

PATIENT INFORMATION LEAFLET

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

Read all of this leaflet carefully before you start taking this medicine, even if you have just had a repeat prescription. Some of the information in your previous leaflet may have changed.

- **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. You should not pass it on to anyone else. It may harm them, even if their symptoms are the same as yours.**
- **If any of the side effects get serious, or if you notice any side effects that are not listed in the leaflet, please tell your doctor or pharmacist.**

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

1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

Losartan belongs 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 $\geq 0.5\text{mg per day}$** (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 - also used to lower blood pressure) is not considered suitable by your doctor

If you have **hypertension (high blood pressure)**, Losartan lowers your blood pressure.

If you have **hypertension with left ventricular hypertrophy**, Losartan can reduce the risk of a stroke.

2. BEFORE YOU TAKE YOUR MEDICINE

DO NOT take Losartan if you:

- are allergic (hypersensitive) to Losartan or any of the other ingredients
- are pregnant, think you may be pregnant or you are planning to become pregnant

- are breast-feeding
- have severe liver disease

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

Before you take Losartan, tell your doctor 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, Dosage in special patient groups)
- 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
- have problems with your heart valves or heart muscle
- 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)

Taking other medicines

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

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

Taking Losartan with food and drink

Losartan can be taken with or without food.

Pregnancy and breast-feeding

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.

3. HOW TO TAKE YOUR MEDICINE

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.

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 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 potassium 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

The usual starting dose for most adult patients is one 12.5mg tablet once a day. Your doctor may gradually increase your dose weekly according to your condition up to the usual maintenance dose of 50mg daily.

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 16

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 potassium 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 heart beat.

If you forget to take your medicine

Try to take Losartan 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 may cause side effects. They are generally mild and do not normally need treatment.

STOP taking Losartan 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, 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 skin
- feeling 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 potassium tablets

Common (affects 1 to 10 patients in 100):

- feeling dizzy
- low blood pressure
- weakness or feeling very tired
- too 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

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

- drowsiness
- headache
- nausea (feeling sick), vomiting (being sick)
- sleep disorders
- 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
- shortness of breath
- severe constipation
- abdominal pain
- localised swelling (oedema)
- diarrhoea
- cough

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

- angioedema
- numbness or tingling sensation (paraesthesia)
- fainting

Not known (cannot be estimated from the available data):

- migraine
- muscle and joint pains, back pain
- flu-like symptoms
- urinary tract infection
- increased sensitivity to the sun (photosensitivity)
- impotence
- low levels of sodium in the blood (hyponatraemia)
- depression
- generally feeling unwell (malaise)
- ringing, buzzing, roaring, or clicking in the ear (tinnitus)

If you develop any of the side effects described, or if you have any other unusual symptoms or feelings not listed in this leaflet, contact your doctor or pharmacist as soon as possible.

5. HOW TO STORE YOUR MEDICINE

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 REACH AND SIGHT 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. FURTHER INFORMATION

What Losartan contains

The active ingredient in Losartan potassium 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

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.

Manufacturer responsible for batch release

Kent Pharmaceuticals Limited, Repton Road, Measham DE12 7DT, U.K.

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent TN24 0GR, U.K **Distributor:**

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