

Uncommon:

- Sleepiness
- Headache
- Sleep disorders
- Increased heart rate (palpitations)
- Severe chest pain (angina pectoris)
- Shortness of breath (dyspnea)
- Abdominal pain
- Obstipation
- Diarrhea
- Nausea
- Vomiting
- Urticaria
- Itching (pruritus)
- Rash
- Regional swelling (edema)
- Cough

Rare:

- Hypersensitivity
- Angioedema (swellings in the hands, feet, face and tongue)
- 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 the discontinuation of treatment.

Not known:

- Reduced number of thrombocytes (platelets)
- Migraine
- Liver function abnormalities
- Muscle and joint pain
- Flu-like symptoms and complaints
- Back pain and urinary tract infection
- Increased sensitivity to the sun (photosensitivity)
- Unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis)
- Impotence (sexual insufficiency)
- Inflammation of the pancreas (pancreatitis)
- Low blood levels of sodium (hyponatraemia)
- Depression
- Generally feeling unwell (malaise)
- Ringing, buzzing, roaring, or clicking in the ears (tinnitus)
- disturbed taste (dysgeusia).

If you encounter any side effect that is not included in this patient information leaflet or any of the side effects grows serious, inform your doctor or pharmacist.

5. How to store LOSARTES

Keep LOSARTES out of the sight and reach of children and in its package.
Keep at room temperature under 25°C in a dry place and away from light.

Use in line with the expiry date.

Do not use LOSARTES after the expiry date on the package.

If you notice defects in product and/or package, do not use LOSARTES.

PATIENT INFORMATION LEAFLET

LOSARTES 50 mg film coated tablet

It is taken orally.

- **Active substance:** Losartan Potassium 50 mg.
- **Excipients:** Lactose monohydrate, cellulose, microcrystalline (E460), pregelatinised starch, croscarmellose sodium, magnesium stearate (E572), hydroxypropyl methyl cellulose (E464), titanium dioxide (E171), polyethylene glycol, potassium.

Read this LEAFLET carefully before you start to use the medicine. It contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please consult your doctor or pharmacist.
- This medicine is prescribed for you personally. Do not give it to others.
- During the use of this medicine, when you visit a doctor or a hospital, tell your doctor that you are using this medicine.
- Follow the directives in this leaflet strictly. Do not use higher or lower dose of the medicine than the one recommended to you.

In this leaflet:

1. What LOSARTES is and what it is used for
2. What you need to know before you take LOSARTES
3. How to take LOSARTES
4. Possible side effects
5. How to store LOSARTES

Topics are included.

1. What LOSARTES is and what it is used for

LOSARTES is blood pressure lowering drug (antihypertensive) belonging to the group of drugs called angiotensin II receptor antagonists (AIIA).

LOSARTES 50 mg film coated tablets are white, round, scored film coated tablets. LOSARTES is presented in packages containing 28 tablets.

Angiotensin II is a substance produced in the body, which binds to the receptors in the 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 II diabetes.

LOSARTES is used

- to lower the blood pressure of the adult patients with high blood pressure (hypertension). The blood pressure is the force exerted by the blood in your blood vessels while your heart beats and then relaxes. If this force is too high, your blood pressure (tension) is high. LOSARTES causes the blood vessels to relax which in turn lowers your blood pressure.
- to protect the kidney in hypertensive (high blood pressure) type 2 diabetic (high blood sugar) patients with laboratory evidence of impaired renal function and ≥ 0.5 g of proteinuria per day (a condition in which urine contains an abnormal amount of protein).
- in patients with high blood pressure (hypertension) and a thickening of the left ventricle, LOSARTES has been shown to decrease the risk of stroke ("LIFE indication").

2. What you need to know before you take LOSARTES

DO NOT USE LOSARTES in the following situations:

If:

- if you are allergic to LOSARTES or any of its ingredients,
- if your liver function is severely impaired,
- if you are pregnant more than 3 months (it is also better to avoid LOSARTES in early pregnancy – see "Pregnancy").
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing alicoren.

USE LOSARTES CAUTIOUSLY in following situations:

If you believe to be pregnant (or if you are likely to be pregnant), you have to tell to your doctor. LOSARTES is not recommended in early period of pregnancy, and LOSARTES should not be taken if you are pregnant more than 3 months as it may cause serious harm to your baby when is used at that stage (see Pregnancy Section).

It is important to tell your doctor before taking LOSARTES:

- if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see Section 4 "Possible side effects").
- if you suffer from excessive vomiting or diarrhea 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 you are under dietary salt restriction (leading to an extreme loss of fluid and salt in your body) (see Section 3 "Special administration conditions").
- if you are known to have narrowing or blockage of the blood vessels supplying blood to your kidneys or if you have received a kidney transplant recently.
- if your liver function is impaired (see Section 2 "Do not use LOSARTES in the following situations" and Section 3 "Special administration conditions").
- 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 heart disease caused by an impairment of your blood vessels or from

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- cerebrovascular disease.
- If you suffer from primary hyperaldosteronism (a condition associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- Use of ARB and ACE inhibitors with aliskiren is not recommended since this leads to dual blockade of the RAAS.

If these cautions apply to you, even for any previous period, please consult to your doctor.

Using LOSARTES with food and drink
LOSARTES may be taken with or without food.

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Pregnancy
Please consult to your doctor or pharmacist before using the medicine.

If you believe to be pregnant (or if you are likely to be pregnant), you have to tell to your doctor. Normally, your doctor will advise you not to take LOSARTES and to take a suitable alternative medicine instead of LOSARTES before that you become pregnant or upon getting known your pregnancy. LOSARTES is not recommended in early pregnancy, and should not be taken if you are pregnant more than 3 months, as LOSARTES may cause serious harm to your baby when used after the third month of the pregnancy. If you realize you are pregnant during the treatment, please consult to your doctor or pharmacist immediately.

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Lactation
Please consult to your doctor or pharmacist before using the medicine.

If you are breastfeeding or plan to breastfeed, please consult to your doctor.
LOSARTES 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 born prematurely.

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Ability to drive and use machines
No studies on the effects of LOSARTES on the ability to drive and use machines have been performed. LOSARTES is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, LOSARTES may cause dizziness or sleepiness in some people. If you experience dizziness or sleepiness, you should consult your doctor before driving or using machines.

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Important information about some of the excipients in LOSARTES
Each tablet contains 4.24 mg of potassium. No negative effect due to the amount of potassium is expected.
Each tablet contains 18 mg of lactose monohydrate. If you have been told by your doctor previously that you have intolerance to some sugars contact your doctor before taking this medicinal product. This medicinal product contains less than 1 mmol (23 mg) of sodium in each tablet, basically in other words it is "sodium-free".

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Using with other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including prescribed or over-the-counter drugs, natural products or herbal medicines during your treatment with LOSARTES. Take particular care if you are taking the following medicines during the treatment with LOSARTES:

- Other blood pressure lowering medicines: they may further 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 (e.g., certain diuretics (amilofide, triamterene, spironolactone) or heparin).
- Non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., indomethacin) including COX-2 inhibitors; they are the medicines that reduce inflammation, and can be used to help relieve pain). They may reduce the blood lowering effect of Losartan.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren, do not take LOSARTES.
- 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 with Losartan without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

If you are using a prescribed or non-prescribed medicine currently, or have used recently, please inform your doctor or pharmacist about these.

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3. How to take LOSARTES

Instructions for proper use and dose/dosing intervals:

- Always take LOSARTES exactly as your doctor has told you.
- Your doctor will decide on the most appropriate dose for you, depending on your condition and whether you are taking other medicines.
- It is important to continue taking LOSARTES for as long as your doctor prescribes it in order to maintain regular control of your blood pressure.

Administration route and method

- You should take this medicine via oral route.
- You can use it on empty stomach or with food.
- Take the tablets with sufficient amount of water without chewing (e.g., a glass of water).
- For convenience and for remembering easily, try to take LOSARTES every day at the same time.

Adult patients with high blood pressure

Treatment usually starts with 50 mg Losartan (one tablet of LOSARTES 50 mg) once a day. The

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maximal blood pressure lowering effect is reached 3-6 weeks after beginning treatment. In some patients the dose may later be increased to 100 mg Losartan (two tablets of LOSARTES 50 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.

Patients with high blood pressure and type 2 diabetes mellitus

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

Various age groups:

Pediatric use:

Losartan was studied in the children. For further information, consult your doctor.

LOSARTES is not recommended for use in children, having renal or hepatic problems or under 6 years old, as limited data is available in these patient groups.

Geriatric use:

LOSARTES generally works equally well in and is equally well tolerated by elderly patients and younger adult patients.

Special administration conditions:

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics at high doses, in patients with liver impairment, or in patients over the age of 75 years.

Renal failure:

If you have renal problem, tell to your doctor.

Liver failure:

The use of Losartan is not recommended in patients with severe hepatic impairment.

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

If you used more LOSARTES than you should:

If you used more LOSARTES than you should, please talk to a doctor or a pharmacist.

Symptoms of overdose are low blood pressure, increased heartbeat, occasionally decreased heartbeat. In case of accidental intake of LOSARTES by the children, ask medical attention immediately.

If you forget to use LOSARTES:

If you forget to take a tablet at usual time, take it as soon as you remember it. If the scheduled time of the next dose is near, resume your normal dose schedule by taking only the next dose as prescribed. Do not take double doses to make up the missed dose.

Possible effects after discontinuing treatment with LOSARTES

Do not discontinue the treatment with LOSARTES before asking to your doctor.

4. Possible side effects

As with all medicines, there may be side effects in the individuals who are sensitive to any of the ingredients of LOSARTES.

If any of the followings occur, stop taking LOSARTES and tell your doctor immediately or go to the emergency department of your nearest hospital:

- A severe allergic reaction which shows itself as rash, itching, swelling of the face, lips, tongue and/or throat that may cause difficulty in swallowing or breathing.

All of these are serious side effects. If you experience any of these, you have a severe allergy to LOSARTES. You may need urgent medical attention or hospitalisation.

Side effects are listed by category as shown below:

Very Common: May be observed at least one in 10 patients.

Common: May be observed in less than one in 10 patients, but more than one in 100 patients.

Uncommon: May be observed in less than one in 100 patients, but more than one in 1000 patients.

Rare: May be observed in less than one in 1000 patients, but more than one in 10000 patients.

Very rare: May be observed in less than one in 10000 patients.

Not known: May be seen in the patients as few as that can not be determined through the current data.

Following side effects were reported with the use of LOSARTES:

Common:

- Drowsiness
- Low blood pressure (especially following excessive loss of fluid from blood vessels in the body; e.g., in the patients with severe heart failure or during the treatment with high doses of diuretics)
- Dose-related orthostatic effects (e.g., lowering of blood pressure appearing when standing up from supine or from sitting position)
- Weakness
- Fatigue
- Too less 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 (anemia)
- Increased blood urea, serum creatinine and serum potassium in the patients with heart failure.