

## Package leaflet: Information for the patient

### **lisinopril/hydrochlorothiazide 10/12.5 mg Tablets** **lisinopril/hydrochlorothiazide 20/12.5 mg Tablets** **lisinopril / 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.

#### **What is in this leaflet**

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

#### **1. What Lisinopril/Hydrochlorothiazide is and what it is used for**

Lisinopril/Hydrochlorothiazide contains two different active substances: Lisinopril and Hydrochlorothiazide.

**Lisinopril** belongs to the ‘ACE inhibitor’ (Angiotensin-Converting Enzyme inhibitor) group of medicines. It stops your body making a blood pressure increasing substance so your blood pressure falls.

**Hydrochlorothiazide** is a water tablet (diuretic). It increases the amount of salt and water you lose in your urine. This also results in a fall in your blood pressure.

Lisinopril/Hydrochlorothiazide is used to lower high blood pressure.

#### **2. What you need to know before you take Lisinopril/Hydrochlorothiazide**

##### **Do not take Lisinopril/Hydrochlorothiazide:**

- if you are allergic to:
  - lisinopril, any other ACE inhibitor, hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6)
  - other medicines known as ACE inhibitors
  - any medicine which contains a ‘sulphonamide’, such as co-trimoxazole (used for water infections)
- if you have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema). This may be inherited or from an unknown cause

- 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
- if you have severe liver or kidney problems
- if you are more than 3 months pregnant (It is also better to avoid Lisinopril/Hydrochlorothiazide in early pregnancy – see pregnancy section.)if you have an inability to produce urine
- if you 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 before taking this medicine.

### Warnings and precautions

Talk to your doctor or pharmacist, before taking Lisinopril/Hydrochlorothiazide:

- if you have **heart problems**, such as a weak heart, problems with your heart valves or thickening of your heart muscle.
- if you have **kidney problems**. There is an increased risk of side effects and the dose may have to be adjusted.
- if you have a **kidney transplant**, as experience is limited.
- if you are taking **‘water tablets’ (diuretic therapy)**. Diuretic therapy should be stopped 2 to 3 days before taking Lisinopril/Hydrochlorothiazide. If this is not possible, treatment should not be started with Lisinopril/Hydrochlorothiazide but with lisinopril alone, in a 5 mg dose.
- if you have a condition called **‘collagen vascular disease’**, especially if you have problems with your kidney.
- 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/Hydrochlorothiazide.
- if you have **liver problems**. There is an increased risk for severe side effects.
- if you have **diabetes**. You may have to monitor your sugar levels more closely and your dose of antidiabetic medicine may have to be adjusted by your doctor.
- 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/Hydrochlorothiazide”

- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) may be increased:
  - sirolimus, temsirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to prevent rejection of transplanted organs and for cancer)
  - racecadotril, a medicine used to treat diarrhoea
  - vildagliptin, a medicine used to treat diabetes
- if you have a **blood vessel problem** known as ‘collagen vascular disease’. You may be at risk of severe infections. Your doctor will check your blood more frequently
- if you have **diarrhoea or are being sick** (vomiting) are on a **low salt diet**. Your blood pressure may get too low

- if you have a **disease of the blood vessels in your brain**. You may be at increased risk for stroke
- if you **are black**, this medicine may be less effective and you may have a higher risk of allergic reactions called ‘angioedema’ (see “Possible side effects”)

If you are about to have any of the following procedures or investigations, you should tell your doctor who is treating you that you are taking Lisinopril/Hydrochlorothiazide:

- any surgery or receive anaesthetics (even at the dentist)
- haemodialysis
- desensitisation treatment, to reduce the effect of an allergy
- a function test of your parathyroid gland
- an anti-doping test. This medicine can produce a positive result.

You must tell your doctor if you think you are (or might become) pregnant.

Lisinopril/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).

Lisinopril/Hydrochlorothiazide can cause cough or serious side effects which require immediate medical attention. It is essential that you read section 4 (“Possible side effects”) and follow the instructions carefully if you get any of the symptoms described.

### **Children**

The use in children is not recommended as safety and effectiveness have not been established.

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

### **Other medicines and Lisinopril/Hydrochlorothiazide**

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

This applies in particular if you are also taking:

#### **Medicines that increase the effect of Lisinopril/Hydrochlorothiazide**

- water tablets (diuretics) and other blood pressure lowering medicines. They can also sometimes change the levels of salts in your blood
- antidepressants and antipsychotics (medicines for depression and other mental problems)

#### **Medicines that lower the effect of Lisinopril/Hydrochlorothiazide**

- sympathomimetics such as ephedrine or adrenaline (medicines usually used to treat asthma, heart conditions, eye problems, or blocked noses)
- NSAIDs or ‘Non-Steroidal Anti-Inflammatory Drugs’ such as aspirin, ibuprofen and diclofenac (medicines for pain). They can also reduce the amount of urine you produce.

#### **Medicines which may have an effect on your blood**

- allopurinol (a medicine for gout)
- procainamide (a medicine for disturbances in your heart rhythm)
- cytotoxics (medicines used to treat cancer)

- steroids or ‘corticosteroids’ such as prednisolone. There is also a risk of low potassium in your blood
- immunosuppressants (medicines to stop rejection after organ or bone marrow transplants). There is also a greater risk of you having too much potassium in your blood. This can cause muscle cramps, diarrhoea, feeling sick, dizziness, or headache

Taking these medicines together with Lisinopril/Hydrochlorothiazide may cause serious infections. Your doctor will monitor your blood.

### **Other medicines which change the levels of salts in your blood**

An example of this would be the lowering of potassium in your blood. Medicines include:

- amphotericin B (for fungal infections)
- carbenoxolone (for ulcers and inflammation in your oesophagus)
- ACTH, used to test whether your adrenal glands are working properly
- laxatives
- potassium supplements (including salt substitutes), potassium-sparing diuretics, and other medicines that can increase the amount of potassium in your blood (such as heparin, a medicine used to thin blood to prevent clots; co-trimoxazole and trimethoprim for infections caused by bacteria; and ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection)
- calcium salts and vitamin D.

### **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/Hydrochlorothiazide” and “Warnings and precautions”).

### **Other medicines to tell your doctor about**

- colestyramine or colestipol resins (medicines used to treat high cholesterol). These medicines can affect how hydrochlorothiazide is absorbed into your body. You should take Lisinopril/Hydrochlorothiazide 1 hour before or 4 to 6 hours after your colestyramine or colestipol resin
- blood sugar-lowering medicines (including vildagliptin). Your doctor will monitor your dose. See also section “Warnings and precautions”.
- Sacubitril/valsartan (used to treat long-term heart failure). See section “Do not take Lisinopril/Hydrochlorothiazide digoxin (a medicine for disturbances in your heart rhythm, or heart failure). There is a risk of serious effects on your heart rhythm
- lithium (a medicine used for mental problems). The level of lithium in your blood can increase and cause harmful side effects
- sotalol (a beta-blocker). The risk for arrhythmias is increased.
- laxatives (medicines to promote defecation)
- medicines that have a side effect which causes abnormalities in the stimulus conduction in the heart such as medicines for disturbances of the heart rhythm and some medicines for psychosis
- lovastatin (a medicine against high blood fats)
- 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”.
- racecadotril (used to treat diarrhea). See section “Warnings and precautions”.
- tubocurarine (a medicine for anaesthesia). The effect may be enhanced by Lisinopril/Hydrochlorothiazide

- injectable gold (for example, sodium aurothiomalate) can lead to nitritoid reactions (symptoms of vasodilatation including flushing, nausea, dizziness and hypotension, which can be very severe) more frequently in patients taking an ACE inhibitor.

**Tell your doctor or pharmacist if you are taking any of the above.**

### **Lisinopril/Hydrochlorothiazide with alcohol**

Drinking alcohol while taking this medicine can increase the blood pressure-lowering effect. You may feel dizzy when standing up.

### **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/Hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lisinopril/Hydrochlorothiazide. Lisinopril/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.

- Lisinopril/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:**

You may feel dizzy or tired while taking this medicine. If this happens, do not drive or operate machines.

### **Lisinopril/Hydrochlorothiazide contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Lisinopril/Hydrochlorothiazide**

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

### **How to take the tablet**

- Take the tablet with plenty of water
- Take the tablet once a day, approximately at the same time every day.
- If you feel that the effect of Lisinopril/Hydrochlorothiazide is too strong or too weak, ask your doctor or pharmacist for advice.

The recommended dose is:

**Adults** - 1 tablet a day. The maximum dose is 40 mg lisinopril and 25 mg hydrochlorothiazide per day.

**Elderly** - No special dose is required. If you have kidney problems, you will usually get a lower dose.

### **Use in children**

The use in children is not recommended as safety and effectiveness have not been established.

### **Previous treatment with a water tablet (diuretic)**

If you are being changed from a water tablet to Lisinopril/Hydrochlorothiazide, your doctor may tell you to stop taking the water tablet 2 to 3 days before you start taking this medicine.

### **Kidney problems**

If you have a kidney problem, your doctor will prescribe a lower dose and monitor your kidney function. Lisinopril/Hydrochlorothiazide should not be used if you have severe kidney problems.

### **Dividing the 20/12.5 mg tablets:**

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

### **If you take more Lisinopril/Hydrochlorothiazide than you should**

If you take more Lisinopril/Hydrochlorothiazide than you should, talk to your doctor or go to hospital immediately. The most common signs of an overdose are a feeling of light-headedness or dizziness (this is because your blood pressure is falling) and changes in your salt balance.

In case of a severe fall in blood pressure, the patient should be placed in the shock position (lying flat on the back with legs elevated).

### **If you forget to take Lisinopril/Hydrochlorothiazide**

- If you have forgotten to take a dose, you can take it when you remember unless it is almost time for your next dose. In that case, skip the missed dose and take your next tablet as normal.
- Do not take a double dose to make up for a forgotten dose.

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.

### **Serious side effects**

Stop taking this medicine and see your doctor or go to hospital immediately, if any of the following serious side effects happen:

The following side effects are uncommon (may affect up to 1 in 100 people):

- **heart attack** which can cause crushing chest pain
- **stroke** which can cause weakness or paralysis of your limbs or face or difficulty speaking

The following side effects are rare (may affect up to 1 in 1,000 people):

- if you develop a **red and lumpy skin rash, swelling of your eyelids, lips and face, mouth, tongue or throat**, start to itch or have **difficulty in breathing or swallowing or dizziness**, this may be a serious allergic reaction
- **not going to the toilet** (low urine output) which can also occur with a high temperature (fever), nausea, tiredness, pain in your sides, swelling of your legs, ankles, feet, face and hands or blood in your urine. These are due to kidney problems (sudden kidney failure).

The following side effects are very rare (may affect up to 1 in 10,000 people):

- **severe or itchy skin rash**, especially if your skin blisters or your eyes, mouth or genital organs become sore
- **severe pain in your abdomen and back** caused by inflammation of the pancreas
- **yellowing of your skin and the whites of your eyes** (jaundice), fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, caused by liver problems
- **constant or frequent colds, bruising and prolonged bleeding, pale skin, weakness, or breathlessness**. These can all occur if you have a very low number of blood cells.

These are serious side effects which require immediate medical attention.

#### **Other side effects of lisinopril include:**

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

- low blood pressure, dizziness and fainting on standing up, loss of consciousness
- dizziness
- cough. Talk to your doctor if you have a dry cough for a long time.
- diarrhoea, being sick (vomiting)
- headache
- kidney problems

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

- weakness, feeling sick (nausea)
- fast or irregular heart beat
- abdominal pain, indigestion, disturbed sense of taste, fatigue, mood alterations
- skin rash
- high levels of potassium in your blood, which can cause changes in your heart rhythm
- an increase in your level of creatinine. This will be seen during tests to see how your kidneys are working called 'kidney function tests'.
- runny or stuffy nose, sneezing
- tingling or numbness in your hands and feet, spinning sensation
- itching
- inability to achieve or maintain erection in men (impotence)
- poor blood circulation which makes the toes and fingers numb and pale
- liver problems, shown by blood tests called 'liver function tests'
- sleep disturbance
- depression

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

- rash with pink-red blotches
- dry mouth
- nettle-rash or hives, hair loss
- confusion
- anaemia
- low levels of sodium in your blood
- enlargement of breasts in men
- a complex side effect has also been reported which may include some or all of the following: high temperature, inflammation of your blood vessels, pain and inflammation

in your muscles and joints, blood problems found by blood tests, rash, hypersensitivity to sunlight and other effects on your skin

- syndrome of inappropriate antidiuretic hormone secretion (SIADH). Symptoms of this include weight gain, nausea, vomiting, muscle cramps, confusions and fits (convulsions).

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

- pain in and around your stomach area (the abdomen) and being sick (vomiting), due to a blockage in your small bowel.
- sore throat and hoarseness, difficulty breathing with wheezing or coughing, sinusitis
- excessive sweating
- low levels of sugar in your blood, which can make you feel sick (nausea), weak, dizzy, sweat, tremble, have a headache
- changes in your lymph glands and lower numbers of blood cells usually seen in blood tests
- sore mouth and tongue, runny or stuffy nose, sneezing
- lung problems with breathlessness, or pneumonia

not going to the toilet or going to the toilet less often (low urine output)

**Other side effects of hydrochlorothiazide include** (not known, frequency cannot be estimated from the available data):

- skin and lip cancer (non-melanoma skin cancer)
- loss of appetite, weight loss, fever, weakness
- restlessness, depression, sleep disturbances, muscle spasms
- dizziness, tingling or numbness in your hands and feet, feeling of light-headedness
- dizziness and fainting on standing up
- spinning sensation
- inflammation of a salivary gland, gastric irritation, diarrhoea, constipation
- temporary blurred vision and visual changes which can make a colourless object look tinged with yellow
- high temperature, coughing, difficulty breathing, wheezing caused by inflammation of the lungs, fluid on your lungs
- inflammation of your blood vessels, often with skin rash
- hypersensitivity to light, rash, rash with pink-red blotches, itching, nettle-rash or hives
- kidney problems
- low levels of potassium in your blood, which can cause muscle weakness, twitching or changes in your heart rhythm
- low levels of sodium in your blood, which can cause tiredness, confusion, muscle twitching, fits or coma
- high levels of sugar, cholesterol, triglycerides or uric acid in your blood.
- painful and swollen joints gout
- decrease in the number of red blood cells and blood platelets

### **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 ([www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)) or search for MHRA Yellow Card in 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/Hydrochlorothiazide

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 label/blister and carton after EXP. The expiry date refers to the last day of that month.

10/12.5 mg: Do not store above 25°C.

20/12.5 mg: 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/Hydrochlorothiazide contains

The active substances are lisinopril and hydrochlorothiazide.

Each tablet contains 10 mg of lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide.

Each tablet contains 20 mg of lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide.

The other ingredients are:

mannitol

calcium hydrogen phosphate dihydrate

pregelatinized maize starch

croscarmellose sodium and

magnesium stearate

Lisinopril/Hydrochlorothiazide 10/12.5 mg Tablets also contain:

yellow iron oxide (E 172) and

red iron oxide (E 172)

### What Lisinopril/Hydrochlorothiazide Tablets look like and contents of the pack

- Lisinopril/Hydrochlorothiazide 10/12.5 mg tablets :  
Peach-coloured, round tablets (diameter 6 mm), marked LH on one side.
- Lisinopril/Hydrochlorothiazide 20/12.5 mg tablets :  
White, round tablets (diameter 8 mm) with break-line, marked LH on one side.

Pack sizes:

Blister:

- 10/12.5 mg: 10, 28, 30, 50, 98, 100, 50x1 (perforated unit dose blisters) and 100x1 (perforated unit dose blisters) tablets.
- 20/12.5 mg: 10, 28, 30, 50, 56, 60, 98, 100, 50x1 (perforated unit dose blisters), 100x1 (perforated unit dose blisters) and 500x1 (perforated unit dose blisters) tablets.

PP-container:

100 tablets

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### Marketing Authorisation Holder:

Sandoz Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey , GU15 3YL, United Kingdom

### Manufacturer:

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

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

Salutas Pharma GmbH, Dieselstraße 5, D-70839 Gerlingen, Germany (Applies to Lisinopril/HCT 20/12.5mg Tablet only)

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