Package leaflet: Information for the patient

Losartan/Hydrochlorothiazide 50 mg/ 12.5 mg film-coated tablets
Losartan/Hydrochlorothiazide 100 mg/ 25 mg film-coated tablets

losartan potassium / 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 Losartan/Hydrochlorothiazide is and what it is used for

Losartan potassium belongs to a group of medicines called angiotensin-II receptor antagonists. These cause the blood vessels to relax which in turn lowers the blood pressure.
Hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets). Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

Losartan/Hydrochlorothiazide 50 mg/12.5 mg film-coated tablets:
These tablets are used to treat high blood pressure. The combination of losartan and hydrochlorothiazide is a suitable alternative for those people who would otherwise have to be treated with losartan potassium and hydrochlorothiazide given as separate tablets.

Losartan/Hydrochlorothiazide 100 mg/ 25 mg film-coated tablets:
These tablets are used to treat high blood pressure in patients who have not responded sufficiently to treatment with Losartan/Hydrochlorothiazide 50/12.5 mg film-coated tablets.

2. What you need to know before you take Losartan/Hydrochlorothiazide

Do not take Losartan/Hydrochlorothiazide if you:
- are **allergic** to *losartan, hydrochlorothiazide* or to any of the other ingredients of this medicine (listed in section 6)
- are **allergic** to *sulphonamide derived substances* (e.g. other thiazides, some antibacterial medicines such as co-trimoxazole, ask your doctor if you are not sure)
- **are more than 3 months pregnant.** (It is also better to avoid Losartan/Hydrochlorothiazide in early pregnancy – see pregnancy section)
- have severely **impaired liver** function
- have severely **impaired kidney** function or your kidneys are not producing any urine

- have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- are suffering from gout
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If you think any of the above conditions applies to you, consult your doctor or pharmacists.

Warnings and precautions
Talk to your doctor or pharmacist before taking Losartan/Hydrochlorothiazide.

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

It is important to tell your doctor before taking Losartan/Hydrochlorothiazide if you:
- have **previously suffered from swelling of the face, lips, throat or tongue**
- take diuretics (**water pills**)
- are on a **salt-restricted diet**
- have or have had **severe vomiting** and/or **diarrhoea**
- have **heart failure**
- have impaired liver function (see sections 2 "Do not take Losartan/Hydrochlorothiazide")
- have **narrow arteries to your kidneys** (renal artery stenosis) or only have **one functioning kidney**, or you have recently had a **kidney transplant**
- are on haemodialysis
- have **narrowing of the arteries** (atherosclerosis), **angina pectoris** (chest pain due to poor heart function)
- have 'aortic or mitral valve stenosis' (**narrowing of the valves of the heart**) or 'hypertrophic cardiomyopathy' (a disease causing **thickening of heart muscle**)
- are **diabetic**
- have had **gout**
- have or have had an **allergic condition**, **asthma** or a condition that causes joint pain, skin rashes and fever (systemic **lupus erythematosus**)
- have **high calcium** or **low potassium levels** or you are on a **low potassium diet**
- need **an anaesthetic** (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking Losartan potassium and Hydrochlorothiazide tablets
- have **primary hyperaldosteronism** (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland)
- are taking any of the following medicines used to treat high blood pressure:
  - an **ACE-inhibitor** (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - **aliskiren**
- 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 Losartan/Hydrochlorothiazide.

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 Losartan/Hydrochlorothiazide if you”.

Children and adolescents
The safety and efficacy of Losartan/Hydrochlorothiazide in children and adolescents under the age of 18 years have not been established. Losartan/Hydrochlorothiazide should not be given to children and adolescents.

Talk to your doctor if you are an **athlete taking a doping test**, as Losartan/Hydrochlorothiazide contain an active substance that can cause positive results in a doping test.

Other medicines and Losartan/Hydrochlorothiazide
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to change your dose and/or take other precautions if you are taking:
- lithium (a medicine for **treatment of mania** or **depression**)
- **potassium supplements**
- **potassium-containing salt** substitutes
- **potassium-sparing medicines**
- other diuretics (**water tablets**)
- some **laxatives**
- medicines for the treatment of **gout**
- medicines to control **heart rhythm**
- medicines for **diabetes** (oral agents or insulins)
- medicines to **reduce** your **blood pressure**
- **steroids**
- medicines to **treat cancer**
- **pain killers**
- **arthritis medicines**
- medicines to treat **fungal infections**
- resins used for **high cholesterol** (e.g. colestyramine)
- medicines which **relax muscles**
- **sleeping tablets**
- **opioid medicines** (e.g. morphine)
- medicines called pressor amines (e.g. **adrenaline**)
- **glycyrrhizin** (found in liquorice root)
- **an ACE-inhibitor** or **aliskiren** (see also information under the headings “Do not take Losartan/Hydrochlorothiazide” and “Warnings and precautions”).

Please also inform your doctor you are taking Losartan/Hydrochlorothiazide if you will be undergoing a radiographic procedure and will be given iodine contrast media.

Losartan/Hydrochlorothiazide with food and drink
You are advised not to drink alcohol whilst taking these tablets: alcohol and Losartan/Hydrochlorothiazide may increase each other’s effects.

Dietary salt in excessive quantities may counteract the effect of Losartan/Hydrochlorothiazide.

Losartan/Hydrochlorothiazide may be taken with or without food.

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 Losartan/Hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losartan/Hydrochlorothiazide. Losartan/Hydrochlorothiazide is not recommended in 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.
Losartan/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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
When you begin treatment with this medicine, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

Losartan/Hydrochlorothiazide contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Losartan/Hydrochlorothiazide

Always take Losartan/Hydrochlorothiazide exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose of Losartan/Hydrochlorothiazide depending on your condition and whether you are taking other medicines. It is important to continue taking Losartan/Hydrochlorothiazide for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

Take the tablet with a glass of water. It may be taken with or without food.

Use in adults
Losartan/Hydrochlorothiazide 50 mg/12.5 mg film-coated tablets:
The usual dose is one tablet once daily. If necessary your doctor may increase your dose to a maximum of two tablets once daily or one tablet of *Losartan/Hydrochlorothiazide 100 mg/25 mg film-coated tablets* once daily.

Losartan/Hydrochlorothiazide 100 mg/25 mg film-coated tablets:
The usual dose is one tablet once daily.

Use in the elderly
Dose adjustment is not usually necessary for the elderly.

Use in kidney impairment and haemodialysis
In case of moderate kidney problems dose adjustment is not usually necessary. However, do not take Losartan/Hydrochlorothiazide if your kidney function is severely impaired.
Losartan/Hydrochlorothiazide is not recommended for patients on haemodialysis.

Use in liver impairment

Losartan/Hydrochlorothiazide should be used with caution in patients with history of mild to moderate liver impairment. However, do not take Losartan/Hydrochlorothiazide if your liver function is severely impaired (see section 2. “Do not take Losartan/Hydrochlorothiazide”).

Use in children and adolescents
Losartan/Hydrochlorothiazide should not be given to children and adolescents under 18 years of age.

Use in black patients
Dose adjustment may be necessary as Losartan/Hydrochlorothiazide may be **less effective in black patients than in non-black patients.**

If you take more Losartan/Hydrochlorothiazide than you should
In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take Losartan/Hydrochlorothiazide
Do not take a double dose to make up for a forgotten tablet. Take your next dose at the usual time.

If you stop taking Losartan/Hydrochlorothiazide
Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

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.

If you experience the following, stop taking Losartan/Hydrochlorothiazide and tell your doctor immediately or go to the casualty department of your nearest hospital:

A **severe allergic reaction** (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalization.

The following side effects have been reported:

Common (may affect up to 1 in 10 people):
- cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder
- diarrhoea, abdominal pain, nausea, indigestion
- muscle pain or cramps, leg pain, back pain
- insomnia, headache, dizziness
- weakness, tiredness, chest pain
- increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels
- changes in kidney function including kidney failure
- too low sugar in the blood (hypoglycaemia).

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

- anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems, reduced number of platelets
- loss of appetite, high level of uric acid in the blood or frank gout, high blood sugar level, abnormal level of electrolyte in the blood
- anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment
- pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting
- blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow
- ringing, buzzing, roaring or clicking in the ears, vertigo
- low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up, angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, "mini-stroke"), heart attack, palpitations
- inflammation of blood vessels, which is often associated with a skin rash or bruising
- sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion
- constipation, obstipation, wind, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache
- jaundice (yellowing of the eyes and skin), inflammation of the pancreas
- hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, Lyell syndrome (skin looking as if it were burnt and peeling off), dry skin, flushing, sweating, hair loss
- pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness
- frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary infection, sugar in the urine
- decreased sexual appetite, impotence
- swelling of the face, localized swelling (oedema), fever.

Rare (may affect up to 1 in 1,000 people):
- hepatitis (inflammation of the liver), abnormal liver function tests.

Not known (frequency cannot be estimated from the available data):
- flu-like symptoms
- unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis)
- low levels of sodium in the blood (hyponatraemia)
- generally feeling unwell (malaise)
- disturbed taste (dysgeusia)
- skin and lip cancer (non-melanoma skin cancer).

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: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Losartan/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 carton/ bottle/ blister after EXP. The expiry date refers to the last day of that month.

50 mg/ 12.5 mg, film-coated tablet:
Blister: Store below 30°C.
Bottle: Store below 30°C. Keep the bottle tightly closed in order to protect from moisture.

100 mg/ 25 mg, film-coated tablet:
Aluminium/ aluminium blister: This medicinal product does not require special storage conditions.
ACLAR/aluminium blister: Store below 30°C.
Bottle: Keep the bottle tightly closed in order to protect from moisture.

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 Losartan/Hydrochlorothiazide contains
The active substances are losartan potassium and hydrochlorothiazide.
Each film-coated tablet contains 50 mg losartan potassium and 12.5 mg hydrochlorothiazide.
Each film-coated tablet contains 100 mg losartan potassium and 25 mg hydrochlorothiazide.

The other ingredients are:
Tablet core: lactose monohydrate, cellulose, microcrystalline, maize starch, pregelatinized, magnesium stearate, silica, colloidal anhydrous.
50 mg/ 12.5 mg, film-coated tablets:
Tablet film-coating: hypromellose, hydroxypropylcellulose, iron oxide yellow (E172), titanium dioxide (E171).
100 mg/ 25 mg, film-coated tablets:
Tablet film-coating: hypromellose, hydroxypropylcellulose, iron oxide yellow (E172), titanium dioxide (E171), macrogol (400), talc.

What Losartan/Hydrochlorothiazide looks like and contents of the pack
50 mg/ 12.5 mg, film-coated tablets:
Light yellow, round and biconvex film-coated tablets with a diameter of 8 mm.

100 mg/ 25 mg, film-coated tablets:
Light yellow, round and biconvex film-coated tablets with a diameter of 10 mm.

The film-coated tablets are packed in aluminium foil blisters or plastic bottles with a screw cap.

50 mg/ 12.5 mg film-coated tablets:
Blister: 7, 10, 14, 28, 30, 50, 50x1, 56, 60, 84, 90, 98 and 100 film-coated tablets
Bottle: 100 film-coated tablets

100 mg/ 25 mg film-coated tablets:
Blister: 7, 10, 14, 28, 30, 50x1, 56, 98 and 100 film-coated tablets
Bottle: 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova 57, SI-1526 Ljubljana, Slovenia.
Lek S.A., Ul. Domaniewska 50 C, 02- 672 Warsaw, Poland.
Salutas Pharma GmbH, Otto von Guericke Allee 1, 39179 Barleben, Germany.
Lek Pharmaceuticals d.d., Trimlini 2 D, 9220 Lendava, Slovenia.

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

Austria:	Losartan-HCT Hexal 50 mg/12,5 mg-Filmtabletten
Germany:	Losartan HEXAL comp 50 mg/12.5 mg Filmtabletten
Ireland:	Losartan/Hydrochlorothiazide 50 mg/12.5 mg film-coated tablets
Italy:	Losartan Idroclorotiazide Angenerico 50 mg / 12,5 mg compresse rivestite con film
Luxembourg:	Losartan HEXAL comp 50 mg/12,5 mg Filmtabletten
United Kingdom:	Losartan Potassium/Hydrochlorothiazide 50 mg/12.5 mg Film-coated Tablets
Austria:	Losartan-HCT Hexal 100 mg/25 mg - Filmtabletten
Germany:	Losartan HEXAL comp 100 mg/25 mg Filmtabletten
Ireland:	Losartan/Hydrochlorothiazide 100 mg/25 mg film-coated tablets
Italy:	Losartan Idroclorotiazide Angenerico 100 mg / 25 mg compresse rivestite con film
Luxembourg:	Losartan HEXAL comp 100 mg/25 mg Filmtabletten
Spain:	Losartan/Hidroclorotiazida HEXAL 100 mg/25 mg comprimidos recubiertos con película EFG
United Kingdom:	Losartan Potassium/Hydrochlorothiazide 100 mg/25 mg Film-coated Tablets

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