

Lisinopril and Hydrochlorothiazide
10 mg/12.5 mg and
20 mg/12.5 mg Tablets
Lisinopril and Hydrochlorothiazide

PACKAGE LEAFLET:
INFORMATION FOR THE USER

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.

Lisinopril and Hydrochlorothiazide will be referred to as "Lisinopril/HCTZ" throughout this leaflet.

What is in this leaflet:

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

1 What Lisinopril/HCTZ is and what it is used for

Lisinopril belongs to a group of drugs called angiotensin-converting enzyme (ACE) inhibitors. ACE inhibitors are vasodilators (drugs which widen the blood vessels) making it easier for the heart to pump blood around the body.

Hydrochlorothiazide belongs to a group of drugs called diuretics or "water tablets". Diuretic medicines increase the amount of water you lose in your urine and therefore reduce the amount of fluid in your blood vessels.

Because each of these drugs reduces blood pressure in a different way, Lisinopril and Hydrochlorothiazide may be used together to treat high blood pressure when taking either of these drugs alone did not control your blood pressure sufficiently.

2 What you need to know before you take Lisinopril/HCTZ

Do not take Lisinopril/HCTZ:

- if you are allergic to lisinopril or hydrochlorothiazide, any other ACE-inhibitors or any of the other ingredients of this medicine (listed in section 6)
- if you are more than 3 months pregnant. (It is also better to avoid Lisinopril/HCTZ in early pregnancy – see section 2: Pregnancy and breast-feeding.)
- if you are allergic to sulphonamide derived drugs, e.g. trimethoprim
- if you have suffered an unexplained allergic reaction or an allergic reaction to any other ACE inhibitors, e.g. captopril, enalapril, which has led to swelling of the face, lips, tongue and/or throat
- if you have been diagnosed with a condition known as hereditary angioedema or have a history of angioedema (a sudden, severe swelling of the skin in a particular area which commonly affects the eyes, lips, nose, tongue, voice box (larynx), hands, or bowel)
- if you have severe liver or kidney problems.
- take the drug aliskiren (to treat hypertension).
- 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 this medicine:

- if you have diabetes (as your insulin requirements may change)
- if you have severe high blood pressure
- if you have hypertrophic cardiomyopathy (disorder of the heart muscle)
- if you have heart failure
- if you have narrowing of the aortic or mitral valve
- if you have insufficient blood supply to your heart (ischaemic heart disease)
- if you have insufficient blood supply to your brain (cerebrovascular disease)
- if you have narrowing of the arteries leading to the kidneys, any other kidney problems, are undergoing dialysis or have had a kidney transplant
- if you have impaired liver function
- if you have a collagen vascular disease (a problem with the immune system that can affect the structure of tendons, bones, and connective tissues) such as: rheumatoid arthritis, systemic lupus erythematosus or scleroderma
- if you have been on a low sodium diet
- if you are suffering from diarrhoea or vomiting
- if you have an imbalance of salts in your blood
- if you suffer from gout
- if you have a history of allergy or bronchial asthma
- if you are up to 3 months of pregnant
- if you are undergoing haemodialysis or having LDL apheresis (removal of cholesterol from the blood by machine).
- if you are of black race or Afro-Caribbean origin as Lisinopril/HCTZ may be less effective in lowering blood pressure
- 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 Lisinopril/HCTZ'.

If any of the above applies to you, or if you are not sure, please talk to your doctor or pharmacist before taking this medicine.

You must tell your doctor if you think you are (or might become) pregnant. Lisinopril/HCTZ 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 section 2: Pregnancy and breast-feeding).

Tell your doctor you are taking Lisinopril/HCTZ if you:

- have to undergo a desensitisation treatment for an allergy e.g. bee or wasp stings
- are to have an operation and/or anaesthetic (including at the dentist): tell the doctor or dentist that you are taking Lisinopril/HCTZ Tablets
- are to have a liver function test or other blood tests, as Lisinopril/HCTZ may affect the results
- are to take an anti-doping test, as Lisinopril/HCTZ may produce a positive result.

While taking Lisinopril and Hydrochlorothiazide Lisinopril/HCTZ Tablets, Your doctor will monitor your condition closely, take blood tests, check your kidney function and monitor the level of salts in your blood from time to time.

Children and adolescents

Lisinopril/HCTZ is not recommended for use in children and adolescents because safety and efficacy of Lisinopril/HCTZ in children has not been established.

Other medicines and Lisinopril/HCTZ

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

- other drugs to reduce blood pressure such as diuretics ("water tablets") e.g. amiloride, vasodilators or nitrates
- anti-psychotics e.g. chlorpromazine (for the treatment of mental disorders)
- tricyclic antidepressants (e.g. amitriptyline)
- lithium
- insulin, or tablets for the treatment of diabetes such as metformin or gliclazide
- muscle-relaxing drugs such as tubocurarine (given sometimes during a general anaesthetic)
- laxatives e.g. lactulose
- carbenoxolone (used to treat stomach and duodenal ulcers)
- Amphotericin B (used in the treatment of fungal infections)
- calcium salts
- cardiac glycosides e.g. digoxin
- medicines used to treat abnormal heart rhythms such as sotalol (a beta-blocker), procainamide
- non-steroidal anti-inflammatory drugs (NSAIDs) which are a type of pain killer, e.g. diflunisal or ibuprofen
- gold preparations
- sympathomimetic drugs e.g. adrenaline, noradrenaline, or ephedrine. Ephedrine may be present in medicines for colds and nasal stuffiness.
- drugs that reduce fat levels in your blood such as lovastatin (a cholesterol lowering agent), colestyramine or colestipol
- potassium supplements, potassium-sparing agents or potassium-containing salt substitutes
- ciclosporin (used following organ transplant)
- trimethoprim (used to treat urinary and respiratory tract infections)
- allopurinol for the treatment of gout
- medicines to treat cancer, or immunosuppressive drugs (used following an organ transplant)
- corticosteroids, e.g. prednisolone and ACTH (to treat inflammation in diseases such as rheumatoid arthritis).
- 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/HCTZ' 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/HCTZ before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lisinopril/HCTZ. Lisinopril/HCTZ is not recommended during 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. Lisinopril/HCTZ 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.

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.

Driving and using machines

- Lisinopril/HCTZ may reduce your ability to drive and use machines at the start of treatment or when the dose is modified, especially when taken in combination with alcohol. If you are affected, DO NOT drive or operate machinery.

3 How to take Lisinopril/HCTZ

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

If you are already taking diuretics your doctor may reduce your dose of these, or even tell you to stop taking them before you start to take Lisinopril/HCTZ.

Your doctor will monitor you during treatment and this may include blood or urine tests.

Adults (including elderly):

- Lisinopril/HCTZ should be taken once a day. The tablets should be swallowed preferably with a glass of water. Your dose will be decided by your doctor, depending on your response to treatment. The maximum daily dose of 40 mg lisinopril/ 25 mg hydrochlorothiazide should not be exceeded.

Children and adolescents under 18 years of age.

Lisinopril/HCTZ is not recommended in children and adolescents under 18 years of age.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Lisinopril/HCTZ than you should

If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause faintness or dizziness (due to a drop in blood pressure), rapid breathing, anxiety and a cough.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Lisinopril/HCTZ

Do not take a double dose to make up for a forgotten dose, take one as soon as you remember, unless it is nearly time to take the next one. Take the remaining doses at the correct time.

If you stop taking Lisinopril/HCTZ

You should continue to take these tablets for as long as your doctor tells you to. Do not stop taking your medicine without talking to your doctor first even if you feel better.

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 the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if any of the following happen:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you experience any of the following effects:

- heart attack or stroke in susceptible patients
- symptoms including feeling or being sick, abdominal and back pain; these may be signs of pancreatitis (inflammation of the pancreas).

These are serious but uncommon (may affect up to 1 in 100 people) side effects.

- a serious illness with blistering of the skin, mouth eyes and genitals (Stevens-Johnson Syndrome), or severe blistering and peeling of large areas of the skin (toxic epidermal necrolysis)
- jaundice (yellowing of the skin and whites of the eyes); this may be a sign of inflammation of the liver (hepatitis), liver failure.

These are serious but very rare (may affect up to 1 in 10,000 people) side effects.

If you are taking Lisinopril/HCTZ tablets for the first time, you may feel dizzy or light-headed for a short time afterwards. This is unlikely to happen when you are taking the tablets regularly. Tell your doctor if you continue to experience these effects and are worried about them.

The following side effects have been reported at the approximate frequencies shown:

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

- dizziness or light-headedness (including feeling faint on standing)
- low blood pressure (which may make you feel dizzy or faint)
- dry cough
- tiredness, lethargy (a feeling of tiredness, drowsiness, or lack of energy)
- headache
- kidney problems
- diarrhoea or being sick.

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

- feeling sick
- feeling weak
- a sensation that your surroundings are spinning (vertigo)
- changes in your sensation of taste
- dry mouth
- indigestion
- abdominal pain
- rash, itching
- gout (sudden, unexpected, burning pain, as well as swelling, redness, warmth, and stiffness in the affected joint)

- chest pain, awareness of your heart beating (palpitations), fast heart rate
- poor circulation, coldness in the fingers and toes
- muscle spasms and/or weakness, 'pins-and-needles' or numbness (usually in the hands, arms, legs or feet)
- impotence (difficulty getting or maintaining an erection)
- mood swings
- sleep difficulties
- runny and itchy nose.
- change in colour in your fingers or toes (Raynaud's phenomenon).

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

- a complex of symptoms including, fever, muscle and joint pain, redness, pain and inflammation of blood vessels, sensitivity to light or other skin problems
- unusual bleeding, unexplained bruising, sore throat, ulcers in the mouth or throat, fever or chill; these may be signs of anaemia
- hair loss
- psoriasis (thick patches of inflamed, red skin covered in silvery scales)
- enlargement of the male breasts
- mental confusion
- itchy rash of the skin (nettle rash).
- kidney failure.
- Syndrome of inappropriate antidiuretic hormone secretion (SIADH).

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

- swollen glands (lymph nodes)
- increased immune response (autoimmune disease)
- breathing difficulties
- blocked or stuffy nose with a headache
- difficulty in passing urine or not passing any at all
- inflammation of lungs (allergic alveolitis, eosinophilic pneumonia)
- swelling of the lining of the gut
- blistering, peeling and other problems of the skin
- excessive sweating
- low levels of blood sugar (symptoms of this may include headache, feeling faint, mental confusion, aggressive or abnormal behaviour, slurred speech).

Not known (frequency cannot be estimated from the available data):

- loss of appetite
- restlessness, depression
- flushing
- blurred vision, or a yellow tint to your vision
- abnormality of the rhythm or rate of heart beat
- constipation
- inflammation of the salivary glands.
- damage to blood vessels causing red or purple spots in the skin.

Results of tests may show:

- sugar in the urine
- high or low levels of potassium, low levels of sodium, high levels of uric acid, high levels of sugar, increase in cholesterol and other fats in the blood, increased levels of liver enzyme, bone marrow depression and other blood disorders.

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 Lisinopril/HCTZ**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 outer packaging. 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 protect the environment.

6 Contents of the pack and other information**What Lisinopril/HCTZ contains:**

- The active substances are either 10 mg of lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide, or 20 mg of lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide.
- The other ingredients are pregelatinised starch, maize starch, calcium hydrogen phosphate anhydrous, mannitol and magnesium stearate.

What Lisinopril/HCTZ looks like and contents of the pack:

- Each Lisinopril/HCTZ 10 mg/12.5 mg tablet is white oval shaped slightly arched, indented "LZ10" on one side and a breakline on the other.
- Each Lisinopril/HCTZ 20 mg/12.5 mg tablet is white oval shaped slightly arched, indented "LZ20" on one side and a breakline on the other.
- The product is available in packs of 28, 30, 50, 98, and 100 tablets and in hospital packs of 50 (EAV: unit dose hospital pack), and 100. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: TEVA UK Limited, Eastbourne, BN22 9AG.

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