

## Losartan potassium 25mg, 50mg and 100mg Film-coated Tablets

**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.
- The full name of this medicine is Losartan potassium 25mg, 50mg and 100mg Film-coated Tablets but within the leaflet it will be referred to as Losartan tablets.

### 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**
- 3 How to take**
- 4 Possible side effects**
- 5 How to store**
- 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, 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  $\geq 0.5g$  per day (a condition in which urine contains an abnormal amount of protein).
- 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").

Losartan tablets may also be prescribed to treat conditions not listed in this leaflet. If you have any questions, ask your doctor or pharmacist.

### 2 What you need to know before you take

#### Do not take Losartan tablets if you:

- are **allergic** to losartan or to any of its other ingredients of this medicine (listed in section 6)
- have **severe liver** problems
- are **more than 3 months pregnant** (It is also better to avoid Losartan tablets in early pregnancy – see pregnancy section).
- 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.

It is important to tell your doctor before taking Losartan tablets if you:

- have had a **history of angio-oedema** (swelling of the face, lips, throat, and/or tongue) (see also section 4 'Possible side effects')
- suffer from **excessive vomiting or diarrhoea** leading to an extreme loss of fluid and/or salt in your body
- take **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')
- are known to have **narrowing or blockage of the blood vessels leading to your kidneys** or if you have received a kidney transplant recently
- have **liver problems** (see sections 2 "Do not take Losartan" and 3 'Dosage in special patient groups')
- suffer from **heart failure** with or without kidney problems or concomitant severe life threatening cardiac arrhythmias. Special caution is necessary when you are treated with a beta-blocker concomitantly
- 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 syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, causing headaches, tiredness, night time urination and high blood pressure)

- 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).
- 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 tablets 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, or children under 6 years old, as limited data are available in these patient groups.

#### 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 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, spironolactone] or heparin).
- non-steroidal anti-inflammatory drugs such as indometacin, 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.

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.

Special caution is necessary if you are being treated concomitantly with another angiotensin-II receptor antagonist (such as valsartan or telmisartan) as the frequency of low blood pressure, fainting, increase in potassium levels and changes in kidney function may be increased. 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")

#### Losartan tablets with food and drink

Losartan tablets may be taken with or without food.

#### Pregnancy and breast-feeding

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

#### 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.

#### 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.

## 3 How to take

Always take this medicine exactly as your doctor 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.

### Dose:

#### Adult patients with high blood pressure

Treatment usually starts with 50mg 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 100mg once daily.

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

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

#### 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").

#### Use in children and adolescents (6 to 18 years old)

For children and adolescents who weigh between 20 and 50kg the recommended dose is 25mg once daily. In exceptional cases the dose can be increased to a maximum of 50mg once daily. For children and adolescents who weigh more than 50kg, the usual dose is 50mg once daily. In exceptional cases the dose can be increased to a maximum of 100mg once daily.

#### 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 product, ask your doctor or pharmacist.

#### If you stop taking Losartan tablets

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. If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

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 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 (less than 1 in 10 users)

- dizziness
- feeling of swaying or spinning (vertigo)
- low blood pressure
- low blood sugar (hypoglycaemia)
- high levels of potassium in the blood (hyperkalaemia)
- debility
- fatigue
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position
- 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 (less than 1 in 100 users)

- drowsiness, sleep disorders
- headache
- feeling of increased heart rate (palpitations)
- severe chest pain (angina pectoris)
- 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)
- shortness of breath (dyspnoea)

- abdominal pain, severe constipation, diarrhoea
- feeling or being sick
- hives (urticaria), itching (pruritus) or rash
- localised swelling (oedema)
- cough.

#### Rare: (less than 1 in 1000 users)

- hypersensitivity
- angioedema
- inflammation of blood vessels (vasculitis including Henocho-Schonlein purpura)
- numbness or tingling sensation (paraesthesia)
- fainting (syncope)
- very rapid and irregular heartbeat (atrial fibrillation) or stroke
- inflammation of the liver (hepatitis, causing tiredness or stomach, muscle or joint pain)
- 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 platelets (thrombocytopenia)
- migraine
- flu-like symptoms
- liver function abnormalities (seen in blood tests)
- muscle and joint pain
- 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)
- taste disturbance (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 side effects not listed in this leaflet. You can also report side effects directly via the internet 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

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 blister and carton after EXP. The expiry date refers to the last day of that month. 25mg: Store in the original package in order to protect from light.

50/100mg: Do not store above 25 °C. Store in the original package in order to protect from light. Tablet containers: This medicinal product does not require any special storage conditions. 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 contains

- The active substance is losartan. Each tablet contains either 25mg, 50mg or 100mg of losartan potassium.
- The other ingredients are:  
*Tablet core:* mannitol, microcrystalline cellulose, croscarmellose sodium, povidone K29/32, magnesium stearate.  
*Tablet film coating:* Hypromellose 6, titanium dioxide (E171), talc, propylene glycol.

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

Appearance of the tablets:

25mg:	White, round biconvex, coated tablets, no score, marked 2 L, size: 8mm
50mg:	White, round biconvex, scored, coated tablets, marked 3 L, size: 10mm
100mg:	White, oval biconvex, scored, coated tablets, marked 4 L, size: 18.3mm x 9.2mm

The 50mg and 100mg tablets can be divided into equal doses

Pack sizes:

Blister packs:	7, 10, 14, 15, 20, 21, 28, 30, 50, 56, 90, 98, 100, 210 film-coated tablets
Clinic pack:	280 film-coated tablets.
Tablet container:	100, 250 tablets

Not all pack sizes may be marketed

### Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

### Manufacturers

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