

## PACKAGE LEAFLET: Information for the patient

### LOSARTAN

Film-coated tablets – 50 mg

(Losartan potassium)

#### **Read all this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Losartan is and what it is used for
2. Before you take Losartan
3. How to take Losartan
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#### **1. WHAT LOSARTAN IS AND WHAT IT IS USED FOR**

Losartan is an angiotensin II receptor antagonist. Angiotensin II is a chemical in your blood that tightens your blood vessels. Losartan blocks this effect causing the blood vessels to relax and so lowers your blood pressure.

Losartan is indicated:

- for the treatment of hypertension;
- for the treatment of heart failure in combination with diuretics and/or digitalis medicine;
- for the prevention of stroke in hypertensive patients with left ventricular hypertrophy;

- in the treatment of renal disease in hypertensive, type 2 diabetic patients with proteinuria, as part of their antihypertensive treatment.

Your doctor may have suggested Losartan for another reason. Ask your doctor if you want to know why you were given Losartan.

## **2. BEFORE YOU TAKE LOSARTAN**

### **Do not take Losartan:**

- if you are allergic (hypersensitive) to losartan potassium or any of the excipients of Losartan;
- if you have severe impairment of hepatic function or if you suffer from liver disease;
- if you are pregnant or breastfeeding;
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

### **Take special care with Losartan**

#### Ask your doctor before taking Losartan:

- if you have a kidney disorder or if you are undergoing dialysis;
- if you have a liver disorder;
- if you are known to have a narrowing or obstruction in the blood vessels leading to your kidneys;
- if you have recently had a kidney transplant;
- if you have had a history of angio-oedema (swelling of the face, lips, throat, and/or tongue);
- if you suffer from hyperaldosteronism, a disorder in which the adrenal glands produce too much of a hormone known as aldosterone; if this applies to you, the use of Losartan is not recommended;
- if you are suffering from severe vomiting or diarrhoea, as this may lead to heavy fluid or salt loss from your body;
- if you are being treated with diuretics (used to increase fluid excretion via the kidneys) or are under dietary salt restriction as this may lead to heavy fluid or salt loss from your body;
- if you are taking potassium-sparing medications or potassium preparations, if you use salt replacements containing potassium, or if you are using other medications (e.g., heparin)

which increase the amount of potassium in your blood; it may be necessary to check the amount of potassium in your blood at regular intervals;

- if you have problems with your heart valves or heart muscle, or if you have any other severe heart disorder;
- if you are being treated for heart failure with or without renal impairment, or concomitant severe life-threatening cardiac arrhythmias or after a heart attack; special caution is necessary when you are treated with a  $\beta$ -blocker concomitantly;
- 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 are taking any of the following medicines used to treat high blood pressure:
  - an “ACE-inhibitor” (e.g. enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems;
  - aliskiren.

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

Your doctor may regularly check your kidney function, blood pressure and the amount of electrolytes (e.g. potassium) in your blood.

Consult your doctor if you are or may become pregnant.

### **Taking other medicines**

Simultaneous treatment with other medicines may affect or be affected by Losartan.

Losartan does not usually interact with other medicines. However, you should tell your doctor or pharmacist about all the medicines you are taking or have recently taken including those obtained without a prescription. It is important to tell your doctor if you are taking potassium supplements, potassium sparing agents or potassium-containing salt substitutes.

Particular caution is advised if you take any of the following medicines during treatment with Losartan:

- other medications to lower your blood pressure, especially water pills (diuretics), as these may lower your blood pressure even further; blood pressure can also be lowered by other classes of drugs such as: tricyclic antidepressants, antipsychotics, baclofen etc.;
- medicines that increase the amount of potassium in your blood, like potassium preparations, salt replacements containing potassium or potassium-sparing drugs such as certain diuretics, or other medicines that increase the amount of potassium in the blood (e.g. heparin);
- certain types of painkillers, called anti-inflammatory drugs (non-steroidal anti-inflammatory drugs); these medicines can make Losartan less effective in lowering your blood pressure; if your kidney function is already impaired, taking these medicines at the same time as Losartan can cause your kidney function to worsen;
- if you are being treated after a heart attack, combination with an ACE inhibitor (used to treat heart attack) is not recommended;
- if you are being treated for heart failure and you are already being treated with both ACE inhibitors and beta-blockers (used to treat heart failure), a triple combination with Losartan is not recommended;
- ACE inhibitors or aliskiren because your doctor may need to change your dose and / or take other measures; see also "Do not take Losartan" and "Take special care with Losartan";
- Losartan may increase the blood concentration of lithium, therefore close supervision by your doctor is necessary.

### **Taking Losartan with food and drinks**

Losartan can be taken with or without meals.

### **Pregnancy and breastfeeding**

Losartan is not recommended during pregnancy or breastfeeding.

If you are pregnant or become pregnant while taking Losartan, stop taking the tablets and talk to your doctor as soon as possible. Ask your doctor or pharmacist for advice before taking any medicine.

## **Driving and using machines**

When you start taking this medicine you should not perform tasks that need special attention (for example driving or operating dangerous machinery) until you know how you tolerate the medicine.

## **3. HOW TO TAKE LOSARTAN**

Always take Losartan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it more important for you to keep your appointments with the doctor even if you are feeling well.

### **General recommendation for dosing**

#### **Patients with high blood pressure**

The starting and maintenance dose is 50 mg, once daily for most patients. The maximal antihypertensive effect is reached 3-6 weeks after initiation of treatment. Some patients may receive an additional benefit by increasing the dose to 100 mg once daily.

*Reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy.*

The usual starting dose is 50 mg of losartan, once daily. A low dose of hydrochlorothiazide may be added and/or the dose of losartan increased to 100 mg once daily, based on the blood pressure response.

*Use in the elderly:*

Patients up to 75 years old: no initial dosage adjustment is necessary for this patient group.

Patients over 75 years old: up to now there is limited clinical experience in this group, however a lower starting dose of 25 mg, once daily is recommended.

#### **Heart failure**

The starting dose of Losartan in patients with heart failure is 12.5 mg, once daily. Generally, this dose may be increased at weekly intervals (i.e., 12.5 mg once daily; 25 mg once daily; 50 mg

once daily) until the usual maintenance dose of 50 mg, once daily is reached, depending on the patient's tolerability.

### **Children and adolescents (below 18 years of age)**

Losartan is not recommended to be used in children and adolescents under the age of 18.

### **Use in renal impairment**

No initial dose adjustment is necessary in patients with mild renal impairment (i.e., creatinine clearance of 20-50 ml/min). For patients with moderate to severe renal impairment (i.e., creatinine clearance < 20 ml/min) or patients on dialysis, the starting dose of 25 mg once daily is recommended.

### **Use in patients with intravascular volume depletion**

For the very small proportion of patients who have intravascular volume depletion (e.g., those treated with high-dose diuretics), a starting dose of 25 mg once daily is recommended.

### **Use in patients with hepatic impairment**

A lower dose should be considered for patients with a history of hepatic impairment. Losartan may be administered with other antihypertensive agents.

### **Renal protection in hypertensive type 2 diabetes patients with proteinuria**

The starting dose for type 2 diabetic patients with proteinuria is 50 mg of Losartan once daily. The dose may be increased to 100 mg according to blood pressure response. Losartan may be administered with other antihypertensive agents (e.g., diuretics, calcium channel blockers, alpha or beta blockers and centrally acting agents) as well as insulin and other commonly used hypoglycaemic agents (e.g., sulfonylureas, glitazones and glucosidase inhibitors).

The renal benefit of losartan in hypertensive, type 2 diabetic patients with proteinuria is based on a study in which losartan is used together with other antihypertensive agents to reach a predetermined blood pressure.

## **Instructions for use and handling**

Always take Losartan with a glass of water (200 – 250 ml water).

### **If you take more Losartan than you should**

If you have accidentally taken more Losartan than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital or call the emergency services to get an opinion on the risk and advice on the actions that should be taken. Signs of an overdose include severe dizziness, drowsiness, weakness, tachycardia and bradycardia can happen.

### **If you forget to take Losartan**

Do not take a double dose to make up for a forgotten dose.

If you forget to take Losartan, take your dose as soon as you remember unless it is time to take the next dose. Use the doses at the right time.

### **If you stop taking Losartan**

Do not stop treatment without consulting a doctor.

Treatment with Losartan must not be stopped abruptly. If you suddenly stop the use of Losartan, your condition may get worse, or your blood pressure may start to rise again. Ask your doctor what you should do to stop the treatment gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, losartan can cause side effects, although not everybody gets them. Side-effects are usually mild.

If you experience the following, stop taking Losartan and tell your doctor immediately or go to the 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.

The frequency of the possible side effects is shown in the table below:

|                     |   |
|---------------------|---|
| <b>Very common:</b> | more than 1 in 10 patients                            |
| <b>Common:</b>      | 1 to 10 patients among 100                            |
| <b>Uncommon:</b>    | 1 to 10 patients among 1,000                          |
| <b>Rare:</b>        | 1 to 10 patients among 10,000                         |
| <b>Very rare:</b>   | less than 1 in 10,000 patients                        |
| <b>Not known:</b>   | Frequency cannot be estimated from the available data |

**Common:**

- dizziness;
- low blood pressure (especially after excessive loss of water from circulating volume 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:**

- somnolence;
- headache;
- sleep disorders;
- feeling of increased heart rate (palpitations);
- severe chest pain (angina pectoris);
- shortness of breath (dyspnea);
- abdominal pain;
- constipation;

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

**Rare:**

- 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) (rapid loss of brain function / functions);
- inflammation of the liver (hepatitis);
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment;
- intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

**Not known:**

- 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).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE LOSARTAN**

Keep out of the reach and sight of children.

Do not use Losartan after the expiry date which is stated on the package.

Store below 25 °C.

Store in the original package.

## **6. FURTHER INFORMATION**

**What Losartan 50 mg film-coated tablets contain**

**The active substance** is losartan potassium.

Each film-coated tablet contains 50 mg losartan potassium.

**The excipients** are:

*tablet core*: colloidal anhydrous silica, microcrystalline cellulose, sodium stearyl fumarate, croscarmellose sodium;

*film coat*: polyvinyl alcohol, titanium dioxide, macrogol, and talc.

**Content of the pack**

Box with 30 film-coated tablets.

**Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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