

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

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 get any side effects, talk to your doctor, pharmacist, or nurse. This also applies to any side effect not mentioned in this leaflet. See section 4.

What is this leaflet?

1. what are LOSAR® and LOSAR FORT® and in which case are they used?
2. what you need to know before you take LOSAR® and LOSAR FORT®?
3. how to take LOSAR® and LOSAR FORT®?
4. possible side effects?

How to store LOSAR® et LOSAR FORT®
 1. Content of the packaging and other information.
 2. **WHAT ARE LOSAR® and LOSAR FORT® AND IN WHICH CASE ARE THEY USED?**
 Pharmacotherapeutic class: 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 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.

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 ≥ 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 inadequate.
 - Treatment of chronic heart failure in adolescents (cough) or 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 adult hypertensive patients with left ventricular hypertrophy at the "electrocardiogram 2".

NEVER 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 breastfeeding").
 • 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 containing aliskiren.

Warnings and precautions
 • Talk to your doctor, pharmacist or nurse before taking LOSAR® or LOSAR FORT®.
 • You must tell your doctor if you think 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 unborn child in early pregnancy (see section "Pregnancy and Breastfeeding").
 • It is important to tell your doctor before taking LOSAR® and 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-reduced 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 any 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 a 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 hyperaldosteronism (a syndrome associated with increased aldosterone secretion following an abnormality of the adrenal glands).
- If you are taking any of the following medicines that treat high blood pressure:
 • an ACE inhibitor (eg enalapril, lisinopril, ramipril), particularly if you have diabetes-related kidney problems, or aliskiren.

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
 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 were 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. Tell your doctor if you are taking potassium supplements, salt substitutes containing potassium, potassium-sparing medicines such as certain diuretics (amilofurone, furosemide, spironolactone), or other medicines which may increase the effect of heparin, medicines containing trimethoprim, because the combination with LOSAR® or LOSAR FORT® is not recommended.

Take special care if you are taking any of the following medicines while being treated with LOSAR® or LOSAR FORT®:
 • Other antihypertensive medicines, as these may further lower your blood pressure. Blood pressure is likely to be lowered by one of the following medicines/classes of medicines: tricyclic antidepressants, antipsychotics, beta-blockers.
 • non-steroidal anti-inflammatory medicines such as indometacin, 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 check the prescribed dose and/or take other precautions:
 • If you are taking any of the medicines listed in the sections "Do not take LOSAR® and LOSAR FORT®" and "Warnings and precautions" (for more information).
 • If you have impaired kidney function, the concomitant use of these medicines may lead to worsening kidney failure. These 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. He 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, ask your doctor for advice before taking this medicine. LOSAR® and LOSAR FORT® are not recommended while you 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.
Drying and using machines
 The effects on the ability to drive and use machines have not been studied.

LOSAR® or LOSAR FORT® are unlikely 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.
 LOSAR® and LOSAR FORT® contain lactose monohydrate. 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 if you are taking other medicines. 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
 The usual starting dose is 50 mg losartan once daily (1 tablet of LOSAR® 50 mg). The blood pressure lowering effect peaks 3-4 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 were not established in this age group.

Children aged 6 to 18
 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.
 The use of 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/or 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 "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.

4. POSSIBLE SIDE EFFECTS?
 LOSAR® and LOSAR FORT® may cause side effects. 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®
 Not applicable.
 If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. POSSIBLE SIDE EFFECTS?
 Like all medicines, this medicine can cause side effects, although not everybody gets them.
 If you experience the following effect, stop taking LOSAR® and LOSAR FORT® and tell your doctor immediately or go to the nearest hospital emergency room:
 • A severe allergic reaction (rash, itching, swelling of the face, lips, throat which may cause difficulty in swallowing or breathing).

This is a serious side effect that 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):

- Dizziness.
- 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).
- Dose-related orthostatic effects such as decrease in blood pressure when going from a supine to a seated position.
- Weakness
- Fatigue
- Too low sugar in the blood (hypoglycaemia).
- Too much potassium in the blood (hyperkalaemia).
- Change in kidney function, including kidney failure.
- Reduction in the number of red blood cells in the blood (anemia).
- Too little blood urea, creatinine, and serum potassium in patients with heart failure.

Uncommon (may affect up to 1 in 100 people):
 • somnolence,
 • Headache,
 • Sleep disorders,
 • Feeling of rapid heartbeat (palpitations),
 • Restlessness

• Shortness of breath (dyspnea),
 • Abdominal pain,
 • Chronic constipation,
 • Diarrhea,
 • Nausea,
 • Vomiting,
 • Rash (hives),
 • Itching (pruritus),
 • Skin rashes,
 • Localized swelling (edema),
 • Cough.

Rare (may affect up to 1 in 1,000 people):
 • Hypersensitivity,
 • Angioedema,
 • Inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura),
 • Numbness or tingling (paresthesia),
 • Fainting (syncope),
 • Very fast and irregular heartbeats (atrial fibrillation),
 • Stroke,
 • Inflammation of the liver (hepatitis),
 • Elevation of alanine aminotransferase (ALT), which usually normalizes when treatment is stopped.

Not known frequency (cannot be estimated from the available data):
 • decreased platelet count,
 • migraine,
 • Abnormalities of liver function,
 • Muscle and joint pain,
 • Flu-like syndrome,
 • Back pain and urinary tract infection,
 • Increased sensitivity to the sun (photosensitivity),
 • Unexplained muscle pain or dark (tea-colored) urine (rhabdomyolysis),
 • Impotence,
 • Inflammation of the pancreas (pancreatitis),
 • Low blood sodium levels (hyponatremia),
 • Depression,
 • General feeling of malaise,
 • Ringing, buzzing or ringing, or popping in the ears (tinnitus),
 • Altered taste (dysgeusia).

Side-effects in children are identical to those reported in adults.
Reporting side effects
 If you get any 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 for 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.
 Check 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 any medicine 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. CONTENT OF THE PACKAGING AND OTHER INFORMATION
What LOSAR® and LOSAR FORT® contain:

LOSAR®	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, Lactose Monohydrate, Magnesium Stearate, OPADRY II HP WHITE..... q-s-p one tablet
Excipients with known effect	Lactose monohydrate	

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

LOSAR®	Form	MAN®	Presentations
LOSAR® 50 mg	Scored film-coated tablet-blistar in white A/PVC	9233411	Box of 30 tablets
		9234134	Box of 90 tablets
LOSAR® 100 mg	Scored film-coated tablet-Blistar in white A/PVC	9233791	Box of 30 tablets
		9233793	Box of 90 tablets

Marketing authorisation holder and manufacturer
 Les Laboratoires MÉSIS,
 Road of Tunis - KM 7 - BP 206 8000 Nabeul - Tunisia
 Tel : +216 72 235 006 / Fax : +216 72 235 016
 e-mail : contact@labomedis.com

Supply and prescription condition: List I/Table A
 This leaflet was last reviewed: 02/2022

THIS IS A MEDICINE

• A medicine is not like other consumer goods,
 • A medicine is a product that affects your health and its consumption without prescription with the prescription exposes you to danger.
 • Strictly 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 and will help you to choose the most suitable treatment.

• Do not stop the treatment on your own initiative during the prescribed period.
 • Do not take it again, do not increase the dosage without consulting your doctor.

Keep medicines out of the reach of children



N000018
V02