

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**



Losartan Potassium 25 mg film-coated tablets

Losartan Potassium 50 mg film-coated tablets

Losartan potassium

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Losartan Potassium is and what it is used for
2. Before you use Losartan Potassium
3. How to use Losartan Potassium
4. Possible side effects
5. How to store Losartan Potassium
6. Further information

1. WHAT LOSARTAN POTASSIUM 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 prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes

Losartan Potassium is used

- to treat patients with high blood pressure (hypertension) in adults and in children and adolescents 6-18 years of age.
- to protect the kidney in hypertensive type 2 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. BEFORE YOU USE LOSARTAN POTASSIUM

Do not use Losartan Potassium

- if you have had any allergic reaction to losartan or to any of the other ingredients in the product,
- if your liver function is severely impaired,
- if you are more than 3 months pregnant (it is also better to avoid Losartan Potassium in early pregnancy see “Pregnancy”).

If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Losartan is not recommended in newborn children or in children with liver disease or serious kidney problems. In such cases, talk to your doctor before giving any tablets to your child.

Take special care with Losartan Potassium

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

- if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see also section 4),
- 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),
- 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 and 3),
- 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).

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines and natural products.

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, triamteren, 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.

Taking Losartan Potassium with food and drink

Losartan Potassium 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 Potassium before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losartan Potassium. Losartan Potassium is not recommended in early 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 Potassium 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 was born prematurely.

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

Use in children and adolescents

Losartan Potassium has been studied in children. For more information, talk to your doctor.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Losartan Potassium 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

Losartan Potassium contains lactose monohydrate. 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 USE LOSARTAN POTASSIUM

Always take Losartan Potassium exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of Losartan Potassium, depending on your condition and whether you are taking other medicines.

It is important to continue taking Losartan Potassium for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

Patients with High Blood Pressure

Treatment usually starts with 50 mg losartan (one tablet 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 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 or adolescents (6 to 18 years old)

The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7 mg of losartan per kg of body weight administered once a day (up to 25 mg of Losartan Potassium). The doctor may increase the dose if blood pressure is not controlled.

Patients with high blood pressure and type 2 diabetes

Treatment usually starts with 50 mg losartan (one tablet Losartan Potassium 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets 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).

Patients with Heart Failure

Treatment usually starts with 12.5 mg Losartan Potassium 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) up to the usual maintenance dose of 50 mg losartan (one tablet Losartan Potassium 50 mg) once daily, according to your condition.

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 use Losartan Potassium").

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 until your doctor tells you otherwise.

If you take more Losartan Potassium 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

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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Losartan Potassium 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:

- depression,
- inflammation of the pancreas (pancreatitis),
- unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis),
- reduced number of thrombocytes (thrombocytopenia),
- stroke,
- very rapid and irregular heartbeat (arterial fibrillation),
- severe chest pain (angina pectoris),
- changes in kidney function including kidney failure,
- changes in kidney function (may be reversible upon discontinuation of treatment) including kidney failure,
- inflammation of the liver (hepatitis),
- liver function abnormalities,
- a severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

The following side effects have been reported with Losartan Potassium:

Common (affects 1 in 100 to 1 in 10 patients):

- dizziness,
- low blood pressure
- debility,
- fatigue,
- insufficient sugar or not enough sugar in the blood (hypoglycaemia),
- too much potassium in the blood (hyperkalaemia).
- reduced number of red blood cells (anaemia),
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure.

Uncommon (affects 1 in 1,000 to 1 in 100 patients):

- somnolence,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- 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,
- fatigue,
- lack or loss of strength (asthenia),
- cough,
- shortness of breath (dyspnoea),
- abdominal pain,
- obstipation,
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- rash,
- too much potassium in the blood (hyperkalaemia),
- localised swelling (oedema).

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

- hypersensitivity,
- angiooedema,
- inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura),

- numbness or tingling sensation (paraesthesia),
- fainting (syncope),
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

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

- reduced number of red blood cells (anaemia),
- migraine,
- muscle and joint pain,
- flu-like symptoms,
- increase in blood urea,
- serum creatinine and serum potassium in patients with heart failure,
- back pain and urinary tract infection.
- increased sensitivity to the sun (photosensitivity),
- impotence,
- low levels of sodium in the blood (hyponatraemia),
- generally feeling unwell (malaise),
- ringing, buzzing, roaring, or clicking in the ears (tinnitus).

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

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LOSARTAN POTASSIUM

Keep out of the reach and sight of children.

Do not store above 25° C.

Do not use Losartan Potassium after the expiry date which is stated on the individual blister and on the carton. It is also stated on the label of tablet bottles.

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 Potassium 25 mg and 50 mg film-coated tablets contains

The active substance is losartan potassium.

Each Losartan Potassium 25 mg contains 25 mg of losartan potassium.

Each Losartan Potassium 50 mg contains 50 mg of losartan potassium.

The other ingredients are microcrystalline cellulose (E460), lactose monohydrate, magnesium stearate (E572), pregelatinised maize starch, hydroxypropylcellulose (E463), hydroxypropylmethylcellulose (E 464), and titanium dioxide (E171).

Losartan Potassium 25 mg, 50 mg contain potassium in the following amounts: 2.12 mg (0.054 mEq) and 4.24 mg (0.108 mEq) respectively.

What Losartan Potassium 25 mg and 50 mg film coated tablets look like and contents of the pack

Losartan Potassium 25 mg: white to off white, oval shaped biconvex film coated tablets, engraved with "A" on one side, and "25" on the opposite side.

Losartan Potassium 50 mg: white to off white, oval shaped biconvex film coated tablets, engraved with "A50" on one side, and a central break line on the opposite side. The tablets can be divided in to equal halves.

White opaque blisters (aluminium PVC / PVdC / PE) of 14 tablets. Packs containing 14, 28, 56, 72, 96, 140, and 168 tablets are available.

Polypropylene tablet container with polypropylene tamper evident closure containing 100 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder & Manufacturer

Brown & Burk UK Ltd.

5 Marryat Close, Hounslow West, Middlesex, TW4 5DQ, UK

This leaflet was last revised in June 2012