PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

LOSARTAN POTASSIUM 25mg, 50mg AND 100mg FILM-COATED TABLETS

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 further questions, please ask your doctor or your pharmacist.**
- **This medication 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 Tablets are and what they are used for
2. What you need to know before you take Losartan Tablets
3. How to take Losartan Tablets
4. Possible side effects
5. How to store Losartan Tablets
6. Contents of the pack and other information

The name of your medicine is Losartan potassium 25mg, 50mg or 100mg film-coated tablets. Your medication is referred to as Losartan Tablets or Losartan throughout this leaflet.

1. WHAT LOSARTAN TABLETS ARE AND WHAT THEY ARE USED FOR

Losartan Tablets belong to a group of medicines known as angiotensin-II receptor antagonists.
Angiotensin II is a chemical in your body, which tightens your blood vessels making it harder for the blood to pass through them and causes your blood pressure to increase.
Losartan blocks this effect, causing the blood vessels to relax and so lowers your blood pressure.
Your doctor has prescribed Losartan to:

- **treat hypertension** (high blood pressure) in adults and in children and adolescents 6-18 years of age
- **protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥ 0.5mg per day** (a condition in which urine contains an abnormal amount of protein)
- **reduce the risk of stroke in hypertension with left ventricular hypertrophy** (thickening of the heart muscle)
- **treat chronic heart failure** when treatment with ACE inhibitors (angiotensin-converting enzyme inhibitors - medicines used to lower blood pressure) is not considered suitable by your doctor

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOSARTAN TABLETS

DO NOT take Losartan Tablets if you:

- are allergic (hypersensitive) to Losartan or any of the other ingredients listed in section 6 of this leaflet (Contents of the pack and other information)
- are pregnant, think you may be pregnant or you are planning to become pregnant
- are breast-feeding
- have severe liver disease
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

If any of the above applies to you, do not take the tablets. Talk to your doctor first and follow their advice.

Warnings and precautions
Talk to your doctor or pharmacist before taking Losartan if you:

- have a history of angioedema (swelling of the face, lips, throat and/or tongue) see also section 4, Possible side effects
- suffer from liver or kidney problems
- have recently suffered from severe vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body
- receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restrictions leading to an extreme loss of fluid and salt in your body (see section 3, Special dosage requirements)
- received a kidney transplant recently
- suffer from problems with your heart valves or heart muscle (e.g. 'aortic stenosis' or 'outflow obstruction')
- suffer from heart failure, with or without renal impairment or concomitant severe life-threatening cardiac arrhythmias. Special caution is necessary when you are treated with a beta-blocker concomitantly
- if you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain)
- suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland)
- have a high level of potassium in your blood (hyperkalaemia)
- 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 Losartan Tablets if you' above.**

Children and adolescents
Losartan has been studied in children. For more information, talk to your doctor. Losartan is not recommended for use in children suffering from kidney or liver problems, or children under the age of 6 years old, as limited data are available in these patient groups.

Other medicines and Losartan
Before you start to take Losartan tell your doctor or pharmacist about any other medication that you are taking or plan to take, including medicines you have bought without a prescription, herbal medicines and natural products.

In particular tell your doctor if you are taking:
- other blood pressure lowering medicines as they may additionally reduce your blood pressure
- tricyclic antidepressants, antipsychotics, baclofen or amifostine as these may lower your blood pressure further
- lithium (used to treat certain types of mental illness)
- non-steroidal anti-inflammatory painkillers (for example, Ibuprofen, Naproxen or Diclofenac); COX-2 inhibitors (for example, celecoxib, etoricoxib or lumiracoxib) or more than 3grams of aspirin a day
- high-dose diuretics (tablets to help you lose water) e.g. amiloride, triamterene, spironolactone
- potassium supplements, potassium sparing agents or potassium-containing salt substitutes or heparin
- Fluconazole or rifampicin as these might decrease the effect of Losartan when metabolised by the body.

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 Losartan Tablets" and "Warnings and precautions."

Your doctor will decide whether you should take these medicines with Losartan.

Taking Losartan Tablets with food and drink
Losartan can be taken with or without food.

Pregnancy, breast-feeding and fertility
You should not take Losartan in the first 12 weeks of pregnancy, and you must not take it at all after the 13th week, as its use during pregnancy may possibly be harmful to the baby. If you become pregnant while taking Losartan, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy. You must not take Losartan if you are breast-feeding. Always ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
You should not drive or operate machinery, until you know how you react to Losartan potassium tablets as it may cause dizziness or drowsiness. If you experience dizziness or drowsiness, you should consult your doctor before attempting to drive or use machines.

Important information about some of the ingredients of Losartan
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE LOSARTAN TABLETS

You should take the tablets with a drink of water. You must take your tablets every day exactly as your doctor has told you. It is important that you take the tablets for as long as your doctor prescribes them.

Dose for Adults

Hypertension (high blood pressure)
The usual dose of Losartan for most adult patients is one 50mg tablet once a day to control your blood pressure over the 24-hour period. The maximal blood pressure lowering effect should be reached 3-6 weeks after beginning treatment.
If a 50mg daily dose is ineffective, your doctor may prescribe a higher dose of 100mg.

Hypertension with left ventricular hypertrophy (thickening of the heart muscle)
The usual dose of Losartan for most adult patients is one 50mg tablet taken once a day.
Your doctor may also prescribe a low dose of a diuretic and/or increase your daily dose of Losartan to 100mg.

Hypertension and Type-2 diabetes
The usual dose of Losartan for most adult patients is one 50mg tablet taken once a day. Your doctor may increase your dose to 100mg based on how your blood pressure responds to the medicine.

Losartan Tablets may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

Heart failure
Treatment usually starts with 12.5mg Losartan once a day. Generally, the dose should be increased weekly step-by-step (i.e. 12.5mg daily during the first week, 25mg daily during the second week, 50mg daily during the third week, 100mg daily during the fourth week, 150mg daily during the fifth week) up to a maintenance dose determined by your doctor.

Special Dosage Requirements
Your doctor may prescribe a lower dose of 25mg once a day if you:

- are over 75 years of age
- have liver problems
- are being treated with high dose diuretics (water losing tablets)

The use of Losartan is not recommended in patients with severe hepatic impairment.
No dose adjustments are needed for patients with kidney disease or patients on dialysis.

Children less than 6 years of age
Not recommended, as limited data is available in this age group.

Hypertension (high blood pressure) in children aged 6 to 18
For children who can swallow and who weigh:

- between 20 and 50kg: the recommended dose is 25mg once a day (your doctor may increase the dose up to 50mg once a day)
- 50kg or over: the starting dose is 50mg once a day (your doctor may increase the dose up to 100mg once a day).

The doctor will adjust the dose according to the weight of the child and how their blood pressure responds to the medicine. ALWAYS follow your doctor's instructions exactly.

If you take more Losartan Tablets than you should
If you take too many tablets, contact your doctor immediately or go to the nearest hospital casualty department. Symptoms of an overdose may be low blood pressure, fast heart beat or slow heartbeat.

If you forget to take your medicine
Try to take Losartan Tablets each day as prescribed. If you miss a dose, just carry on with the next dose as normal. **DO NOT** take an extra tablet to make up the dose.

If you stop taking your medicine
Do not stop taking your medicine without talking to your doctor, even if you feel better. It is important to continue the course of treatment prescribed to you by your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines Losartan Tablets may cause side effects although not everybody gets them. They are generally mild and do not normally need treatment.

STOP taking Losartan Tablets and contact your doctor or nearest casualty department immediately if you develop any of these symptoms:

- an allergic or hypersensitivity reaction – symptoms may include: rash, itching, hives, swelling of the face, lips, throat or tongue which may cause difficulty in breathing or swallowing; inflammation of the blood vessels, causing hard, purple blotches on the skinfeeling of increased heart rate (palpitations), severe chest pain (angina pectoris)
- inflammation of the liver (hepatitis) – may result in yellowing of the eyes and skin
- anaemia, abnormal bruising or bleeding – may be caused by a reduction in the number of blood cells
- difficulty in passing water or blood in the urine (may be a sign of kidney problems)
- inflammation of the pancreas (pancreatitis) – you may notice severe upper abdominal pain spreading to the back
- unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis)
- stroke

Other side effects reported with Losartan Tablets
Common (affects 1 to 10 patients in 100):

- feeling dizzy
- changes in kidney function including kidney failure
- increase in blood urea and serum creatinine
- weakness or feeling very tiredtoo little sugar in the blood (hypoglycaemia)
- too much potassium in the blood (hyperkalaemia)
    - your doctor will take regular blood samples to monitor the levels of potassium in your blood
- low blood pressure (due to excessive loss of water from the body) or a rapid drop in blood pressure - symptoms of which may be feeling light-headed or dizzy, particularly when standing up

Uncommon (affects 1 to 10 patients in 1,000):

- drowsiness
- headachenausea (feeling sick)
- vomiting (being sick)
- sleep disorders
- difficulty breathing, shortness of breath
- severe constipation
- abdominal painlocalised swelling (oedema)
- diarrhoea
- cough
- rash
- itching
- hives (raised red bumps on skin)

Rare (affects 1 to 10 patients in 10,000):
- angioedema (swelling of the face, lips, throat and/or tongue)
- numbness or tingling sensation (paraesthesia)
- inflammation of blood vessels (vasculitis including Henöch-Schonlein purpura)
- faintingvery rapid and irregular heartbeat (atrial fibrillation)
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment

Not known (cannot be estimated from the available data):
- migraine
- muscle and joint pains, back painflu-like symptoms
- Low platelet count
- Bleeding from gums or nose, prolonged bleeding from cuts (Thrombocytes)
- urinary tract infection
- increased sensitivity to the sun (photosensitivity)
- impotence, erectile dysfunction
- low levels of sodium in the blood (hyponatraemia)
- depression
- generally feeling unwell (malaise)
- ringing, buzzing, roaring, or clicking in the ear (tinnitus)
- distortion of taste
- liver function abnormalities

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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 LOSARTAN TABLETS

Do not take the tablets after the expiry date shown on the carton. The expiry date refers to the last day of that month.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not remove the tablets from the blister pack until you are ready to take them.
There are no special requirements to store the tablets at a particular temperature.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Losartan Tablets contain
The active ingredient in Losartan Tablets is losartan potassium.
Losartan potassium 25mg film-coated tablets contain 25mg of losartan potassium.
Losartan potassium 50mg film-coated tablets contain 50mg of losartan potassium.
Losartan potassium 100mg film-coated tablets contain 100mg of losartan potassium.

Other ingredients include: microcrystalline cellulose, sodium stearyl fumarate, croscarmellose sodium, colloidal anhydrous silica, polyoxyethylene stearate, hypromellose and titanium dioxide (E171).

What Losartan looks like and the contents of the pack
Losartan comes in blister packs containing 28 tablets.
Losartan potassium 25mg tablet is available as a white, oblong, plain, film-coated tablet.
Losartan potassium 50mg tablet is available as a white, oblong, score-line, film-coated tablet.
Losartan potassium 100mg tablet is available as a white, oblong, plain, film-coated tablet.

Marketing authorisation holder

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