

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Losardex[®] Tablets 12.5, 50 mg

Losardex[®] Caplets, 100 mg

Each tablet/caplet contains Losartan Potassium at a dosage of 12.5, 50 or 100 mg respectively.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. 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 medical condition seems similar to yours.

1. What is the medicine intended for?

Losardex is used for the treatment of heart failure.

Losardex 50 and **Losardex 100** are also indicated for the treatment of high blood pressure to help lower the risk of cardiovascular events, such as stroke, in patients with high blood pressure and a thickening of the left ventricle (the heart's main pumping chamber). **Losardex 50** and **Losardex 100** also provide kidney protection by delaying the worsening of kidney disease in Type-2 diabetic patients with protein in their urine (proteinuria).

Therapeutic group: belongs to angiotensin II receptor blockers group.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (losartan) or to any of the other ingredients of this medicine (see section 6).
- You are more than 3 months pregnant (it is also better to avoid **Losardex** in early pregnancy - see section "Pregnancy and breast-feeding").
- Your liver function is severely impaired.
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Special warnings concerning use of the medicine

- Talk to your doctor or pharmacist before taking the medicine.
- You must tell your doctor if you think you are (or might become) pregnant. **Losardex** 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 used at that stage (see section "Pregnancy and breast-feeding").

Before treatment with Losardex, tell your doctor if:

- You have a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see also section 4, "Side effects").
- You suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salts in your body.
- 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 salts in your body (see section 3 "How to use this medicine").
- 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.
- Your liver function is impaired (see sections "Do not use the medicine if" and 3 "How to use this medicine").
- 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.
- You have problems with your heart valves or heart muscle.

- 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).
- 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).
- You are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (such as 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 in section 2 "Do not use the medicine if".

- You are taking other medications that may increase serum potassium levels (see also information in section "Drug interactions").

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.

Tell your doctor if you are taking potassium supplements, potassium salt substitutes, potassium-sparing medicines such as certain diuretics (amiloride, triamterene, spironolactone), or other medicines that may increase serum potassium levels (e.g., heparin, trimethoprim-containing medicines) as the combination with **Losardex** is not recommended.

Take particular care if you are taking the following medicines during treatment with **Losardex**:

- Other blood pressure lowering medicines, as they may additionally reduce your blood pressure. Blood pressure may also be lowered by taking one of the following drugs/class of drugs: tricyclic antidepressants, antipsychotics, baclofene, amifostine.
- Non-steroidal anti-inflammatory drugs such as indomethacin, 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 dosage and/or to take other precautions:

If you are taking an ACE-inhibitor or aliskiren (see also information in section "Do not use the medicine if" and in section "Special warnings concerning use of the medicine").

If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function.

Losardex should not be taken in combination with lithium containing medicines without close supervision by your doctor. Special precautions (e.g., blood tests) may be appropriate.

Use of this medicine with food and drink

Losardex can be taken with or without food.

Drinking grapefruit juice should be avoided while taking **Losardex**

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 **Losardex** before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of **Losardex**. **Losardex** is not recommended in early pregnancy and must not be taken when you are more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or are about to start breast-feeding. **Losardex** is not recommended for breast-feeding mothers, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is a new-born, or was born prematurely.

Consult your doctor or pharmacist before taking this medicine.

Driving and using machines

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

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

Important information about some of the ingredients of the medicine:

Losardex tablets contain lactose. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

3. How to use the medicine?

Always use according to the doctor's instructions. You should check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and administration will be determined only by the doctor.

Your doctor will determine the right dosage of **Losardex**, considering your condition and whether you are taking other medicines.

The usual dosage is:

Adult patients with High Blood Pressure

Treatment usually starts with 50 mg losartan once a day. The maximal blood pressure lowering effect should be reached 3-6 weeks after starting treatment. Sometimes, in certain patients, it might be necessary later to increase the dosage of the medicine to 100 mg losartan, once daily.

If you have the impression that the effect of losartan is too strong or too weak, consult your doctor or pharmacist.

Adult patients with high blood pressure, Type 2 diabetes and protein in the urine

Treatment usually starts with 50 mg losartan once a day. Sometimes, in certain patients, it will be necessary to increase the dosage of the medicine to 100 mg losartan, once daily, depending on the effect of the medicine on blood pressure.

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 once a day. Usually, the dose should be increased gradually every week (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 doctor. The maximal dose is 150 mg, once daily.

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 function stronger and more efficient) and/or a beta-blocker.

Dosage in special patient groups:

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with high dose diuretics, in patients with liver impairment, or in patients over the age of 75 years. Patients with severe hepatic impairment should not use losartan (see section "Do not use the medicine if").

Do not exceed the recommended dose.

Administration

The medicine 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 **Losardex** until your doctor tells you otherwise.

Losardex 12.5: do not halve since there is no score line!

Losardex 50: you may divide into four quarters.

Losardex 100: you may halve.

There is no information regarding crushing or chewing.

If you have accidentally taken a higher dosage

Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you miss a daily dose, do not take a double dose. Take the next dose as usual and consult a doctor.

Continue with the treatment as instructed by the doctor to maintain control of your blood pressure.

Even if there is an improvement in your health condition, do not stop the treatment without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine.

Wear glasses if you need them.

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

4. Side effects

Like any medicine, using **Losardex** can cause side effects in some of the users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop taking the medicine and refer immediately to the doctor or to the nearest emergency room if the following appears:

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 appears in a frequency of 1-10 patients out of 10,000. You may need urgent medical attention or hospitalisation.

Additional side effects:

Common side effects (effects that occur in 1-10 out of 100 users):

- Dizziness, vertigo.
- 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 low sugar in the blood (hypoglycaemia).
- Too high 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 side effects (effects that occur in 1-10 out of 1,000 users):

- Somnolence.
- Headache.
- Sleep disorders.
- Feeling of increased heart rate (palpitations).
- Severe chest pain (angina pectoris).
- Shortness of breath (dyspnoea).
- Abdominal pain.
- Severe constipation.
- Diarrhoea.
- Nausea.
- Vomiting.
- Hives (urticaria).
- Itching (pruritus).
- Rash.
- Localised swelling (oedema).
- Cough.

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- 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).
- Stroke.
- Inflammation of the liver (hepatitis).
- Elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- 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.
- Ringing, buzzing, roaring, or clicking in the ears (tinnitus).
- Disturbed taste.

If a side effect occurs, if one of the side effects gets worse or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "[דיווח על תופעות לוואי עקב טיפול](https://sideeffects.health.gov.il)" [תורפתי](https://sideeffects.health.gov.il)" found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine

- **Avoid Poisoning!** This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store in the original package, in a dark, dry and cool place, at a temperature no higher than 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Cellulose microcrystalline, lactose monohydrate, starch pregelatinised, hypromellose, silica colloidal anhydrous, magnesium stearate, titanium dioxide (E-171), macrogol 400, carnauba wax.

What the medicine looks like and what the package contains:

Losardex 12.5: white round coated biconvex tablets.

Losardex 12.5 package sizes: 2, 7, 10, 14, 20, 21, 28 or 30 tablets.

Losardex 50: white round coated biconvex tablets, scored to four equal parts on one side of the tablet.

Losardex 50 package sizes: 2, 10, 14, 20, 28 or 30 tablets.

Losardex 100: white coated biconvex caplets, with a score line on both sides of the caplet.

Losardex 100 package sizes: 2, 10, 14, 20, 28 or 30 caplets.

Not all package sizes may be marketed.

Manufacturer and his address: Dexcel Ltd., 1 Dexcel Street, Or Akiva 3060000, Israel.

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Drug registration numbers at the national medicines registry of the Ministry of Health:

Losardex 12.5: 138 18 31490

Losardex 50: 138 19 31491

Losardex 100: 138 20 31492

Registration holder: Dexcel Pharma Technologies Ltd., 21 Haftzadi Nahum Street, Jerusalem 9548402, Israel