

**LOSARTAN POTASSIUM 12.5 mg FILM-COATED TABLETS**  
**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 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. 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.

**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 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 Tablets are 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  $\geq 0.5$  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 Tablets have 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 to any of its other ingredients of this medicine (listed in section 6),
- 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,
- if you are more than 3 months pregnant. (It is better to avoid Losartan Tablets in early pregnancy – see pregnancy section.)

**Warnings and precautions**

**Talk to your doctor, pharmacist or nurse 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).

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

- if you have had a history of angiooedema (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 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 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".

**Children and adolescents**

Losartan has been studied in children. For more information, talk to your doctor. Losartan Tablets are not recommended for use in children suffering from kidney or liver problems, as limited data are 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**

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 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, baclofene, 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 heparine),
- 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.
- ACE (angiotensin-converting enzyme) inhibitors (for the treatment of blood pressure, certain heart conditions, kidney disease in patients with diabetes)- Concomitant treatment should be limited to individually defined cases with close monitoring of renal function.

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 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 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 newborn, or was 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 Tablets are 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 contain lactose**

Losartan Tablets contain 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 TAKE LOSARTAN TABLETS**

Always take Losartan Tablets 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 Losartan 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**

Treatment usually starts with 50 mg losartan 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 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 Tablets are not recommended for use in children under 6 years old as it has not been shown to work in this age group.



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#### Children aged 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 Tablets). The doctor may increase the dose if blood pressure is not controlled.

#### Adult patients with high blood pressure and type 2 diabetes

Treatment usually starts with 50 mg losartan once a day. The dose may later be increased to 100 mg losartan 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 maintenance dose as determined by your physician.

A maximum dose of 150 mg losartan 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 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 Tablets until your doctor tells you otherwise.

#### If you take more Losartan 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 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.

#### 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:

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

- dizziness,
- vertigo,
- 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,
- fall in blood pressure, including a dose-related orthostatic effect, appearing when rising from lying or sitting position. It may cause dizziness, light headedness or fainting (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).

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,
- severe constipation,
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- rash,
- localised swelling (oedema),
- cough.

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

- hypersensitivity reactions,
- angiooedema,
- inflammation of blood vessels (vasculitis including Henoch-Schonlein 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,
- 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),
  - distorted sense of taste (dysgeusia).

Side effects in children are similar to those in adults.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### 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). 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 reach and sight of children.

Do not use Losartan Tablets after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Do not store Losartan Tablets above 25°C. Store Losartan Tablets in the original package. Do not open the blister pack until you are ready to take the medicine.

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 to protect the environment.

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

##### What Losartan Tablets contain

The active substance is losartan potassium.

Each Losartan potassium 12.5 mg Tablet contains 12.5 mg of losartan potassium.

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

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

Each Losartan potassium 100 mg Tablet contains 100 mg of losartan potassium.

The other ingredients are lactose monohydrate, starch pregelatinized, colloidal anhydrous silica, microcrystalline cellulose, magnesium stearate, carnauba wax, hypromellose, titanium dioxide (E171) and macrogol 400.

Losartan potassium 12.5 mg, 25 mg, 50 mg and 100 mg Tablets contain potassium in the following amounts: 1.06 mg (0.027 mEq), 2.12 mg (0.054 mEq), 4.24 mg (0.108 mEq) and 8.48 mg (0.217 mEq) respectively.

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

Losartan potassium 12.5 mg Tablets are supplied as a white, film-coated round, biconvex tablet.

Losartan potassium 12.5 mg Tablets come in calendar packs of 28 tablets.

Losartan potassium 25mg Tablets are supplied as white, film-coated, round, biconvex tablets, scored on both sides. Losartan potassium 25 mg Tablets come in calendar packs of 28 tablets.

Losartan potassium 50mg Tablets are supplied as white, film-coated, round, biconvex tablets, quadrisected on one side.

Losartan potassium 50 mg Tablets come in calendar packs of 28 tablets.

Losartan potassium 100mg Tablets are supplied as white, film-coated, oblong, biconvex tablets, scored on both sides. Losartan potassium 100 mg Tablets come in calendar packs of 28 tablets.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer:

Dexcel® - Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK.

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