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

The medicine is dispensed with a doctor's prescription only

Losarta Plus

Tablets

Each tablet contains:
Losartan Potassium 50 mg
Hydrochlorothiazide 12.5 mg
For a list of inactive ingredients and allergens see section 2 "Important information about some ingredients of the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before using the medicine.

- This leaflet contains concise information about **Losarta Plus**. If you have other questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Losarta Plus is not intended for children and adolescents under the age of 18.

1. What is the medicine intended for?

Losarta Plus is intended for treatment of hypertension, and to help lower the risk of stroke in patients with high blood pressure and a thickening of the left ventricle (the heart's main pumping chamber).

Therapeutic class: Losarta Plus is a combination of Angiotensin-II receptor blocker (losartan) and a thiazide diuretic (hydrochlorothiazide).

Angiotensin II is a substance produced in the body, that binds to receptors in the blood vessels and causes them to tighten. This results in an increase in blood pressure. Losartan inhibits the binding of angiotensin II to these receptors and causes the blood vessels to relax, resulting in lower blood pressure. Hydrochlorothiazide functions by causing the kidneys to pass more water and salt. This also helps to lower the blood pressure.

2. Before using the medicine:

☒ Do not use this medicine if:

- You are sensitive (allergic) to losartan, hydrochlorothiazide or any other ingredient in this medicine (see additional information in section 6).
- You are sensitive (allergic) to other substances which are sulfonamide derivatives (e.g. other thiazides, certain anti-bacterial medicines such as co-trimoxazole - ask the doctor if you are unsure).
- You have a severe impairment in liver function.
- You have low potassium levels, low sodium levels or high calcium levels, which cannot be corrected with treatment.
- You have gout.
- You are more than 3 months pregnant (it is also better to avoid **Losarta Plus** in early pregnancy, see section "Pregnancy, breastfeeding and fertility").
- You have a serious impairment in your kidney function or your kidneys do not produce urine at all.
- You have diabetes or impaired kidney function and you are taking 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.

If you experience a decrease in vision or eye pain, these may be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or of an increase in intraocular pressure, and may occur within hours to weeks of taking **Losarta Plus**. If not treated, this condition can lead to permanent vision loss. If you have had an allergic reaction to penicillin or sulfonamide in the past, you may be at a higher risk of developing these effects.

You must tell your doctor if you think you are pregnant (or might become pregnant). **Losarta Plus** is not recommended in early pregnancy, and must not be taken after the third month of pregnancy, as it may cause serious harm to your baby if taken at this stage (see "Pregnancy, breastfeeding and fertility" section).

❗ Before treatment with the medicine, tell the doctor if:

- You have previously had breathing or lung problems (including inflammation or fluid in the lungs) as a result of taking hydrochlorothiazide. If you develop severe shortness of breath or breathing difficulties after taking **Losarta Plus**, seek medical attention immediately.
- You have previously suffered from swelling of the face, lips, tongue or throat.
- You are taking diuretics.
- You are on a low-salt diet.
- You are suffering or have suffered from serious vomiting and/or diarrhea.
- You are suffering from heart failure.
- You have impaired liver function (see section 2 "Do not use this medicine if").
- You have a narrowing of the renal arteries (renal artery stenosis) or if you only have one functional kidney, or if you have recently undergone a kidney transplant.
- You have a narrowing of the arteries (atherosclerosis), angina pectoris (chest pains due to impaired cardiac function).
- You have an aortic or mitral valve stenosis (narrowing of the valves of the heart) or hypertrophic cardiomyopathy (a disease causing thickening of the heart muscle).
- You are diabetic.
- You had gout.
- You have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus).
- You have high calcium levels or low potassium levels, or you are on a low-potassium diet.
- You need to undergo anesthesia (even if at the dentist's) or before surgery, or if you are about to have your parathyroid function tested, you must tell your doctor or the medical staff that you are taking **Losarta Plus** tablets.
- 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:
  - ACE inhibitor (e.g. enalapril, lisinopril, ramipril), particularly if you have kidney problems associated with diabetes.
  - Aliskiren.

  Your doctor may test your kidney function, blood pressure and amount of electrolytes (e.g. potassium) in your blood at regular intervals.
  See also information under the heading "Do not use this medicine if".
- You are taking other medications that may increase serum potassium levels (see section 2, "Drug interactions").
- You have previously had skin cancer, or if you are developing an unexpected skin lesion while using the medicine.
  Using hydrochlorothiazide may increase the risk for developing cancer in the skin and lips (non-melanoma skin cancer), particularly during long-term use in high dosage.
  The skin should be protected from exposure to the sun and to ultraviolet (UV) radiation while using **Losarta Plus**.

❗ 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 or other medicines that may increase serum potassium levels (e.g., trimethoprim-containing medicines), whose combination with **Losarta Plus** is not recommended.

Diuretic agents such as the hydrochlorothiazide contained in **Losarta Plus** may interact with other medicines.

Do not take **Losarta Plus** in combination with lithium-containing medicines without careful supervision by your doctor.

Special precautions (e.g. blood tests) may be appropriate if you are taking other diuretics, certain laxatives, medicines for gout, medicines for controlling heart rhythm or for diabetes (oral medicines or insulin).

It is also important that your doctor will know if you are taking:

- Other medicines for lowering blood pressure.
- Steroids.
- Medicines to treat cancer.
- Analgesics.
- Medicines for treatment of fungal infections.
- Medicines for treatment of arthritis.
- Preparations containing resins for treatment of high cholesterol, such as colestyramine.
- Muscle relaxants.
- Sleeping pills.
- Opioid medicines such as morphine.
- Pressor amines such as adrenaline or other medicines from the same group.
- Oral medicines for diabetes or insulin.

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 under the headings "Do not use this medicine if" and "Special warnings regarding the use of the medicine").

Please also inform your doctor that you are taking **Losarta Plus** if you are about to undergo an x-ray and you will be given an iodine-containing contrast agent.

❗ Use of the medicine with food and drink:

Excessive amounts of salt in the diet may counteract the effects of **Losarta Plus** tablets.

Losarta Plus tablets may be taken with or without food.

You should avoid drinking grapefruit juice while taking **Losarta Plus**.

❗ Use of the medicine and Alcohol consumption:

It is recommended not to drink alcohol while taking these tablets: alcohol and **Losarta Plus** tablets may increase each other's effects.

❗ Pregnancy, breastfeeding and fertility:

Pregnancy

You must tell your doctor if you think you are pregnant (or might become pregnant). Your doctor will usually recommend to stop taking **Losarta Plus** before becoming pregnant or as soon as you find out you are pregnant, and will recommend you to take another medicine instead of **Losarta Plus**. **Losarta Plus** is not recommended in early pregnancy, and must not be taken after the third month of pregnancy, as it may cause serious harm to your baby if taken after the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. **Losarta Plus** is not recommended for breastfeeding mothers, and your doctor may choose another treatment for you if you want to breastfeed.

❗ Use in children and adolescents:

No information is available regarding the use of **Losarta Plus** in children. Therefore, **Losarta Plus** should not be given to children.

❗ Use in the elderly:

Losarta Plus works equally well, and is equally well-tolerated in most adult patients, both elderly and younger. For most elderly patients the same dose is required as for younger patients.

❗ Driving and operating machinery:

When beginning treatment with this medicine, tasks requiring special attention (e.g. driving a car or operating dangerous machinery) should not be performed until you know what your reaction to the medicine is.

❗ Important information about some ingredients of the medicine:

Each **Losarta Plus** tablet contains about 66 mg of lactose. If you have been told by your doctor that you have intolerance to some sugars, consult your doctor before using this medicine.

3. How should you use the medicine?

Always take **Losarta Plus** 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.

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

Losarta Plus may be taken with or without food. The tablet should be swallowed with a glass of water.

The dosage and treatment regimen will be determined by the doctor only.

The generally accepted dosage is:

Hypertension:

The regular dose of **Losarta Plus** for most hypertensive patients is one tablet of **Losarta Plus** a day, in order to control blood pressure for 24 hours. The maximum daily dose is two tablets of **Losarta Plus** once a day.

Patients with hypertension and left ventricular hypertrophy:

The dosage will be determined by the doctor only.

Do not exceed the recommended dose.

Crushing/halving/chewing:

Do not chew. The tablet is intended to be swallowed.

Do not halve, as the dose is not equal in each half tablet. The marking line is not intended for halving the tablet.

No information is available regarding crushing\ pulverizing the tablet.

If you accidentally take a higher dosage

Overdose may cause blood pressure drop, palpitations, slow heartbeat, changes in blood composition and dehydration.

If you took an overdose or by mistake a child swallowed this medicine, go immediately to the emergency room of the hospital and take the package of the medicine with you.

If you forgot to take the medicine

Try to take **Losarta Plus** every day as you have been prescribed. However, 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 Plus** as long as your doctor prescribed it for you in order to maintain control over your blood pressure.

Do not take medicines in the dark! Check the label and the dose every time you take a 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 Plus** 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 using the medicine and refer to a doctor or to the nearest emergency room if there is:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat, which may cause swallowing or breathing difficulties). This is a serious but rare side effect, which occurs in 1-10 out of 10,000 users. You may need urgent medical attention or hospitalization.

Very rare side effects – side effects that occur in less than one out of 10,000 users:

- Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion).

Other side effects:

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

- Cough, upper respiratory tract infection, nasal congestion, sinusitis, sinus problems.
- Diarrhea, abdominal pain, nausea, indigestion.
- Muscle pains or cramps, leg pain, back pain.
- Sleeplessness, headache, lightheadedness.
- Weakness, tiredness, chest pain.
- Rise in blood potassium levels (which may cause abnormal heart rate), decline in hemoglobin level.
- Changes in kidney function, including kidney failure.
- Too low blood sugar (hypoglycemia).

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

- Anemia, red or brown spots on the skin (sometimes especially on the feet, legs, arms and buttocks, along with joint pains, swelling of the hands and feet and abdominal pain), bruises, decline in white blood cells, problems with blood coagulation, decline in the number of platelets.
- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels.
- Anxiety, agitation, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleeping problems, drowsiness, memory impairment.
- Sensation of "pins and needles" or similar sensations, limb pain, tremor, migraine, fainting.
- Blurry vision, burning or tingling sensation in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow.
- Ringing, buzzing, roaring or clicking sounds in the ears, vertigo.
- Low blood pressure, which may be related to position changes (feeling of dizziness or weakness when standing up), angina (chest pain), abnormal heart rate, TIA (transient ischemic attack, "mini stroke"), heart attack, palpitations.
- Vasculitis, frequently accompanied by skin rash or bruises.
- Throat pain, shortness of breath, bronchitis, pneumonia, water in the lungs (which cause breathing difficulties), nosebleed, rhinitis, congestion.
- Constipation, severe constipation, flatulence, abdominal discomfort, abdominal cramps, vomiting, dry mouth, inflammation of the salivary glands, tooth ache.
- Jaundice (yellowing of the eyes and the skin), pancreatitis.
- Hives, itching, dermatitis, rash, skin redness, sensitivity to light, dry skin, flushing, sweating, hair loss.
- Pain in the arms, shoulders, thighs, knees or other joints, swelling in the joints, stiffness, muscle weakness.
- Excessive urination, including at night, abnormal renal function including kidney inflammation, urinary tract infection, sugar in the urine.
- Decreased libido, impotence.
- Swelling of the face, local swelling (edema), fever.

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

- Hepatitis (inflammation of the liver), abnormal liver function tests.

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

- Flu-like symptoms.
- Unexplained muscle pains with dark (tea-colored) urine (rhabdomyolysis).
- Low blood sodium levels (hyponatremia).
- General bad feeling.
- Impairment of taste sensation.
- Skin and lips cancer (a non-melanoma skin cancer).
- Decrease in vision or eye pain due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute closed-angle glaucoma).

If a side effect occurs, or one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your 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 **Losarta Plus** after the expiry date (EXP) indicated on the package. The expiry date refers to the last day of that month.

Store at a temperature lower than 25°C.

Do not discard medicines in the toilet or domestic trash. 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 ingredients the medicine also contains:
Lactose, Microcrystalline Cellulose, Pregelatinised Starch, Opadry OY-L-32965 Yellow (contains: Lactose Monohydrate, Hypromellose, Titanium Dioxide, Macrogol, Quinoline Yellow Aluminium Lake, Yellow Iron Oxide, Red Iron Oxide), Magnesium Stearate, Macrogol 6000.

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

A yellow, round, biconvex, film-coated tablet, with a marking line.

Package sizes of 7, 10, 30, 60, 100 tablets are available.

Not all package sizes may be marketed.

Address of marketing authorization holder/ manufacturer: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

This leaflet was revised in February 2023 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 141-24-31703-00.

LFL 570 02/23