Heart failure**
Usually given with a diuretic (water tablet) and where necessary, medicines used to reduce heart function.
Initial dose is 2.5mg once daily, up to a maximum of 35mg once daily.
 - **After a heart attack**
The first dose is 5mg, followed by 5mg after 24 hours, 10mg after another 24 hours and then a maintenance dose of 10mg once daily for 6 weeks.
 - **Diabetic kidney disease in patients with high blood pressure**
The usual maintenance dose is 10mg – 20mg once daily.

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• Children under 6 years

- **The use of Lisinopril is not recommended.**

• Children and adolescents aged 6 and 16 years

The dose depends on your 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. Patients with kidney problems should take a lower dose. Your doctor will decide the correct dose for you

Impaired kidney function

If you have impaired kidney function your doctor will decide on the best dose for you, up to a maximum of 40mg once daily.

Lisinopril tablets are not recommended for use in kidney transplant patients.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include low blood pressure, disturbed circulation due to low blood pressure in blood vessels (circulatory shock), electrolyte imbalance, kidney failure, rapid breathing (hyperventilation), a racing heart beat, palpitations, a slow heart beat, dizziness, anxiety, cough.

If you forget to take the tablets

Do not take a double dose to make up for a forgotten tablet. Simply skip the forgotten dose and continue on schedule.

4 Possible side effects

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

Stop taking Lisinopril tablets and contact your doctor immediately if you develop:

- yellowing of the skin or whites of the eyes (jaundice).
- an increase in liver enzymes (seen in a blood test).
- symptoms of an allergy (hypersensitivity): swelling of the face, lips, tongue, throat, hands or feet, difficulty breathing or swallowing.

Tell your doctor if you notice any of the following side effects or they get worse:

Common (may affect up to 1 in 10 people)
Dizziness, low blood pressure (causing dizziness especially on standing), cough, diarrhoea, being sick, headache, impaired kidney function.

Uncommon (may affect up to 1 in 100 people):
Changes in mood, ‘pins and needles’ or tingling, spinning sensation, taste disturbance, sleep disorder, heart attack or stroke possibly as a result of excessive low blood pressure in high risk patients, palpitations, a racing heart beat, condition causing pain, numbness, coldness

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