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# Losartan Potassium film-coated tablets POM

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## 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 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.

#### In this leaflet:

1. What Losartan Potassium tablet is and what it is used for
2. What you need to know before you take Losartan Potassium tablet
3. How to take Losartan Potassium tablet
4. Possible side effects
5. How to store Losartan Potassium tablet
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 (narrow). This results in an increase in blood pressure. Losartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax (widen) 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 tablet is used:

- to treat high blood pressure (hypertension) in adults and in children and adolescents aged 6 to 18 years old;
- to protect the kidney in patients with high blood pressure and type 2 diabetes who have laboratory evidence of impaired renal function and proteinuria  $\geq 0.5$  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 Tablet has been shown to decrease the risk of stroke ("LIFE indication").

This medicine may also be authorised to treat other conditions which are not mentioned in this leaflet. Ask your doctor or pharmacist if you have further questions.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOSARTAN POTASSIUM TABLET

##### Do not take Losartan Potassium tablet if:

- you are allergic (hypersensitive) to losartan or any of the other ingredients of this medicine (listed in section 6);
- you suffer from severe liver problems;
- you are, think you may be or are planning to become pregnant (see 'Pregnancy');
- you are more than 3 months pregnant (It is also better to avoid taking Losartan Potassium tablet in early pregnancy - see 'Pregnancy');
- 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 tablet. You must tell your doctor if you think you are (or might become) 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 if used at that stage (see pregnancy section).

Talk to your doctor before taking this medicine if you:

- have had a history of angioedema (swelling of the face, lips, throat and/or tongue) (see also section 4 'Possible side effects');
- have suffered from excessive vomiting (being sick) or diarrhoea leading to an extreme loss of fluid and/or salt in your body;
- are taking diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are on a low salt diet (see section 3 'Dosage in special patient groups');
- have a narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently;
- have problems with the way your liver works (see sections 2 'Do not take Losartan Potassium tablets' and 3 'Dosage in special patient groups');
- suffer from heart failure, with or without kidney problems or accompanying severe life threatening cardiac arrhythmias (irregular heart rhythm). You will need to take special care when taking this medicine if you are also taking beta-blockers (used to treat high blood pressure and some heart problems);
- have problems with your heart valves or heart muscle;
- 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 condition where your adrenal gland produces too much of the hormone aldosterone).
- 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 tablet". If you are taking other medications that may increase serum potassium (see section 2 "Other medicines and losartan potassium tablet").

#### Children and adolescents

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

Losartan Potassium Tablet is not recommended for use in children suffering from kidney or liver problems, or children under 6 years old, as limited data are available in these patient groups.

#### Other medicines and losartan potassium tablet

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 tablets:

- Other blood pressure lowering medicines, as they may reduce your blood pressure further. Blood pressure may also be lowered by one of the following drugs/class of drugs: tricyclic antidepressants, antipsychotics, baclofen (used in treatment of spasticity), amifostine (used in chemotherapy);
- medicines which may raise the levels of potassium in your body (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamterren, spironolactone] or heparin, trimethoprim-containing medicines);
- non-steroidal anti-inflammatory drugs (that are used to relieve pain and inflammation) such as indomethacin and cox-2-inhibitors, as they may reduce the blood lowering effect of this medicine. If your kidneys do not work properly, using these medicines together may make the problem worse; 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 (used to treat mania) should not be taken in combination with these tablets without close supervision by your doctor. You may need to have regular blood tests to make sure that you are taking the right dose of lithium.

#### Taking Losartan Potassium tablets with food and drink

These tablets may be taken with or without food.

#### Pregnancy and breast-feeding

##### Pregnancy

You must tell your doctor if you think you are (or may 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 suggest you take another medicine instead of Losartan Potassium tablets. These tablets are not recommended in early pregnancy and must not be taken if you are more than 3 months pregnant, as they 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 breast-feed, especially if your baby is newborn, or was born prematurely.

##### Use in black patients

This medicine is less effective in lowering blood pressure in black patients and the dose may need to be adjusted in this group of patients.

##### Driving and using machines

These tablets are unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, this medicine 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 tablet contains lactose

This medicine contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

#### 3. HOW TO TAKE LOSARTAN POTASSIUM TABLET

Always take Losartan Potassium tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose, 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 them in order to maintain smooth control of your blood pressure.

##### Adult patients with high blood pressure

The usual starting dose is 50 mg losartan (one Losartan Potassium 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 tablets of Losartan Potassium 50 mg or one tablet of Losartan Potassium 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 tablet 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 to 18 years old

The recommended starting dose in patients who weigh between 20 and 50 kg is 25 mg of losartan once a day. In patients who weigh more than 50 kg, the usual dose is 50 mg once daily. The doctor may increase the dose if blood pressure is not controlled. Doses above 100 mg daily have not been studied in children.

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

#### 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 and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

#### Dosage in special patient groups

When starting treatment in certain patients, such as those taking high doses of diuretics, patients with liver problems, or those over the age of 75 years, the doctor may recommend a lower dose.

Losartan Potassium tablets are not recommended in patients with severe liver problems (see section "Do not take Losartan Potassium tablets").

If this medicine has been prescribed for a child or adolescent, the doctor will decide the appropriate dose for them to take.

#### How to take the tablets

The tablets should be swallowed with a glass of water. You should try to take your 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 related to a fall in blood pressure, such as dizziness or feeling faint and changes in heart rate, which may get faster or slower.

#### If you forget to take Losartan Potassium tablets

If you accidentally miss a dose, just take the next dose when it is due. 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 tablets can cause side effects, although not everybody gets them.

If you experience the following, stop taking the 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 hospitalization.

The following side effects have been reported:

##### 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;
- weakness (debility);
- fatigue;
- occasional low blood sugar levels (hypoglycaemia);
- too much potassium in the blood (hyperkalemia);
- changes in kidney function including kidney failure;
- reduced numbers 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):

- drowsiness (sommolence);
- headache;
- sleep disorders;
- feeling of increased heart rate (palpitations);
- severe chest pain (angina pectoris);
- shortness of breath (dyspnoea);
- abdominal pain;
- severe constipation (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-Schoenlein purpura);
- numbness or tingling sensation (paraesthesia);
- fainting (syncope);
- very rapid and irregular heartbeat (arterial fibrillation);
- brain attack (stroke);
- inflammation of the liver (hepatitis);
- elevated blood alanine aminotransferase (ALT) levels (a type of liver enzyme). This would be detected by a blood test and levels usually go back to normal once treatment is stopped.

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

- reduced number of thrombocytes (thrombocytopenia), common signs of which are unusual bruising or bleeding under the skin;
- migraine;
- problems with the way your liver works;
- 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, pharmacist, or nurse. 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](http://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 POTASSIUM TABLETS

Keep out of the sight and reach of children. Do not use Losartan Potassium tablets after the expiry date which is stated on the blister and carton.

The expiry date refers to the last day of that month. There are no special storage conditions for these tablets. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

##### What Losartan Potassium tablets contain

- Each film-coated tablet contains 25 mg of losartan potassium.
- Each film-coated tablet contains 50 mg of losartan potassium.
- Each film-coated tablet contains 100 mg of losartan potassium.

- The other ingredients are:

Tablet core: Lactose monohydrate, microcrystalline cellulose (E460), pregelatinised starch and magnesium stearate (E572).  
Tablet film-coating: Hypromellose (E464), titanium dioxide (E171) and hydroxypropylcellulose (E463).

##### What Losartan Potassium tablet looks like and contents of the pack

Losartan Potassium 25 mg tablets are white to off-white, oval shaped, film-coated tablets, debossed with "J" on one side and "25" on the other side. Losartan Potassium 50 mg tablets are white to off-white, oval shaped, film-coated tablets, scored on one side, debossed with "J" on scored side and "50" on the other side. Losartan Potassium 100 mg tablets are white to off-white, capsule shaped, film-coated tablets, debossed with "J" on one side and "100" on the other side.

Pack sizes:  
10, 28, 30, 50, 56, 90, 98 and 100 tablets in blisters of 10 or 14 tablets in a cardboard box. Not all pack sizes may be marketed.

##### Marketing Authorization Holder and Manufacturer

*Marketing Authorization Holder*  
Flamingo Pharma (UK) Ltd.  
1<sup>st</sup> Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, Ha1 2AX, United Kingdom.

*Manufacturer*  
PSI supply nv, Axxes Business Park, Guldensporenpark 22, Block C, 9820 Merelbeke, Belgium.

Waymade Healthcare Plc, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR, United Kingdom

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