

**Package leaflet:
Information for the user**

**LOSARTAN POTASSIUM
25 mg FILM-COATED
TABLETS**

**LOSARTAN POTASSIUM
50 mg FILM-COATED
TABLETS**

**LOSARTAN POTASSIUM
100 mg FILM-COATED
TABLETS**

Losartan Potassium

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Losartan Potassium Tablets is and what it is used for

Losartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevent the effect of angiotensin-II, causing the blood vessels to relax which in turn lowers your blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type II diabetes.

Losartan Potassium is used

- to treat patient with high blood pressure (hypertension) in adults and in children and adolescents 6-18 years of age
- to protect the kidney in hypertensive type II diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥ 0.5 g per day (a condition in which urine contains an abnormal amount of protein).
- to treat patients with chronic heart failure when therapy with specific medicines called angiotensin-converting-enzyme inhibitors (ACE inhibitors, medicine used to lower high blood pressure) is not considered suitable by your doctor. If your heart failure has been stabilised with an ACE inhibitor you should not be switched to losartan.
- in patients with high blood pressure and a thickening of the left ventricle, Losartan potassium has been shown to decrease the risk of stroke ("LIFE indication").

2. What you need to know before you take Losartan Potassium Tablets

Do not take Losartan Potassium Tablets:

- if you are allergic (hypersensitive) to Losartan or any of its other ingredients (listed in section 6)
- if your liver function is severely impaired
- if you are more than 3 months pregnant (it is also better to avoid Losartan Potassium tablets in early pregnancy – see Pregnancy),
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before taking Losartan Potassium tablets.

You must tell your doctor if you think you are (or might be) pregnant. Losartan Potassium tablet 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 is used at that stage (see pregnancy section).

It is important to tell your doctor before taking Losartan Potassium Tablets:

- if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see also section 4 'possible side effects')
- if you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body
- if you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body (see section 3 'dosage in special patient groups')
- if you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently
- if your liver function is impaired (see sections 2 "Do not take Losartan Potassium tablets" and 3 "Dosage in special patient groups"),
- if you 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 β -blocker concomitantly
- if you 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)
- if you 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)
- 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 Potassium Tablets"

Children and adolescents

Losartan Potassium Tablets has been studied in children. For more information, talk to your doctor. Losartan Potassium Tablets is not recommended for use in children suffering from kidney or liver problems, as limited data are available in these patient groups. Losartan Potassium Tablets is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Other medicines and Losartan Potassium Tablets : Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Take particular care if you are taking the following medicines while under treatment with Losartan Potassium:

- other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following drugs/ class of drugs: tricyclic antidepressants, antipsychotics, baclofen, amifostine,
- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamterene, spironolactone] or heparin),
- non-steroidal anti-inflammatory drugs such as indomethacin, including cox-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood lowering effect of losartan.

If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function. Lithium containing medicines should not be taken in combination with losartan without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

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 Potassium Tablets" and "Warnings and precautions").

Losartan Potassium Tablets with food and drink:

Losartan Potassium Tablets 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. You should not take losartan in the first 12 weeks of pregnancy, and you must not take them at all after the 13th week as their use during pregnancy may possibly be harmful to the baby. If you become pregnant while on losartan, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

Breast-Feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Losartan 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 a newborn, or born prematurely. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

No studies on the effects on the ability to drive and use machines have been performed. Losartan Potassium Tablet is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

Important information about some of the ingredients of Losartan Potassium Tablets

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars (e.g. Lactose), contact your doctor before taking this medicine.

3. How to take Losartan Potassium Tablets

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

Adult patients with High Blood Pressure (Hypertension)

- Treatment usually starts with 50 mg losartan (one tablet of Losartan Potassium 50 mg) once a day.
- The maximal blood pressure lowering effect should be reached 3-6 weeks after beginning treatment. In some patients the dose may later be increased to 100 mg losartan (two tablets of Losartan Potassium 50 mg) once daily

If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

Use in children and adolescents

Children below 6 years of age

Losartan Potassium tablets is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Children aged 6 - 18 years old

- The recommended starting dose in patients who weigh between 20 and 50kg is 0.7mg of losartan per kg of body weight administered once a day (up to 25mg of Losartan).
- The doctor may increase the dose if blood pressure is not controlled.
- Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Patients with high blood pressure and type 2 diabetes

- Treatment usually starts with 50 mg losartan (one tablet of Losartan Potassium 50 mg) once a day.
- The dose may later be increased to 100 mg losartan (two tablets of Losartan Potassium 50 mg) once daily depending on your blood pressure response.





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).

Adult Patients with Heart Failure

Treatment usually starts with 12.5 mg losartan (one tablet Losartan Potassium 12.5 mg) once a day. Generally, the dose should be increased weekly step-by-step (i.e., 12.5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as determined by your physician. A maximum dose of 150 mg losartan (for example, three tablets of Losartan Potassium 50 mg or one tablet each of Losartan Potassium 100 mg and Losartan Potassium 50 mg) once daily may be used.

In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

Dosage in special patient groups

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics in high doses, in patients with liver impairment, or in patients over the age of 75 years. The use of losartan is not recommended in patients with severe hepatic impairment (see section "Do not take Losartan Potassium tablets").

Administration

The tablets should be swallowed with a glass of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take Losartan Potassium Tablets until your doctor tells you otherwise.

If you take more Losartan Potassium Tablets than you should

If you accidentally take too many tablets, or a child swallows some, contact your doctor immediately. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

If you forget to take Losartan Potassium Tablets

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Losartan Potassium Tablets

Do not discontinue the treatment without consulting your doctor even if you feel better. It is important that you take Losartan Potassium Tablets for as long as your doctor prescribes it.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 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.

Possible side effects are listed under headings of frequency, using the following categories:

very common:	affects more than 1 user in 10
common:	affects 1 to 10 users in 100
uncommon:	affects 1 to 10 users in 1,000
rare:	affects 1 to 10 users in 10,000
very rare:	affects less than 1 user in 10,000
not known:	frequency cannot be estimated from the available data

Common:

- dizziness,
- low blood pressure, (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics),
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position.
- debility,
- fatigue,
- too less sugar in the blood (hypoglycaemia),
- too much potassium in the blood (hyperkalaemia).
- changes in kidney function (may be reversible upon discontinuation of treatment) including kidney failure,
- reduced number of red blood cells (anaemia)
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure.

Uncommon:

- somnolence,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris),
- shortness of breath (dyspnoea),
- abdominal pain,
- severe constipation,
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- rash,
- localised swelling (oedema).
- cough

Rare:

- hypersensitivity
- angioedema
- inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura),
- numbness or tingling sensation (paraesthesia),
- fainting (syncope),
- very rapid and irregular heartbeat (atrial fibrillation)
- brain attack (stroke) (rapidly developing loss of brain function(s)),
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

Not known:

- reduced number of thrombocytes,
- migraine,
- liver function abnormalities,

- muscle and joint pain,
- flu-like symptoms,
- back pain and urinary track infection.
- Increased sensitivity to the sun (photosensitivity)
- Unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis)
- Impotence
- Inflammation of the pancreas (pancreatitis)
- Low levels of sodium in the blood (hyponatraemia)
- Depression
- Generally feeling unwell (malaise)
- Ringing, buzzing, roaring, or clicking in the ears (tinnitus)
- Disturbed taste (dysgeusia)

Side effects in children are similar to those seen in adults.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

For UK - You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

For Malta- ADR Reporting

Website:

www.medicinesauthority.gov.mt/adportal

For Ireland - 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

5. How to store Losartan Potassium Tablets

- Keep out of the sight and reach of children
- Do not use this medicine after the expiry date, which is stated on the carton (EXP). The expiry date refers to the last day of that month.
- Do not store above 25°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 Losartan Potassium Tablets contains:

The active substance is Losartan Potassium.

For 25mg: Each film-coated tablet contains 25 mg of losartan potassium, equivalent to 22.9 mg of losartan.

For 50mg: Each film-coated tablet contains 50 mg of losartan potassium, equivalent to 45.8 mg of losartan.

For 100mg: Each film-coated tablet contains 100 mg of losartan potassium, equivalent to 91.7 mg of losartan.

The other ingredients are:

Core tablet: Lactose, pregelatinised maize starch, povidone K-90 (E1201), colloidal anhydrous silica (E551), talc (E553b), magnesium stearate (E572).

Coating materials: Hyprollose (E463), hypromellose (E464), polyethylene glycol 400, titanium dioxide (E171), talc (E553b).

What Losartan Potassium Tablets looks like and content of the pack:

Losartan Potassium Tablets 25mg: White to off white, round, biconvex, film coated tablets with breakline on one side and "25" debossing on other side.

The break line is only to facilitate breaking for ease of swallowing and not to divide into equal doses

Losartan Potassium Tablets 50mg: White to off white, round, biconvex, film coated tablets with breakline on one side and "50" debossing on other side.

The break line is only to facilitate breaking for ease of swallowing and not to divide into equal doses

Losartan Potassium Tablets 100mg: White to off white, round, biconvex, film coated tablets plain on one side and "100" debossing on other side.

Losartan Potassium Tablets are available in blisters in pack of 21, 28, 30, 90 or 98 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder :

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North Harrow, Middlesex,
HA1 4HF, United Kingdom

Manufacturer :

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