



**LOSAR® 50 mg, scored film-coated table**  
 ® Losartan potassique  
**LOSAR® 100 mg, scored film-coated table**  
 Losartan potassique

**Read this leaflet carefully before taking this medicine as 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 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 are taking other medicines, talk to your doctor, pharmacist, or nurse. This also applies to any side effect not mentioned in this leaflet. See section 4.

**What is in this leaflet?**

1. what are **LOSAR®** and **LOSAR FORT®** and in which case are they used?
2. how do you take **LOSAR®** and **LOSAR FORT®**?
3. how to take **LOSAR®** and **LOSAR FORT®**?
4. possible side effects?
5. how to store **LOSAR®** and **LOSAR FORT®**?
6. Content of packaging and other information.

**1. WHAT ARE LOSAR® AND LOSAR FORT® AND IN WHICH CASE ARE THEY USED?**  
 Pharmacotherapeutic group: Angiotensin II antagonists, uncombined - ATC code: C09CA01  
**Losartan** belongs to a group of medicines called angiotensin II receptor antagonists. Angiotensin II is a substance produced by your body that binds to receptors in the wall of blood vessels causing them to contract. It causes an increase in blood pressure. Losartan prevents angiotensin II from binding to these receptors resulting in dilation of blood vessels and lower blood pressure. Losartan slows deterioration of kidney function in patients with high blood pressure and type 2 diabetes.

**Therapeutic indications:**  
**LOSAR®, LOSAR FORT®:**  
 - Treatment of essential hypertension in adults and children and adolescents aged 6 to 18 years.  
 - Treatment of renal impairment in adult patients with type 2 diabetes, hypertension, with proteinuria  $\geq 0.5$  g/day, as part of antihypertensive treatment.  
 - Treatment of chronic heart failure in adult patients, when treatment with an enzyme-converting enzyme (ACE) inhibitor is inappropriate due to intolerance (cough) or to a contraindication. Losartan should not be used as a relay treatment in patients with heart failure, stabilized by an ACE inhibitor.  
 - Patients should have left ventricular ejection fraction  $>40\%$  and should be clinically stabilized and on regular treatment for chronic heart failure.  
 - Reduced risk of stroke in left ventricular hypertrophy with left ventricular hypertrophy at the electrocardiogram.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOSAR® AND LOSAR FORT®?**  
 - If you are allergic to losartan or any of the other ingredients of this medicine (listed in section 6).  
 - If you are more than 3 months pregnant (It is also preferable to avoid taking **LOSAR®** OR **LOSAR FORT®** in early pregnancy – see section "Pregnancy and breast-feeding").  
 - If your liver function is severely impaired.  
 - If you have diabetes or kidney failure and you are being treated with a medicine to reduce blood pressure.

**Warnings and precautions**  
 Talk to your doctor, pharmacist or nurse before taking **LOSAR®** or **LOSAR FORT®** :  
 - Do not tell your doctor or pharmacist you are (or are likely to become) pregnant. **LOSAR®** and **LOSAR FORT®** are not recommended in early pregnancy and should not be taken if you are more than 3 months pregnant as it could seriously harm your child if used from this stage of pregnancy (see section "Pregnancy and Breastfeeding").  
 - Do not tell your doctor or pharmacist you are (or are likely to become) pregnant if you are taking **LOSAR®** or **LOSAR FORT®** .  
 - If you have ever had angioedema (swelling of the face, lips, throat and/or tongue) (see also section 4 "Possible side effects").  
 - If you have had severe vomiting or diarrhea, causing a very significant loss of fluids and/or salts from your body.  
 - If you are taking diuretics (medicines which increase the amount of water passing through your kidneys) or if you are on a salt-free diet (which may lead to a significant loss of fluid and salt from your body) (see section 3 "Dosage in specific patient groups").  
 - If you have narrowing or blockage of the kidney arteries or have recently had a kidney transplant.  
 - If your liver function is impaired (see sections 2 "Do not take **LOSAR®** and **LOSAR FORT®**" and 3 "Dosage in specific patient groups").  
 - If you suffer from heart failure with or without kidney failure or concomitant severe cardiac arrhythmia which may be life-threatening. Special attention is needed when you are simultaneously treated with beta-blockers.  
 - If you have heart valve or heart muscle problem.  
 - If you have coronary artery disease (caused by reduced blood flow to the heart vessels), or cerebrovascular disease (caused by reduced blood flow to the brain).  
 - If you have primary aldosteronism (a syndrome associated with increased aldosterone secretion following an abnormality of the adrenal glands).  
 - If you are taking any of the following medicines to treat high blood pressure:  
 o an ACE inhibitor (eg enalapril, lisinopril, ramipril), particularly if you have diabetes-related kidney problems, or a diuretic.  
 o an aldosterone (eg enalapril, lisinopril, ramipril), particularly if you have diabetes-related kidney problems, or a diuretic.

Your doctor may need to check your kidney function, blood pressure, and levels of electrolytes (eg. potassium) in your blood at regular intervals. See also the section "Do not take **LOSAR®** and **LOSAR FORT®**" for more information.  
 - If you are taking other medicines likely to increase serum potassium (see section 2 "Other medicines and **LOSAR®** and **LOSAR FORT®**").

**Children and adolescents**  
**Losartan** has been studied in children. For more information, ask your doctor.  
 The use of **LOSAR®** and **LOSAR FORT®** is not recommended in children with kidney or liver problems, as the available data are limited in these patients.  
**LOSAR®** and **LOSAR FORT®** are not recommended for children under 6 years of age, safety of use and efficacy are not established in this age group.

**Other medicines and **LOSAR®** and **LOSAR FORT®****  
 Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.  
 - If you are taking any of the following medicines, your doctor may need to adjust the dosage of potassium-sparing medicines such as certain diuretics (amilofrile, furosemide, spironolactone), or other medicines which may increase serum potassium (eg, heparin, medicines containing trimethoprim), because the combination with **LOSAR®** or **LOSAR FORT®** is not recommended.  
 Tell special care if you are taking any of the following medicines while being treated with **LOSAR®** or **LOSAR FORT®** :  
 - Non-steroidal anti-inflammatory medicines, as these may further lower your blood pressure. Blood pressure is likely to be lowered by one of the following medicines/classes of medications: tricyclic antidepressants, antipsychotics, baclofen, amilorine.  
 - Non-steroidal anti-inflammatory medicines such as indomethacin, including COX-2 inhibitors (medicines that reduce inflammation and can be used to reduce pain) as they may reduce the blood pressure lowering effect of losartan.  
 - Your doctor may need to change the prescribed dose and/or take other precautions:  
 - If you are taking an ACE inhibitor or aldosterone (see also the sections "Do not take **LOSAR®** and **LOSAR FORT®**" and "Warnings and precautions" for more information).  
 - If you are taking any of the following medicines or use of these medicines may lead to worsening kidney failure. Lithium medicines should only be taken with losartan under close supervision by your doctor. Special precautions (blood work) may be appropriate.

**LOSAR® and **LOSAR FORT®** with food and drinks**  
**LOSAR®** and **LOSAR FORT®** can be taken with or without food.  
**Pregnancy and breastfeeding**  
**Pregnancy**  
 You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally recommend that you stop taking **LOSAR®** and **LOSAR FORT®** before you become pregnant or as soon as you know you are pregnant. It will recommend that you take another medicine instead of **LOSAR®** or **LOSAR FORT®** . **LOSAR®** and **LOSAR FORT®** are not recommended in early pregnancy and should not be taken if you are more than 3 months pregnant as it could seriously harm your child.  
 - If you are breastfeeding, do not take **LOSAR®** or **LOSAR FORT®** before taking this medicine. **LOSAR®** and **LOSAR FORT®** are not recommended for women who are breastfeeding, and your doctor may choose another treatment if you wish to breastfeed, especially if your child is newborn or premature.  
 Ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**  
 The effects on the ability to drive and use machines have not been studied.  
 - If you are taking **LOSAR®** or **LOSAR FORT®** to affect your ability to drive or use machines. However, as with many other medicines used in the treatment of hypertension, losartan may cause dizziness or drowsiness in some patients. In case of dizziness or drowsiness, consult your doctor before driving or using machines.  
**LOSAR®** and **LOSAR FORT®** contain lactose. If your doctor has told you that you have an intolerance to some sugars, contact him before taking this medicine.

**3. HOW TO TAKE LOSAR® AND LOSAR FORT®**  
 Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt. Your doctor will decide on the appropriate dose of **LOSAR®** or **LOSAR FORT®** depending on your condition and on your blood pressure. It is important to continue taking **LOSAR®** or **LOSAR FORT®** for as long as your doctor prescribes, to allow regular control of your blood pressure.  
**Adult hypertensive patients**  
 - If you usually start taking 50 mg losartan once daily (1 tablet of **LOSAR®** 50 mg). The blood pressure lowering effect peaks 3-6 weeks after starting treatment. In some patients the dose may later be increased to 100 mg losartan once daily (2 tablets of **LOSAR®** 50 mg or 1 tablet of **LOSAR FORT®** 100 mg).  
 - If you have the impression that the effect of **LOSAR®** or **LOSAR FORT®** is too strong or too weak, talk to your doctor or pharmacist.

**Use in children and adolescents**  
**Children under 6 years of age**  
**LOSAR®** and **LOSAR FORT®** are not recommended for children under 6 years of age, safety of use and efficacy have not been established in this age group.  
**Children aged 6 to 12**  
 The usual starting dose for patients with a body weight between 20 and 50 kg is 0.7 mg losartan per kg once daily (up to 25 mg losartan). The doctor may increase the dose if your blood pressure is not controlled.  
 - If you are taking this medication may be more suitable for children, talk to your doctor or pharmacist.  
**Adult hypertensive patients with type 2 diabetes**  
 The usual starting dose is 50 mg losartan once daily (1 tablet of **LOSAR®** 50 mg). The dose may then be increased to 100 mg losartan once daily (2 tablets of **LOSAR®** 50 mg or 1 tablet of **LOSAR FORT®** 100 mg) depending on blood pressure response.  
**Losartan tablets can be taken with other antihypertensive medicines** (such as diuretics, calcium channel blockers, beta-blockers, and centrally acting antihypertensives) as well as insulin and other commonly used antidiabetic medications (for example, sulfonylureas, glitazones and glucosidase inhibitors).

**Adult patients with heart failure**  
 The usual starting dose is 12.5 mg losartan once daily. Usually, the dose should be increased in increments each week (i.e., 12.5 mg per day the first week, 25 mg per day the second week, 50 mg per day the third week, 100 mg per day the fourth week, 150 mg daily in the fifth week) up to the maintenance dose established by your doctor. A maximum dose of 150 mg losartan once a day can be used (for example, 3 tablets of **LOSAR®** 50 mg or 1 tablet of

**LOSAR FORT®** 100 mg and 1 tablet of **LOSAR®** 50 mg.  
 In the treatment of heart failure, losartan is usually combined with a diuretic (medicine which increases the passage of water through the kidney) and/or digitalis (medicine which helps the heart to work more efficiently) and/or a beta-blocker.  
**Dosage in special patient groups**  
 The doctor may prescribe a lower dose, especially at the start of treatment in some patients, such as those treated with high-dose diuretics, or patients with hepatic impairment or patients over 75 years of age. The use of losartan is not recommended in patients with severe hepatic impairment (see section 2 "Do not take **LOSAR®** and **LOSAR FORT®**").

**Method of administration**  
 The tablets should be swallowed whole with a glass of water. Try to take your daily treatment at the same time each day. It is important not to stop treatment with **LOSAR®** without the advice of your doctor.  
**If you take more **LOSAR®** and **LOSAR FORT®** than you should**  
 - If you accidentally take too many tablets, contact your doctor immediately. Symptoms of an overdose are low blood pressure, increased or sometimes decreased heart rate.  
**If you forget to take **LOSAR®** and **LOSAR FORT®****  
 - If you accidentally forget to take your daily dose, just take the next dose as normal. Do not take a double dose to make up for the dose you forgot to take.  
**If you stop taking **LOSAR®** and **LOSAR FORT®****  
 - Do not stop taking this medicine suddenly without the advice of 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 side effect, stop taking **LOSAR®** and **LOSAR FORT®** and tell your doctor immediately or go to the nearest hospital emergency room:  
 o A severe allergic reaction (rash, itching, swelling of the face, lips, throat which may cause difficulty in swallowing or breathing).  
 This is a rare side effect which may occur in more than 1 in 10,000 patients but less than 1 in 1,000 patients. You may need urgent medical supervision or hospitalization.  
 The following side effects have been reported with losartan:  
**Common (may affect up to 1 in 10 people):**  
 o Dizziness.  
 o Lowering of blood pressure (particularly after excessive water loss from the blood vessels, for example in patients with severe heart failure or on treatment with high doses of diuretics).  
 o Dose-related orthostatic effects such as dizziness or lightheadedness when getting up from a supine to a seated position.  
 o Weakness  
 o Fatigue  
 o Too low sugar in the blood (hypoglycemia).  
 o Too much potassium in the blood (hyperkalemia).  
 o Change in kidney function, including kidney failure.  
 o Reduction in the number of red blood cells in the blood (anemia).  
 o Elevated blood urea, creatinine, and serum potassium in patients with heart failure.  
**Uncommon (may affect up to 1 in 100 people):**  
 o somnolence,  
 o Headache,  
 o Hypersensitivity disorders,  
 o Feeling of rapid heartbeat (palpitations),  
 o Chest pain (angina),  
 o Shortness of breath (dyspnea),  
 o Abdominal pain,  
 o Chronic constipation,  
 o Diarrhea,  
 o Nausea,  
 o Weakness  
 o Rash (hives),  
 o Itching (pruritus),  
 o Skin rash,  
 o Localized swelling (edema),  
 o Cough.

**Rare (may affect up to 1 in 1,000 people):**  
 o Hypersensitivity disorders,  
 o Angioedema,  
 o Inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura),  
 o Numbness or tingling (paresthesias),  
 o Fainting (syncope),  
 o Very fast and irregular heartbeats (atrial fibrillation),  
 o Stroke,  
 o Inflammation of the liver (hepatitis),  
 o Elevation of alanine aminotransferase (ALT), which usually normalizes when treatment is stopped.  
**Not known (frequency cannot be estimated from the available data):**  
 o decreased platelet count,  
 o migraine,  
 o Abnormalities of liver function,  
 o Muscle and joint pain,  
 o Flu-like syndrome,  
 o Back pain and urinary tract infection,  
 o Increased sensitivity to the sun (photosensitivity),  
 o Unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis),  
 o Impotence,  
 o Inflammation of the pancreas (pancreatitis),  
 o Low blood sodium levels (hyponatremia),  
 o General feeling of malaise,  
 o Ringing, buzzing, rumbling, or popping in the ears (tinnitus),  
 o Altered taste/dysgeusia.

**Side effects in children are identical to those reported in adults.**  
**Reporting side effects**  
 If you get side effects, talk to your doctor, pharmacist, or nurse. This also applies to any side effect not mentioned in this leaflet. You can also report side effects directly via the national reporting system: CNPV (Centre de Pharmacovigilance).  
 By reporting side effects you help provide more information about the safety of the medicine.  
**5. HOW TO STORE LOSAR® AND LOSAR FORT®**  
 Store at a temperature below 30°C.  
 Keep this medication out of the sight and reach of children.  
 Do not use this medicine after the expiry date which is stated on the box or vial label after "EXP". The expiry date refers to the last day of that month.  
 Do not dispose of your medicine in wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. CONTENT OF THE PACKAGING AND OTHER INFORMATION**  
**What **LOSAR®** and **LOSAR FORT®** contain:**

Excipients	LOSAR®	LOSAR FORT®
Losartan potassium	50 mg	100 mg
Excipients	Pregelatinized Corn Starch, Microcrystalline Cellulose, Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, OPADRY II HP WHITE, q.s.p one tablet	Microcrystalline Cellulose, Lactose Monohydrate, Croscarmellose Sodium, Pregelatinized Corn Starch, Magnesium Stearate, Colloidal Anhydrous Silicon Dioxide, OPADRY II HP 86374736, q.s.p one tablet
Excipients with known effect	Lactose monohydrate	

**What do **LOSAR®** and **LOSAR FORT®** look like and content of the outer packaging**

Speciality	Form	MAN <sup>1</sup>	Presentations
<b>LOSAR®</b> 50 mg	Scored film-coated tablet-blisters in white Alu/PVC	9233411	Box of 30 tablets
		9233413	Box of 90 tablets
<b>LOSAR®</b> 100 mg	Scored film-coated tablet-blisters in white Alu/PVC	9233791	Box of 30 tablets
		9233793	Box of 90 tablets

**Marketing authorization holder and manufacturer**  
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**Supply and prescription condition:** List I Table A  
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**THIS IS A MEDICIN**

- A medicine is not like other consumer goods.  
 - A medicine is a product that affects your health and its consumption without compliance with the prescription exposes you to danger.  
 - Specially follow your doctor's prescription and the instructions for use which are prescribed for you, follow the advice of your pharmacist.  
 - Your doctor and your pharmacist are familiar with the medicine, its indications, and its contraindications.  
 - Do not stop the treatment on your own initiative during the prescribed period.  
 - Do not take it again to not increase the dosage without consulting your doctor.

**Keep medicines out of the reach of children**