PACKAGE LEAFLET: INFORMATION FOR THE USER

Lozitar Comp 100 mg / 12.5 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 Lozitar Comp is and what it is used for
2. What you need to know before you take Lozitar Comp
3. How to take Lozitar Comp
4. Possible side effects
5. How to store Lozitar Comp
6. Contents of the pack and other information

1. What Lozitar Comp is and what it is used for

Lozitar Comp is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide).

Lozitar Comp is indicated for the treatment of essential hypertension (high blood pressure).

2. What you need to know before you take Lozitar Comp

Do not take Lozitar Comp
- if you are allergic to losartan and/or hydrochlorothiazide 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 Lozitar Comp in early pregnancy - see pregnancy section.); if you have severely impaired liver function; cholestasis and biliary obstructive disorders
- if you have serverely impaired kidney function (i.e. creatinine clearance <30 ml/min);
- if your kidneys are not producing any urine;
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment;
- if you are suffering from gout.
- If you have diabetes or impaired kidney function and you are treated with blood pressure lowering medicine containing aliskiren.

Warnings and precautions
Talk to your doctor or pharmacist before taking using Lozitar Comp.
- if you have previously suffered from swelling of the face, lips, throat or tongue
- if you take diuretics (water pills)
- if you are on a salt-restricted diet,
- if you have or have had severe vomiting and/or diarrhoea,

- if you have heart failure,
- if you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant,
- if you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function),
- if you have 'aortic or mitral valve stenosis' (narrowing of the valves of the heart) or 'hypertrophic cardiomyopathy' (a disease causing thickening of heart muscle),
- if you are diabetic,
- if you have had gout,
- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematodus).
- if you have high calcium or low potassium levels or you are on a low potassium diet,
- if you need to have 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,
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion, of the hormone aldesterone by the adrenal gland, caused by an abnormality within the gland).
- if you 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

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

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

Diuretic agents such as the hydrochlorothiazide contained in Lozitar Comp may interact with other medicines.

Preparations containing lithium should not be taken with Lozitar Comp without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics ("water tablets"), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins). It is also important for your doctor to know if you are taking other medicines to reduce your blood pressure, steroids, medicines to treat cancer, pain killers, drugs for treatment of fungal infections, or arthritis medicines, resins used for high cholesterol, such as colestyramine, medicines which relax your muscles, sleeping tablets, opioid medicines such as morphine, 'pressor amines' such as adrenaline or other drugs from the same group; (oral agents for diabetes or insulins).

Your doctor may need to change your dose and/or to take other precautions:
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take <Invented name> " and "Warnings and precautions")

Please also inform your doctor when it is planned to apply iodine contrast media about taking Lozitar Comp.

Lozitar Comp with food and drink and alcohol

You are advised not to drink alcohol whilst taking these tablets: alcohol and Lozitar Comp tablets may increase each other's effects.
Dietary salt in excessive quantities may counteract the effect of Lozitar Comp.
Lozitar Comp tablets may be taken with or without food.

Pregnancy and breast-feeding
If you are pregnany or breast-feeding, think you might 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 Lozitar Comp before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lozitar Comp. Lozitar Comp 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. Lozitar Comp is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.
Use in children and adolescents
Lozitar Comp is not recommended for use in children below the age of 18 years due to a lack of data on safety and efficacy.

Use in elderly patients
Lozitar Comp works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

Driving and using machines
When you begin treatment with this medication, 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.

Lozitar Comp contains lactose
– If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Lozitar Comp

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

Lozitar Comp is available in three strengths: Lozitar Comp 50 mg/12.5 mg film-coated tablets, Lozitar Comp 100 mg/12.5 mg film-coated tablets, and Lozitar Comp 100 mg/25 mg film-coated tablets.

High Blood Pressure
The usual dose of Lozitar Comp for most patients with high blood pressure is 1 tablet of Lozitar Comp 50 mg/12.5 mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of Lozitar Comp 50 mg/12.5 mg film-coated tablets or changed to 1 tablet daily of Lozitar Comp 100 mg/25 mg film-coated tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Lozitar Comp 50 mg/12.5 mg film-coated tablets or 1 tablet daily of Lozitar Comp 100 mg/25 mg film-coated tablets.

Lozitar Comp 100 mg/12.5 mg (losartan 100 mg/HCTZ 12.5 mg) film-coated tablets are available for those patients titrated to 100 mg of losartan who require additional blood pressure control.

If you take more Lozitar Comp 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 Lozitar Comp
Try to take Lozitar Comp daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

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 Lozitar Comp tablets 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 hospitalisation.

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.

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 and bruising,
- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels,
- 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,
- 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, 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, 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)
– Rhabdomyolysis

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 HPRA Pharmacovigilance Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. by reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lozitar Comp

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 packaging after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package 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 Lozitar Comp contains

- The active substances are losartan potassium and hydrochlorothiazide. Each film-coated tablet contains 100 mg losartan potassium, equivalent to 91.52 mg losartan and 12.5 mg hydrochlorothiazide.
- The other ingredients are:

pregelatinised maize starch, microcrystalline cellulose, lactose monohydrate and magnesium stearatein the tablet core and hypromellose, macrogol 4000, talc and titanium dioxide (E171) in the film coating.

What Lozitar Comp looks like and contents of the pack

Lozitar Comp tablets are white, oval, biconvex, film-coated tablets.

Tablets are supplied in cartons containing 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90 and 98 film-coated tablets in Al/PVC/PVDC blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

PA Number: 281/141/1

Manufacturers

1. KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
2. TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

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

Name of the Member State	Name of the medicinal product
Austria	Losartan/HCT Krka
Bulgaria, Poland, Romania	Lorista HL
Czech Republic, Estonia, Latvia, Lithuania, Slovak Republic	Lorista H
Cyprus, Finland, Norway, Sweden	Losartan/Hydrochlorothiazide Krka
Denmark	Losartankalium/hydrochlorthiazid Krka
Germany	Losartan-Kalium HCTad
Hungary	Lavestra H
Ireland	Lozitar Comp
Portugal	Losartan+ Hidroclorotiazida Krka
Spain	Losartan/Hidroclorotiazida Krka
United Kingdom	Losartan Potassium/Hydrochlorothiazide
Italy	Losartan e Idroclorotiazide Krka

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