

Package leaflet: Information for the user

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

The name of this medicine is Losartan Potassium 25, 50 & 100 mg Film-coated Tablets which will be referred to as Losartan Tablets throughout this 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 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 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.

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 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 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 stabilized 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 has been shown to decrease the risk of stroke (LIFE indication).

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 of this medicine (listed in Section 6),
- if you are more than 3 months **pregnant** (It is also better to avoid Losartan 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 or pharmacist before taking Losartan Tablets:

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

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Losartan Tablets. Your doctor will decide on further treatment. Do not stop taking Losartan Tablets on your own.

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

- if you have ever 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 patients 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 section 2 "Do not take Losartan Tablets" and section 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 muscles,
- 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 tablets",

- if you are taking other medications that may increase serum potassium (see section 2 "Other medicines and Losartan Tablets").

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, as limited data is available in these patient groups. Losartan 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.

Tell your doctor if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines such as certain diuretics (amiloride, triamteren, spironolactone), or other medicines that may increase serum potassium (e.g., heparin, trimethoprim-containing medicines), as the combination with Losartan is not advisable.

Take particular care if you are taking the following medicines while under treatment with Losartan 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,
- 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 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 Tablets with food and drink

Losartan Tablets can 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 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 Tablets. Losartan Tablets are 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 Tablets are 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 new-born, or born prematurely.

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

Driving and using machines

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

Losartan 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.

Losartan Tablets contains Lactose.

These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

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 Tablets depending on your condition and whether you are taking other medicines. It is important to continue taking the tablets for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

Adults, adolescents and elderly

Treatment usually starts with one 50 mg tablet 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 50 tablets 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.

Patients with high blood pressure and type 2 diabetes

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

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Product LOSARTAN POTASSIUM	Market Export (Hexagon Pharma - UK)	Dimension 240 x 400 mm
Item code OETF0771	Mfg. Location Dholka	Component leaflet - Front Side
Substrate: 28 gsm Bible paper printed pack insert (Folding size: 120 x 25 mm)		Change part Layout: NA
Superseded item code No. : NA	Color : Black	No. of. Colors : 01
Version : 00	Reason for issue : New Artwork	

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 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 the tablets until your doctor tells you otherwise. For the 50 mg tablet there is a score line which allows the tablet to be divided into equal doses.

If you take more Losartan Tablets than you should

If you have accidentally taken more than your prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you. The most common signs and symptoms of overdose are a fall in blood pressure (causing dizziness and light headedness) accompanied by either a fast or slow heart rate.

If you forget to take Losartan 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, pharmacist, or nurse.

Note: This product is not available as a 12.5 mg dose. Your doctor will prescribe an alternative if necessary.

4. Possible side effects

Like all medicines, Losartan Tablets 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.

The following side effects have been reported with Losartan Tablets:

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

- dizziness, sensation of spinning,
- 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,
- weakness,
- 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):

- feeling drowsy,
- 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 (may affect up to 1 in 1,000 people):

- hypersensitivity,
- angioedema,
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea,
- 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 pain, 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),
- erectile dysfunction with 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 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

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from light and moisture. Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton or the bottle label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any signs of deterioration in the packaging or if the tablets do not match description given in section 6. (Contents of the pack and other information).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you are no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Losartan Tablets contains:

The active ingredient is losartan potassium. Each tablet contains 25, 50 or 100 mg of losartan potassium, equivalent to 22.9 mg, 45.8 mg or 91.6 mg of losartan. Tablet core: Microcrystalline cellulose, dibasic calcium phosphate, colloidal anhydrous silica, croscarmellose sodium, talc, magnesium stearate. Film-coating: Opadry White 31F58914* *consists of Hypromellose, (E464), lactose monohydrate, titanium di oxide (E171), polyethylene glycol 4000, sodium citrate dihydrate (E331).

What Losartan Tablets look like and the contents of the pack:

Losartan Potassium 25 mg Film-coated Tablets are white, round-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.

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

Losartan Potassium Film-coated Tablets are supplied in blister packs containing 28 tablets.

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CADILA PHARMACEUTICALS LTD.

Product LOSARTAN POTASSIUM	Market Export (Hexagon Pharma - UK)	Dimension 240 x 400 mm
Item code OETF0771	Mfg. Location Dholka	Component leaflet - Back Side
Substrate: 28 gsm Bible paper printed pack insert (Folding size: 120 x 25 mm)		
Superseded item code No. : NA	Color : Black	No. of. Colors : 01
Version : 00	Reason for issue : New Artwork	