PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Losarta 50 tablets

Each tablet contains:

Losartan Potassium 50 mg

For a list of inactive ingredients – see section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about **Losarta 50**. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. 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?

Losarta 50 is indicated for treatment of heart failure.

Losarta 50 is also indicated for treatment of hypertension (high blood pressure) and to help lower the risk for cardiovascular events, such as a stroke, in patients with high blood pressure and a thickening of the left ventricle (the heart's main pumping chamber).

Losarta 50 also provides kidney protection by delaying the worsening of kidney disease in type-2 diabetic patients with protein in their urine (proteinuria).

Therapeutic class: the active ingredient belongs to the angiotensin II receptor antagonists group.

2. Before using the medicine:

☒ Do not use this medicine if:

- You are sensitive (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 **Losarta 50** in early pregnancy) (see the section "Pregnancy, breastfeeding and fertility").
- You have a severe impairment in liver function.
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Special warnings regarding the use of the medicine:

Talk to your doctor, pharmacist or nurse before taking this medicine.

- You must tell your doctor if you think you are pregnant (or might become pregnant). **Losarta 50** 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 the section "Pregnancy, breastfeeding and fertility").

❗ Before treatment with Losarta 50, tell the doctor if:

- You have a history of angioedema (swelling of the face, lips, throat and/or tongue) (see also section 4, "Side effects").
- You are suffering from excessive vomiting or diarrhea that lead to an extreme loss of fluids and/or salts from your body.
- You are receiving diuretics (medicines that increase the amount of water that you excrete through your kidneys) or are under dietary salt restriction, leading to an extreme loss of fluids and salts from your body (see section 3, "How should you use the medicine?").
- You are known to have a 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 the sections "Do not use this medicine if" and "How should you use the medicine?").
- You are suffering from heart failure, with or without renal impairment, or concomitant severe and life-threatening cardiac arrhythmias. Special caution is necessary when you are treated with a beta-blocker concomitantly.
- You are suffering from a coronary heart disease (caused by reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by reduced blood flow in the brain).
- You are suffering from primary hyperaldosteronism (a disorder caused by an adrenal gland impairment and associated with an increase in the secretion of the hormone aldosterone by that gland).
- You are taking any of the following medicines used for treatment of high blood pressure:
  - An ACE-inhibitor (e.g., 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 the section "Do not use this medicine if".
- You are taking other medicines that may increase serum potassium levels (see also information in the section "Drug-drug interactions").

❗ Drug-drug interactions:

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

Tell your doctor if you are taking potassium supplements, potassium-containing 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), whose combination with **Losarta 50** is not recommended.

Take particular care if you are taking the following medicines while under treatment with **Losarta 50**:

- Other blood pressure lowering medicines, as they may lower your blood pressure even more. Blood pressure may also be lowered by any of the following drugs/classes 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 adjust the dose and/or take other precautions:

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

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

Do not take losartan in combination with lithium-containing medicines without careful supervision by your doctor. Special precautions (e.g., blood tests) may be appropriate.

❗ Use of the medicine and food:

Losarta 50 may be taken with or without food.

❗ Pregnancy, breastfeeding and fertility:

Pregnancy

You must tell your doctor if you think you are pregnant (or might become pregnant). Your doctor will normally advise you to stop taking **Losarta 50** before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of **Losarta 50**. **Losarta 50** 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 taken after the third month of the pregnancy.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. **Losarta 50** is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is a newborn, or born prematurely.

Ask your doctor or pharmacist for advice before taking this medicine.

❗ Driving and operating machinery:

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

Losarta 50 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 ingredients of the medicine:

Losarta 50 tablets contain 89 mg lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only, depending on your condition and whether you are taking other medicines. It is important to continue taking **Losarta 50** for as long as your doctor prescribes it for you, in order to maintain smooth control of your blood pressure.

The generally accepted dosage is:

Adult patients with High Blood Pressure

Treatment usually starts with 50 mg losartan (one tablet of **Losarta 50**) once a day. The maximal blood pressure lowering effect should be achieved 3-6 weeks after beginning treatment. Sometimes, in certain patients, it might be necessary to later increase the dosage of the medicine to 100 mg losartan (two tablets of **Losarta 50**), 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.

Adult patients with High Blood Pressure, Type-2 Diabetes and Protein in the Urine

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

Losartan may be taken 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 for lowering blood glucose levels (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 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 doctor. The maximal dose is 150 mg (three tablets of **Losarta 50**), once daily.

In the treatment of heart failure, losartan is usually combined with a diuretic (a medicine that increases the amount of water that you excrete through your kidneys) and/or digitalis (a medicine that helps to make the heart's activity stronger and more efficient) and/or a beta-blocker.

Dosage in special patient groups

The doctor may recommend 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. Losartan should not be used in patients with severe hepatic impairment (see the section "Do not use this medicine if").

Do not exceed the recommended dose.

Method of administration

The tablets should be swallowed with a glass of water.

You should try to take your daily dose at about the same time every day. It is important that you continue to take **Losarta 50** until your doctor tells you otherwise.

Crushing/halving/chewing:

The tablet can be halved if needed. No information is available regarding crushing/chewing of the tablets.

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine

It is important to continue taking **Losarta 50** for as long as your doctor prescribes it for you, in order to maintain smooth control of your blood pressure.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using **Losarta 50** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop taking the medicine and contact the doctor or go to the nearest emergency room immediately 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 severe but rare side effect, which occurs in 1-10 users out of 10,000. You may need urgent medical attention or hospitalization.

Common side effects - side effects that occur in up to one out of ten users:

- Dizziness.
- Low blood pressure (especially after excessive loss of water from the body from within blood vessels, e.g., in patients with severe heart failure or under treatment with high doses of diuretics).
- Dose-related orthostatic effects, such as lowering of blood pressure upon standing up from a lying or sitting position.
- Debility.
- Tiredness.
- Too low blood sugar (hypoglycemia).
- Too much potassium in the blood (hyperkalemia).
- Changes in kidney function, including kidney failure.
- Decrease in red blood cells count (anemia).
- Increase in blood urea, serum creatinine and serum potassium in patients with heart failure.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:

- Somnolence.
- Headache.
- Sleeping disturbances.
- Feeling of increased heart rate (palpitations).
- Severe chest pain (angina pectoris).
- Shortness of breath (dyspnea).
- Abdominal pains.
- Severe constipation.
- Diarrhea.
- Nausea.
- Vomiting.
- Hives (urticaria).
- Itching (pruritus).
- Rash.
- Localized swelling (edema).
- Cough.

Rare side effects - side 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 (paresthesia).
- Fainting (syncope).
- Very rapid and irregular heartbeat (atrial fibrillation).
- Stroke.
- Inflammation of the liver (hepatitis).
- Elevated blood alanine transaminase (ALT) levels, which usually resolves upon discontinuation of treatment.

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Reduced number of thrombocytes.
- Migraine.
- Liver function impairment.
- Muscle and joint pain.
- Flu-like symptoms.
- Back pain and urinary tract infection.
- Increased sensitivity to the sun (photosensitivity).
- Unexplained muscle pains with dark (tea-colored) urine (rhabdomyolysis).
- Impotence.
- Inflammation of the pancreas (pancreatitis).
- Low blood sodium levels (hyponatremia).
- Depression.
- General bad feeling.
- Ringing, buzzing, roaring, or clicking in the ears (tinnitus).
- Disturbed taste (dysgeusia).

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

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.

Store at a temperature lower than 25°C.

Medicines should not be disposed of via wastewater or household waste. Consult the pharmacist about the way to dispose of medicines you no longer need. Taking these measures will help protect the environment.

6. Additional information:

In addition to the active ingredient the medicine also contains: Lactose, Microcrystalline Cellulose, Pregelatinised Starch, Opadry White, Magnesium Stearate, Macrogol 6000.

What does the medicine look like and what are the contents of the package:

White, round, biconvex, film-coated tablet, with a score line.

Pack sizes of 7, 10 ,30, 60, 100 tablets per pack are available. Not all package sizes may be marketed.

Name and address of the manufacturer and marketing authorization holder: CTS Chemical Industries Ltd., Kiryat Malachi.

This leaflet from 03/2020 is formatted according to the requirements of the Ministry of Health, and its content matches the leaflet of the original preparation, which was checked and approved by the Ministry of Health in 07/2016 and updated in 11/2019.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1399331578.