

Lispril-Hydrochlorothiazide 10 mg/12.5 mg tablets

Active substances: Lisinopril and Hydrochlorothiazide

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT LISPRIL-HYDROCHLOROTHIAZIDE IS AND WHAT IT IS USED FOR

Lisinopril belongs to a group of medicines called angiotensin converting enzyme inhibitors (ACE inhibitors) and lowers blood pressure by widening the blood vessels.

Hydrochlorothiazide belongs to a group of drugs called diuretics (“water tablets”) and lowers blood pressure by increasing urine output.

Lispril-Hydrochlorothiazide contains a combination of lisinopril and hydrochlorothiazide and is used as a treatment for high blood pressure when treatment with lisinopril as a single agent on its own has proven insufficient.

Your doctor may also prescribe Lispril-Hydrochlorothiazide instead of separate tablets of the same doses of lisinopril and hydrochlorothiazide. This fixed dose combination is not suitable for initial therapy.

2. BEFORE YOU TAKE LISPRIL-HYDROCHLOROTHIAZIDE

Do NOT take Lispril-Hydrochlorothiazide:

- if you are allergic (hypersensitive) to lisinopril, hydrochlorothiazide or any of the other ingredients of this medicine
- if you are allergic (hypersensitive) to other ACE inhibitors e.g. ramipril or to sulphonamide-derived medicines (mostly antibiotics e.g. sulphamethoxazole)
- if you have previously suffered from swelling of the extremities, face, lips, throat, mouth or tongue (angioedema) when treated with other medicines belonging to a group of drugs called ACE inhibitors (angiotensin-converting enzyme inhibitors) such as ramipril
- if you have previously suffered from swelling of the extremities, face, lips, throat, mouth or tongue (angioedema) under any other circumstances
- if anyone among your blood relatives has previously suffered from swelling of the extremities, face, lips, throat, mouth or tongue (angioedema)
- if you have severe kidney problems
- if you have severe liver problems
- if you suffer from an inability to pass water (anuria)
- if you are more than 3 months pregnant (It is also better to avoid Lispril-Hydrochlorothiazide 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 before taking Lispril-Hydrochlorothiazide:

- if you have narrowing of the arteries (atherosclerosis), cerebrovascular problems such as a stroke or transient ischaemic attack (TIA, a “mini-stroke”)
- if you have heart failure
- if you have low blood pressure, are on a salt restricted diet or are taking diuretics (“water tablets”)
- if you have abnormal levels of water and minerals in your body (fluid/electrolyte imbalance)
- if you have heart muscle disease (hypertrophic cardiomyopathy), a narrowing of the main artery carrying blood away from the heart, the aorta (aortic stenosis), or other forms of a heart problem called outflow obstruction
- if you undergo LDL apheresis (removal of cholesterol from the blood by a machine)
- if you undergo desensitisation therapy to some insect venoms, such as bee or wasp stings
- if you have diabetes
- 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 Lispril-Hydrochlorothiazide”.

- if you suffer from gout, have high levels of uric acid in your blood or are being treated with allopurinol
- if you need to have an anaesthetic
- if you have recently suffered from prolonged, violent vomiting and/or serious diarrhoea
- if you are going to have tests to check your parathyroid function
- if you have or have had liver or kidney problems, or you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you are undergoing haemodialysis
- if you have collagen vascular disease such as systemic lupus erythematosus (SLE) or scleroderma, which may be associated with skin rashes, joint pain and fever
- if you have allergy problems or asthma
- if you are taking lithium, used for the treatment of some psychiatric illness
- if you think you are (or might become) pregnant. Lispril-Hydrochlorothiazide 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 being treated with other water tablets (diuretics). To other treatment should be stopped 2-3 days before starting treatment with Lispril-Hydrochlorothiazide.

Lispril-Hydrochlorothiazide is not generally recommended if the following apply, so talk to your doctor before starting to take this medicine:

- if you have recently had a kidney transplant
- if you have high levels of potassium in your blood.

Please refer also to “Other medicines and Lispril-Hydrochlorothiazide” below.

Talk to your doctor if you are an athlete taking a doping test, as Lispril-Hydrochlorothiazide contains an active ingredient that can cause positive results in a doping test.

Elderly or malnourished patients should be particularly careful when using Lispril-Hydrochlorothiazide.

Lispril-Hydrochlorothiazide may be less effective in black people.

This medicine is not recommended for use in children.

While taking Lispril-Hydrochlorothiazide:

If you develop any of the following symptoms you should let your doctor know immediately:

- You feel dizzy after your first dose. A few people react to their first dose or when their dose is increased by feeling dizzy, weak, faint and sick
- Sudden swelling of the lips and face neck, possibly also hands and feet, or wheezing or hoarseness. This condition is called angioedema. This may occur at any time during treatment. ACE inhibitors cause a higher rate of angioedema in black patients than in non-black patients.
- High temperature, sore throat or mouth ulcers (these may be symptoms of infection caused by the lowering of the number of white blood cells)
- Yellowing of the skin and whites of eyes (jaundice) that may be sign of liver disease.
- A dry cough which is persistent for a long time. Cough has been reported with the use of ACE inhibitors but may be also a symptom of other upper respiratory track disease.
- Short sightedness or glaucoma.

Other medicines and Lispril-Hydrochlorothiazide

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

This particularly applies to:

- potassium supplements, or potassium-containing salt substitutes and potassium-sparing diuretics
- other medicines used to treat high blood pressure
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 Lispril-Hydrochlorothiazide” and “Warnings and precautions”).
- anesthetics and medicines for mental disorders or depressions, medicines to treat psychoses, tricyclic antidepressants, or sedatives
- lithium (medicines for depression)
- painkillers and anti-inflammatory medicines, such as acetylsalicylic acid (> 3000 mg/day) or indomethacin
- Sodiummaurothiomalat (gold), a medicine to injection against rheumatic arthritis
- sympathomimetics, drugs such as ephedrine, noradrenaline or adrenaline used for the treatment of hypotension, shock, cardiac failure, asthma or allergies
- blood sugar lowering medicines, such as insulin or those taken orally
- colestyramine resin and colestipol, active substances for lowering blood lipid values
- corticosteroids, anti-inflammatory hormone-like substances
- ACTH, used to test whether your adrenal glands are working properly
- muscle relaxants (e.g. tubocurarine chloride, medicines for relaxing muscles that are used in operations)
- allopurinol, medicinal products used to treat gout
- medicines to treat cancer, such as cyclophosphamide or methotrexate
- medicines that inhibit your body’s immune system, medicines to prevent rejection reactions after organ or bone marrow transplants
- cyclosporine medicines to prevent rejection reactions after organ or bone marrow transplants
- cardiac glycosides (e.g. digoxin, medicines for strengthening the heart)
- medicines that as a side effect cause abnormalities in the stimulus conduction in the heart such as medicines for disturbances for heart rhythm, some medicines for psychosis and other medicines such as drugs used to treat bacterial infections
- calcium salts, elevated calcium levels in the blood
- amphotericin B, medicines against fungal infections
- laxatives, medicines to promote defecation
- carbenoxolone active substance for the treatment of gastrointestinal diseases
- trimethoprim, medicines against bacterial infections
- lovastatin medicine against high cholesterol
- sotalol (a beta-blocker), the risk for arrhythmias is increased.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, herbal or natural products.

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 Lispril-Hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lispril-Hydrochlorothiazide. Lispril-Hydrochlorothiazide 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. Lispril-Hydrochlorothiazide 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

Dizziness and tiredness have been reported by people taking Lispril-Hydrochlorothiazide. If you experience either of these do not drive a car and do not operate machinery (see also “4. Possible side effects”).

3. HOW TO TAKE LISPRIL-HYDROCHLOROTHIAZIDE

Always take Lispril-Hydrochlorothiazide exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

The usual dose is one tablet taken once a day.

The maximum daily dose is 40 mg lisinopril and 25 mg hydrochlorothiazide.

Children

Safety and effectiveness in children and adolescents have not been established.

Elderly

No special dosage adjustment is necessary.

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Kidney problems

Use of Lispril-Hydrochlorothiazide is contraindicated if you have severely impaired kidney function. If you suffer from a kidney disorder, the doctor should prescribe the lowest possible dose and monitor your kidney function.

Previous treatment with a water tablet (diuretic)

If you are being changed from a water tablet to Lispril-Hydrochlorothiazide, you should have stopped taking the water tablet 2-3 days before you start taking this medicine.

Method of administration

Take the tablet or half the tablet with plenty of water. Try to take the medicine at the same time each day.

Dividing:

Place the tablet on a hard, flat surface with the break-line facing upwards. Press with a finger on the middle of the tablet and the tablet breaks into two parts.

If you take more Lispril-Hydrochlorothiazide 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, seek medical advice immediately.

An overdose is likely to cause low blood pressure, circulatory shock, electrolyte disturbances, renal failure, hyperventilation (rapid breathing, feeling and being sick), an excessively fast or slow heartbeat, palpitations (a feeling of unduly rapid or irregular heart beat), dizziness, anxiety and 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 a Lispril-Hydrochlorothiazide tablet

Do not take a double dose to make up for a forgotten tablet, take your next dose at the normal time.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking Lispril-Hydrochlorothiazide

The treatment of hypertension is a long term treatment and interruption of treatment must be discussed with the doctor. Interruption or stopping your treatment could cause your blood pressure to increase.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lispril-Hydrochlorothiazide can cause side effects, although not everybody gets them.

Side effects can occur with the following frequencies:

| | |
|-------------|---|
| Very common | more than 1 user in 10 |
| Common | 1 to 10 users in 100 |
| Uncommon | 1 to 10 users in 1,000 |
| Rare | 1 to 10 users in 10,000 |
| Very rare | less than 1 user in 10,000 |
| Not known | frequency cannot be estimated from available data |

If you experience the following, stop taking Lispril-Hydrochlorothiazide and tell your doctor immediately or go to the emergency department of your nearest hospital:

- A severe allergic reaction called angioedema (rash, itching, swelling of the extremities, face, lips, mouth or throat that may cause difficulty in swallowing or breathing).
This is a serious and **rare** side effect. You may need urgent medical attention or hospitalisation.
- Jaundice (yellowing of the skin and the whites of the eyes).
This is a potentially serious but **very rare** side effect indicative of inflammation of the liver. You may need urgent medical attention or hospitalisation.

Lispril-Hydrochlorothiazide **commonly** causes low blood pressure which may be associated with feelings of light-headedness and weakness. In some patients, this may occur after the first dose or when the dose is increased. If you experience these symptoms, you should contact your doctor immediately.

Lispril-Hydrochlorothiazide may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience 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 you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.

A dry cough, which may persist for a long time, has been reported **commonly** with the use of Lispril-Hydrochlorothiazide and other ACE inhibitors, but may be also a symptom of other upper respiratory tract disease. You should contact your doctor if you develop this symptom.

The following side effects have also been reported:

Common

- dizziness, headache, sudden loss of consciousness
- low blood pressure associated with changes in posture (such as feeling lightheaded or weak when you stand up after lying down)
- cough (see beginning of this section)
- diarrhoea, vomiting
- kidney problems.

Uncommon

- mood changes
- tingling feeling or numbness, vertigo, taste abnormalities, difficulty in sleeping
- heart attack or cerebrovascular accident ("mini-stroke") (mainly in patients suffering from low blood pressure)
- palpitations (a sensation of a fast or particularly strong or irregular heartbeat)
- excessively fast heartbeat (tachycardia)
- raynaud's syndrome, a blood vessel disorder which may cause your fingers and toes to tingle, and turn pale, then blueish, then reddish.
- inflammation of the lining of the nose causing the nose to run (rhinitis)
- nausea, abdominal pain and indigestion
- increase in the amount of enzymes and waste products produced by the liver
- skin rash and /or itching
- impotence
- tiredness, general weakness
- increase in the amount of urea in the blood
- high levels of potassium in the blood, which can cause an abnormal heart rhythm; increase in the amount of creatinine in the blood.

Rare

- decrease of the red blood pigment haemoglobin and number of red blood cells (haematocrit)
- mental confusion
- dry mouth
- hypersensitivity/angioneurotic oedema (see beginning of the section), itchy rash, hair loss, thickened patches of red/silver skin
- kidney problems
- breast enlargement including in men
- low levels of sodium in the blood, which can cause tiredness and confusion, muscle twitching, fits or coma, also leading to dehydration and low blood pressure that makes you feel dizzy when you stand up
- blood tests showing less sodium than usual in your blood.

Very rare

- reduction in the number of white blood cells, which makes infection more likely, reduction in the number of other blood cells, poor production of bone marrow, disease of the lymph nodes, autoimmune disease, in which the body attacks itself.
- reduction in the number of red blood cells, which can make the skin pale and cause weakness or breathlessness (anaemia)
- hypoglycaemia (low blood sugar levels) (see "Take special care with Lispril-Hydrochlorothiazide" in section 2)
- difficulty breathing, wheezing
- inflammation of nasal sinuses
- lung problems including pneumonia
- inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis)
- swelling in the intestines
- liver problems *
- excessive sweating (diaphoresis), severe skin disorders including Stevens-Johnson Syndrome and aggregate of mature or abnormal looking lymphocytes in the dermis (cutaneous pseudolymphoma) **
- reduced urine production.

* Very rarely, it has been reported that in some patients the undesirable development of hepatitis has progressed to hepatic failure. Patients receiving lisinopril/hydrochlorothiazide combination who develop jaundice or marked elevations of hepatic enzymes should discontinue lisinopril-hydrochlorothiazide combination and receive appropriate medical follow up.

** A symptom complex has been reported which may include one or more of the following: fever, inflammation of a blood vessel (vasculitis), muscle pains (myalgia), pains in the joints (arthralgia) and inflammation of the joints (arthritis), increased quantity of antibodies (ANA), increased blood sedimentation rate, rash and increase in the number of white blood cells (eosinophilia and leukocytosis), rash, photosensitive to light or other skin reactions can occur.

Not known

- inflammation of a salivary gland
- increased blood sugar, fat or uric acid levels, glucose in the urine; low levels of potassium in the blood, which can cause muscle weakness, twitching or abnormal heart rhythm; high levels of calcium in the blood causing abdominal pain, feeling sick and being sick, constipation, loss of appetite, excessive thirst, excessive urinating, tiredness, weakness and weight loss, painful and swollen joints, decreased level of magnesium and chloride in the blood
- restlessness
- vision disturbances
- necrotising vasculitis (inflammatory condition of blood vessels)
- sensitivity of the skin to light, skin conditions with red scaly patches over the nose and cheeks (lupus erythematosus) – this condition may be worsened in patients who already have it, severe allergic reactions
- muscle spasms, muscle weakness
- inflammation in the kidneys (interstitial nephritis)
- fever
- depressive symptoms.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LISPRIL-HYDROCHLOROTHIAZIDE

Keep out of the reach and sight of children.

Do not use Lispril-Hydrochlorothiazide after the expiry date which is stated on the blister and the carton after "EXP". The expiry date refers to the last day of that month.

Storage conditions

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Lispril-Hydrochlorothiazide contains:

The **active substances** are: lisinopril and hydrochlorothiazide

Each tablet contains lisinopril dihydrate equivalent to 10 mg lisinopril and 12.5 mg hydrochlorothiazide.

The **other ingredients** are: calcium hydrogen phosphate dihydrate, croscarmellose sodium, mannitol, maize starch, magnesium stearate and red iron oxide (E172).

What Lispril-Hydrochlorothiazide looks like and contents of the pack

The tablets are pink, round, biconvex and scored on one side.

The tablet can be divided into equal halves.

The tablets are packed in PVC/aluminium blisters and inserted into a carton.

Lispril-Hydrochlorothiazide are available in pack sizes of 14, 28, 30, 50, 56, 98, 100 and 400 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

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

BE: Co-Lisinopril Sandoz 10/12.5 mg tabletten
IE: Lispril-Hydrochlorothiazide 10 mg/12.5 mg Tablets
UK: Lisinopril + HCT 10/12.5 mg Tablets

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