

Package leaflet: Information for the patient

LOSANET 50 mg tablets

LOSANET 100 mg 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

What is in this leaflet

1. What Losanet is and what it is used for
2. What you need to know before you take Losanet
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1. What Losanet is and what it is used for

Losanet tablets contain losartan potassium. Losartan potassium 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 potassium prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan potassium slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Losanet 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 stabilised with an ACE inhibitor you should not be switched to losartan.
- to decrease the risk of stroke in patients with high blood pressure and a thickening of the left ventricle.

2. What you need to know before you take Losanet

Do not take Losanet

- If you are allergic to losartan or to 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 Losanet 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.

If any of the above applies to you, do not take Losanet and talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

Take special care with Losanet:

- If you have 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 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 Losanet" 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 β -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 LOSANET"**.

If any of these apply to you, talk to your doctor.

Children and adolescents

Losanet is not recommended for use in children suffering from kidney or liver problems as limited data are available in these patient groups. Losanet is 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 Losanet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Caution should be used with:

- 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 [amilofide, 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.

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 LOSANET"** 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.

Losanet with food and drink

You can take Losanet 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 this medicine before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losanet.

This medicine 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 it is used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. This medicine is 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 newborn or was born prematurely.

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.

Driving and using machines

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

Losanet is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan potassium may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

Losanet contains lactose

Losanet contains 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 Losanet

Always take this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure. Your doctor will decide on the appropriate dose of Losanet, depending on your condition and whether you are taking other medicines. It is important to continue taking Losanet for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

Taking this medicine

- 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 Losanet until your doctor tells you otherwise.

Adult patients with High Blood Pressure

Treatment usually starts with 50 mg losartan potassium (one tablet Losanet 50 mg) 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 potassium (two tablets Losanet 50 mg or one tablet of Losanet 100 mg) once daily if you have the impression that the effect of this medicine is too strong or too weak, please talk to your doctor or pharmacist.

Adult patients with high blood pressure and Type 2 diabetes

Treatment usually starts with 50 mg losartan (one tablet Losanet 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets Losanet 50 mg or one tablet of Losanet 100 mg) once daily depending on your blood pressure response.

Losartan 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 fourth tablet Losanet 50 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 Losanet 50 mg or one tablet each of Losanet 100 mg and Losanet 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.

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.

Use in children and adolescents (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 potassium corresponding to half the tablet of Losanet 50 mg). The doctor may increase the dose if blood pressure is not controlled.

Dosage in special patient groups

Your 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 Losanet").

If you take more Losanet than you should

If you have accidentally taken too many Losanet tablets, talk to a doctor immediately. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

If you forget to take Losanet

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.

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 Losanet tablets and talk to your doctor immediately or go to 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. You may need urgent medical attention or hospitalization.

The following side effects have been reported with losartan potassium:

Common: 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, debility, fatigue, too little sugar in the blood (hypoglycemia), too much potassium in the blood (hyperkalemia), changes in kidney function including kidney failure, reduced number of red blood cells (anemia), 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, diarrhea, 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), inflammation of the liver (hepatitis), elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

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-colored) urine (rhabdomyolysis), impotence, inflammation of the pancreas (pancreatitis), low levels of sodium in the blood (hyponatremia), 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.

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

5. How to store Losanet

- Keep this medicine out of the sight and reach of children.
- Do not use Losanet after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Store below 30°C.
- Store in the original package in order to protect from light and humidity.
- Do not use any Losanet pack that is damaged.
- Do not throw away any medicines via wastewater. 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 Losanet contains

- Losanet 50 mg: Each tablet contains 50 mg losartan potassium.
- Losanet 100 mg: Each tablet contains 100 mg losartan potassium.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, magnesium stearate, pregelatinized starch.

What Losanet looks like and contents of the pack

- Losanet tablets are white round tablets.
- Losanet 50 mg is available in boxes containing 30 tablets.
- Losanet 100 mg is available in boxes containing 30 tablets.

Marketing Authorisation Holder and Manufacturer

Pharmaline - Lebanon
P.O.Box 90201 Jdeidet El Metn, Lebanon
Contact us: pharmaline@mallagroup.com

Registration N° for Losanet 50 mg in Lebanon: 195018/04

Registration N° for Losanet 100 mg in Lebanon: 222208/07

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

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Council of Arab Health Ministers
Union of Arab Pharmacists

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