

Package leaflet: Information for the user

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

lisinopril and hydrochlorothiazide

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.

Teva 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/HCTZ contains lisinopril and hydrochlorothiazide.

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/HCTZ 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 or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to ACE inhibitors
- if you are allergic to sulphonamides (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
- if you are more than 3 months pregnant. (It is also better to avoid Lisinopril/HCTZ in early pregnancy – see section 'Pregnancy and breast-feeding')
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lisinopril/HCTZ:

- if you think you are (or might become) pregnant. Lisinopril/HCTZ Tablets are not recommended in early pregnancy and may cause serious harm to your baby after three months of pregnancy (see section 'Pregnancy and breast-feeding').
- if you are at risk of high levels of potassium in your blood e.g. from taking potassium-containing salt substitutes or supplements
- 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 have heart (aortic or mitral) valve disease or an enlarged heart
- if you have liver disease or liver problems
- if you have kidney problems, need dialysis treatment or have had a kidney transplant
- if you have diabetes. You may need a different dose of your antidiabetic medicine (including insulin).
- if you suffer from gout
- if you have a history of allergy, bronchial asthma or SLE (system lupus erythematosus is an allergic condition causing joint pain, rashes and fever)
- if you need blood separation treatment (apheresis) or desensitisation treatment e.g. following a wasp or bee sting; your doctor may wish to interrupt treatment with this medicine to prevent a possible allergic reaction
- if you need to have surgery or a general anaesthetic. Tell the doctor, dentist or hospital staff you are taking this medicine, as there may be a sudden fall in blood pressure.
- if you take lithium (a medicine for mood stabilisation)
- if you play competitive sports, as hydrochlorothiazide is a banned substance and may give a positive result in anti-doping tests
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Lisinopril/HCTZ.
- if you are of black race or Afro-Caribbean origin: ACE inhibitors may be less effective in lowering blood pressure in this group of patients and a higher dose of this medicine may be needed.
- 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 are taking any of the following medicines, the risk of angioedema may be increased:
 - racecadotril, a medicine used to treat diarrhoea;
 - medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus);
 - vildagliptin, a medicine used to treat diabetes.

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'.

While taking 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.

If you experience sudden swelling of the lips, face, neck, and possibly hands and feet, a rash, difficulty swallowing or breathing, hoarseness, these are signs of a serious allergic reaction called angioedema. This may occur at any time during treatment. There is a higher risk in patients of black race or Afro-Caribbean origin. If this occurs **stop taking the tablets and tell your doctor immediately** or go to the casualty department at your nearest hospital.

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:

- diuretics ("water tablets") such as furosemide, torasemide, amiloride
- non-steroidal anti-inflammatory drugs (NSAIDs) which are a type of pain killer, e.g. aspirin or ibuprofen
- gold preparations
- other drugs to reduce blood pressure, as your blood pressure may become too low
- 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')
- tricyclic antidepressants (e.g. amitriptyline), as these will further reduce your blood pressure
- anti-psychotics e.g. chlorpromazine (used for the treatment of mental disorders), which may cause low blood pressure
- sympathomimetic drugs e.g. adrenaline, noradrenaline, or ephedrine as the effectiveness of lisinopril may be reduced. Ephedrine may be present in medicines for colds and nasal stuffiness.
- insulin or tablets for the treatment of diabetes, as the risk of 'hypos' may be increased
- allopurinol for the treatment of gout, as there is an increased risk of blood disorder called leukopenia (a reduction in the number white blood cells) and of kidney failure
- ciclosporin (used following organ transplant), as the risk of kidney failure may be increased
- lovastatin (a drug that reduces fat levels in your blood)
- procainamide, used to treat abnormal heart rhythms as there is an increased risk of blood disorder called leukopenia (a reduction in the number white blood cells)
- cytostatics (drugs for treatments of cancer) and immunosuppressives
- amphotericin B (used for the treatment of serious infections caused by fungi)
- carbenoxolone (used in the treatment of stomach and duodenal ulcers)
- corticosteroids e.g. prednisolone
- hormone called corticotropine (ACTH)
- laxatives e.g. lactulose
- calcium supplements
- cardiac glycosides e.g. digoxin
- drugs that reduce the fat levels in your blood such as colestyramine or colestipol, as they may impair the absorption of hydrochlorothiazide. Lisinopril/HCTZ must be taken at least one hour before or four to six hours after these drugs.
- sotalol (beta-blocker), as there is an increased risk of abnormalities of the heart rhythm
- 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)
- lithium, as lithium levels may be increased

- 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”.

Lisinopril/HCTZ with alcohol:

Drinking alcohol when taking Lisinopril/HCTZ can have addictive effects and cause dizziness or light-headedness.

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 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

Driving and using machines

If you feel tired or dizzy do not drive or operate machines, especially at the start of your treatment or if you medicine has changed, or if taken with alcohol.

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 older people):

Lisinopril/HCTZ should be taken once a day. The tablets should be swallowed with a drink of water. Your dose will be decided by your doctor, depending on your response to treatment.

The maximum daily dose of 40mg Lisinopril/ 25 mg Hydrochlorothiazide should not be exceeded.

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 or 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 develop any of the following symptoms let your doctor know if:

- you feel dizzy after your first dose. A few people react to their first dose or when the dose is increased by feeling dizzy, weak, faint and sick. Lie down if your blood pressure drops too low. This is a common (may affect up to 1 in 10 people) side effect.
- you develop a cough which is persistent and dry. This is a common (may affect up to 1 in 10 people) side effect.
- you develop complaints such as a dry mouth, thirst, lethargy, muscle pain or cramps, a racing heart, dizziness, feeling or being sick, and passing less urine. These are signs of a fluid or mineral imbalance in the body. This is rare (may affect up to 1 in 1,000 people) side effect.
- you develop a high temperature, sore throat and mouth ulcers, which are signs of a low white cell count in the blood. This is very rare (may affect up to 1 in 10,000 people) side effect.

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

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

- 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)
- increased levels of some substance in your blood (urea, creatinine, potassium, liver enzymes).

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
- 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)
- hair loss (alopecia)
- kidney failure.

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

- reduced number of platelets in your blood
- swollen glands (lymph nodes)
- increased immune response (autoimmune disease)
- breathing difficulties
- blocked or stuffy nose with a headache (sinusitis)
- inflammation of lungs (allergic alveolitis, eosinophilic pneumonia)
- swelling of the lining of the gut
- difficulty in passing urine or not passing any at all
- 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):

- skin and lip cancer (Non-melanoma skin cancer)
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V*. 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 carton. The expiry date refers to the last day of that month.

Do not store above 30 °C.

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, mannitol and magnesium stearate.

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

- Each Lisinopril/HCTZ 10mg/12.5mg tablet is white oval shaped slightly arched, indented “LZ10” on one side and a breakline on the other.
- Each Lisinopril/HCTZ 20mg/12.5mg 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

<To be completed nationally>

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

<To be completed nationally>

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APPROVALS

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