

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

(Referred to as Losartan Potassium Tablets in the remainder of the leaflet)



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 Losartan Potassium Tablets are and what they are 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 are and what they are 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 blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidneys function in patients with high blood pressure and type 2 diabetes.

Losartan Potassium Tablets are used

- to treat patients with high blood pressure (hypertension) in adults, and in children and adolescents between 6 - 18 years of age
- to protect the kidneys in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria $\geq 0.5g$ per day (a condition in which the 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, medicines 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 Potassium Tablets
- in patients with high blood pressure and a thickening of the left ventricle. Losartan Potassium Tablets have 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 to losartan or any of the other ingredients of this medicine (listed in section 6)
- if you are more than three months pregnant (It is also better to avoid Losartan Potassium Tablets in early pregnancy - see **Pregnancy**)
- if your liver function is severely impaired
- 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 become) pregnant. Losartan Potassium Tablets are not recommended in early pregnancy, and must not be taken if you are more than three months pregnant, as it may cause serious harm to your baby if used at that stage (see '**Pregnancy, breast-feeding and fertility**' section')

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 had 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 beta-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 have 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 have been studied in children. For more information, talk to your doctor.

Losartan Potassium Tablets are not recommended for use in children suffering from kidney or liver problems, as limited data are available in these patient groups. Losartan Potassium Tablets are 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 Tablets

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

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

- 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 or 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 pressure lowering effect of losartan

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**").

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.

Losartan Potassium Tablets with food and drink

Losartan Potassium Tablets may be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

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

Your doctor will normally advise you to stop taking Losartan Potassium Tablets 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 Tablets. Losartan Potassium Tablets are not recommended in early pregnancy and must not be taken when more than three 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 Tablets are not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is a newborn, or born prematurely.

Driving and using machines

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

Losartan Potassium Tablets contain lactose

This medicine contains lactose. 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 take Losartan Potassium Tablets

Always take this medicine exactly as your doctor or pharmacist 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 as long as your doctor prescribes them in order to maintain smooth control of your blood pressure.

Adult Patients with high blood pressure

Treatment usually starts with 50 mg losartan (one tablet 50 mg) once a day. The maximal blood pressure lowering effect should be reached three to six weeks after beginning treatment. In some patients the dose may later be increased to 100mg losartan (two tablets of 50mg or one tablet of 100 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 are 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). Your 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.

Adult patients with high blood pressure and type 2 diabetes

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

Losartan 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. sulfonylurease, glitazones and glucosidase inhibitors).

Adult Patients with 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 the maintenance dose as determined by your physician. A maximum dose of 150 mg losartan (for example, three tablets of Losartan Potassium 50mg Tablets or one tablet each of Losartan Potassium 100mg Tablets and Losartan Potassium 50mg Tablets) 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 whole 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, contact your doctor or go to your nearest hospital casualty department immediately. Take this leaflet and any unused tablets with you to show the doctor. 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 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 Losartan Potassium 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 with Losartan Potassium Tablets:

Common (may affect up to 1 in 10 people):

- 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 little sugar in the blood (hypoglycaemia),
- too much potassium in the blood (hyperkalaemia),
- changes in kidney function 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 (may affect up to 1 in 100 people):

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

Rare (may affect up to 1 in 1,000 people):

- 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),
- inflammation of the liver (hepatitis),
- 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 thrombocytes
- migraine
- liver function abnormalities
- muscle and joint pain
- flu-like symptoms
- back pain and urinary tract infection
- increased sensitivity to the sun (photosensitivity)
- unexplained muscle pain with dark (tea-coloured)

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland:

HPR 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 Losartan Potassium Tablets

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 outer carton and blister. 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 Tablets contain

The active substance is losartan potassium.

Each Losartan Potassium 25 mg tablet contains 25 mg of losartan potassium equivalent to 22.9mg of losartan.

Each Losartan Potassium 50 mg tablet contains 50 mg of losartan potassium equivalent to 45.8mg of losartan.

Each Losartan Potassium 100 mg tablet contains 100 mg of losartan potassium equivalent to 91.6mg of losartan.

The other ingredients are:

- Tablet core: microcrystalline cellulose (E460), lactose (anhydrous), pregelatinised maize starch, magnesium stearate (E572)
- Film-Coating: Hydroxypropylcellulose (E463), hypromellose (E464), titanium dioxide (E171).

What Losartan Potassium Tablets look like and contents of the pack

Losartan Potassium Tablets are available in white, opaque blister packs (Alu/PVC Aclar) with outer cardboard cartons in the following pack sizes:

Losartan Potassium 25mg Film-Coated Tablets – 7 or 28

Losartan Potassium 50mg Film-Coated Tablets – 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 280 or 500 tablets and-unit dose packages of 28, 56 and 98 tablets for hospital use.

Losartan Potassium 100mg Film-Coated Tablets – 7, 10, 14, 15, 20, 28, 30, 50, 56, 84, 90, 98 or 280 tablets and-unit-dose packages of 28, 56, and 98 tablets for hospital use.

Not all pack sizes may be marketed.

Losartan Potassium 25 mg Film-Coated Tablets are white, oval-shaped, film-coated tablets, plain on both sides.

Losartan Potassium 50 mg Film-Coated Tablets are white, oval-shaped, film-coated tablets with a central break line on one side and plain on the other side. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Losartan Potassium 100 mg Film-Coated Tablets are white, almond-shaped, film-coated tablets, plain on both sides.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

This medicinal product is authorised in the Member

States of the EEA under the following names:

UK: Losartan Potassium 25/50/100mg Film-Coated Tablets

Cyprus: Losartan Potassium Wockhardt 25/50/100mg Film-Coated Tablets

Germany: Losartan-Kalium Wockhardt 25/50/100mg Filmtabletten

Ireland: Losartan Potassium 25/50/100mg Film-Coated Tablets

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference number
Losartan Potassium 25mg Film-Coated Tablets	29831/0378
Losartan Potassium 50mg Film-Coated Tablets	29831/0379
Losartan Potassium 100mg Film-Coated Tablets	29831/0380

This is a service provided by the Royal National Institute of Blind People.

For the Republic of Ireland please call +44 1978 661261

This leaflet was last revised in 12/2016

105203/4
222918

 WOCKHARDT