PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

LOTAN PLUS

Tablets

Composition:

Each **Lotan Plus** tablet contains:

Losartan potassium 50 mg

Hydrochlorothiazide 12.5 mg

For the list of the inactive and allergenic ingredients in the preparation, see section 2 "Important information about some of the ingredients of **Lotan Plus**" and section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about **Lotan Plus**.

If you have further 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 their medical condition is similar to yours.

Lotan Plus is not intended for children and adolescents under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Lotan Plus is intended for the treatment of hypertension, as well as to lower the risk of stroke in patients with high blood pressure and thickening of the left ventricle (the primary ventricle) of the heart.

Therapeutic group: Lotan Plus is a combination of an angiotensin II receptor antagonist (losartan) and a thiazide diuretic (hydrochlorothiazide).

Angiotensin II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

2. BEFORE TAKING LOTAN PLUS

Do not take Lotan Plus if:

- You are sensitive (allergic) to losartan, hydrochlorothiazide or to any of the other ingredients of this medicine (see section 6 "Further information").
- You are allergic to other sulfonamide-derived substances (e.g. other thiazides, some antibacterial drugs such as co-trimoxazole; ask your doctor if you are not sure).
- You have severely impaired liver function.
- You have low potassium, low sodium or high calcium levels which cannot be corrected by treatment.
- You are suffering from gout.
- You are more than 3 months pregnant (it is also better to avoid **Lotan Plus** in early pregnancy - see section "Pregnancy, breast-feeding and fertility").
- You have severely impaired kidney function or your kidneys are not producing any urine.
- You have diabetes or impaired kidney function and you are being treated with a blood pressure lowering medicine containing aliskiren.

Special warnings regarding the use of Lotan Plus

Talk to your doctor or pharmacist before taking **Lotan Plus**.

If you experience reduced vision or eye pain, these can be symptoms of accumulation of fluid in the vascular layer of the eye (choroidal effusion) or of increased intraocular pressure and can occur within hours to weeks of taking **Lotan Plus**. If this condition is left untreated, it may lead to permanent vision loss. If you have had an allergy to penicillin or sulfonamide in the past, you may be at higher risk of developing these effects.

You must tell your doctor if you think you are pregnant (or might become pregnant). **Lotan 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 section "Pregnancy, breast-feeding and fertility").

Before treatment with **Lotan Plus**, it is important to tell your doctor if:

- you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking **Lotan Plus**, seek medical attention immediately.
- you have previously suffered from swelling of the face, lips, throat or tongue.
- you are receiving diuretics.
- you are on a salt-restricted diet.
- you have or have had severe vomiting and/or diarrhea.
- you have heart failure.
- your liver function is impaired (see section 2 "Do not take **Lotan Plus** if").
- you have narrowing in the arteries leading to your kidneys (renal artery stenosis) or have only one functioning kidney, or if you recently underwent a kidney transplant.
- you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function).
- you have 'aortic or mitral valve stenosis' (narrowing of the valves of the heart) or hypertrophic cardiomyopathy (a disease causing thickening of the heart muscles).
- you are diabetic.
- you have 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 or low potassium levels or you are on a low potassium diet.
- you need to undergo anesthesia (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking **Lotan Plus** tablets.
- you suffer from primary hyperaldosteronism (a syndrome caused by an abnormality within the adrenal gland and associated with increased secretion of the hormone aldosterone by the gland).
- you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example 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 take **Lotan Plus** if".

- you are taking other medicines that may increase the serum potassium levels (see section 2 "Drug interactions").
- you have previously suffered from skin cancer, or if you have developed an unexpected skin lesion while using the medicine.

Use of hydrochlorothiazide, especially following long-term use at high dosages, may increase the risk of developing some types of skin and lip cancer (a non-melanoma type of skin cancer).

Protect the skin from exposure to sunlight and ultra violet radiation (UV) while using **Lotan Plus**.

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or 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 **Lotan Plus** is not recommended.

Interaction may occur between diuretic agents such as the hydrochlorothiazide, found in **Lotan Plus**, and other medicines.

Do not take **Lotan Plus** together with medicines containing lithium without close supervision by your doctor.

Special precautionary measures (e.g., blood tests) may be appropriate if you take other diuretics, some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral medicines or insulin).

It is also important for your doctor to know if you are taking:

- other medicines to reduce your blood pressure.
- steroids.
- medicines to treat cancer.
- pain killers.
- medicines for treatment of fungal infections.
- arthritis medicines.
- preparations containing resins, to treat high cholesterol, such as cholestyramine.
- medicines which relax your muscles.
- sleeping tablets.
- 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 change your dose and/or to take other precautions:

If you are taking an ACE-inhibitor or aliskiren (see also information in section 2 "Do not take **Lotan Plus** if" and "Special warnings regarding the use of **Lotan Plus**").

Please inform your doctor you are taking **Lotan Plus** if you will also be undergoing a radiographic procedure and will be given iodine contrast media.

Use of the medicine and food

Dietary salt in excessive quantities may counteract the effect of **Lotan Plus** tablets.

Lotan Plus tablets may be taken with or without food.

Avoid drinking grapefruit juice while taking **Lotan Plus** tablets.

Use of the medicine and alcohol consumption

It is advisable not to drink alcohol while taking these tablets. Alcohol and **Lotan Plus** tablets may increase each other's effects.

Pregnancy, breast-feeding and fertility

Pregnancy

You must tell your doctor if you think you are pregnant (or may become pregnant). Your doctor will normally advise you to stop taking **Lotan Plus** before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of **Lotan Plus**. **Lotan Plus** is not recommended during 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.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. **Lotan Plus** is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Use in children and adolescents

There is no information regarding the use of **Lotan Plus** in children. Therefore, **Lotan Plus** should not be given to children.

Use in the elderly

Lotan Plus works well and is equally well tolerated by most adults, adolescents and younger patients. Most older patients require the same dose as younger patients.

Driving and using machinery

When you begin treatment with this medicine, you should not perform tasks which require special attention (for example: driving an automobile or operating dangerous machinery) until you know how you respond to the medicine.

Important information about some of the ingredients of Lotan Plus

Lotan Plus tablets contain potassium (for potassium content, see section 6 "Further information").

Lotan Plus tablets contain lactose (for lactose content, see section 6 "Further information").

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.

You should check with the doctor or pharmacist if you are uncertain regarding the preparation dosage and treatment regimen. It is important to continue taking **Lotan Plus** for as long as your doctor prescribes it, in order to maintain control of your blood pressure.

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

Lotan Plus can be taken with or without food. Swallow the medicine with a glass of water.

The usually recommended dosage is:

Hypertension

The usual dose of **Lotan Plus** for most patients with high blood pressure is one **Lotan Plus** tablet daily to control blood pressure over a 24 hour period. The maximum daily dosage is two **Lotan Plus** tablets once daily.

Patients with high blood pressure and a thickening of the left ventricle

The dosage will be determined by the doctor only.

Do not exceed the recommended dose.

If necessary, the tablet may be halved for immediate use.

There is no information on crushing or chewing the tablet.

If you took more Lotan Plus than you should

An overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

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 Lotan Plus

Try to take **Lotan Plus** daily as prescribed for you. However, if you forgot to take a dose, do not take an extra dose. Just resume your normal dosing schedule.

Adhere to the treatment regimen as recommended by the doctor.

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

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

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

4. SIDE EFFECTS

As with any medicine, use of **Lotan Plus** may cause side effects in some of the users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using the medicine and proceed immediately to the doctor or to the nearest emergency room if there 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 affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients.** You may need urgent medical attention or hospitalisation.

Very rare (may affect up to 1 in 10,000 people):

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

Other side effects that may occur:

Common (may affect up to 1 in 10 people):

Cough, upper respiratory tract infection, congestion in the nose, sinusitis, sinus problems; diarrhea, abdominal pain, nausea, indigestion; muscle pain or cramps, leg pain, back pain; insomnia, headache, dizziness; weakness, tiredness, chest pain; increased potassium levels (which can cause an abnormal heart rhythm), decreased hemoglobin levels; changes in kidney function including kidney failure; too low sugar in the blood (hypoglycemia).

Uncommon (may affect up to one in 100 people):

Anemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, blood clotting problems, reduced number of platelets; loss of appetite, increased uric acid levels or gout, increased blood sugar levels, abnormal blood electrolyte levels; anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment; sensation of "pins and needles" or similar sensations, pain in the extremities, trembling, migraine, fainting; blurred vision, sensation of burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing objects in yellow; ringing, buzzing, roaring or clicking in the ears, vertigo; low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when standing up), angina (chest pain), abnormal heart rhythm, cerebrovascular accident (TIA - Transient Ischemic Attack, "mini-stroke"), heart attack, palpitations; inflammation of blood vessels, which is frequently accompanied by a skin rash or bruising; sore throat, breathlessness, bronchitis, pneumonia, water in the lungs (which causes difficulty in breathing), nosebleed, runny nose, congestion; constipation, severe constipation, flatulence, stomach discomfort, stomach cramps, vomiting, dry mouth, inflammation of a salivary gland, toothache; jaundice (yellowing of the eyes and skin), inflammation of the pancreas; hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss; pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness; frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary tract infection, sugar in the urine; decreased sex drive, impotence; swelling of the face, localized swelling (edema), fever.

Rare (may affect up to one in 1,000 people):

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

Unknown (frequency cannot be estimated from the available data):

Skin and lip cancer (a non-melanoma type of skin cancer); flu-like symptoms; unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis); low blood sodium levels (hyponatremia); general unwell feeling; disturbed taste; reduced vision or eye pain as a result of high pressure (possible signs of accumulation of fluid in the vascular layer of the eye (choroidal effusion) or acute narrow-angle glaucoma).

If a side effect occurs, 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 can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

Additionally, you can report to "Unipharm Ltd.".

5. HOW SHOULD LOTAN PLUS BE STORED?

- Avoid poisoning! This medicine, as any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use **Lotan Plus** after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25°C and in a place protected from light.

6. FURTHER INFORMATION

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

Lactose anhydrous, Microcrystalline cellulose, Pregelatinized starch, Magnesium stearate, Opadry white Y-1-7000.

Lotan Plus contains potassium in the following amount: 4.24 mg (0.108 mEq).

Lotan Plus contains lactose in the following amount: 94.2 mg.

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

Lotan Plus is packed in trays (blister) that are inserted into a carton package. Each package contains 5, 7, 10, 14, 15, 20, 28 or 30 tablets. Not all package sizes may be marketed.

Lotan Plus tablets are white, film-coated, oval, biconvex, with a break line on one side.

Registration holder and address: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 137 95 31535 01

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