

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

The medicine is dispensed with a doctor's prescription only

LOTAN 12.5, 50, 100 Tablets

Composition:

Each **Lotan 12.5** tablet contains:

Losartan potassium 12.5 mg

Each **Lotan 50** tablet contains:

Losartan potassium 50 mg

Each **Lotan 100** tablet contains:

Losartan potassium 100 mg

For the list of inactive and allergenic ingredients in the preparation, please see section 6.

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

- This leaflet contains concise information about **Lotan**. If you have further questions, ask your doctor or pharmacist.

- This medicine has been prescribed to treat you. Do not pass it on to others. It may cause harm, even if it seems that their medical condition is similar to yours.

1. WHAT IS LOTAN AND WHAT IS IT USED FOR?

1.1 What is Lotan?

Therapeutic group: **Lotan** is an angiotensin II receptor antagonist.

1.2 What is Lotan used for?

Lotan 12.5 mg, 50 mg and 100 mg are indicated for the treatment of heart failure.

Lotan 50 and **Lotan 100** are also indicated for the treatment of hypertension (high blood pressure), and to help lower the risk for cardiovascular events, such as stroke, in patients with high blood pressure and thickening of the left ventricle (the main chamber) of the heart.

Lotan 50 and **Lotan 100** also provide kidney protection by delaying the worsening of kidney disease in type 2 diabetic patients with protein excreted in their urine (proteinuria).

2. BEFORE TAKING LOTAN

2.1 Do not take Lotan if:

- you are sensitive (allergic) to 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 **Lotan** in early pregnancy - see section 2.5 "Pregnancy and breast-feeding")
- your liver function is severely impaired
- you have diabetes or impaired kidney function and you are being treated with a blood pressure lowering medicine containing aliskiren

2.2 Special warnings regarding use of Lotan:

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

You must tell your doctor if you think you are pregnant (or might become pregnant). **Lotan** is not recommended at the beginning of pregnancy and it must not be taken if you are more than 3 months pregnant, since it may cause serious harm to your baby if taken at this stage (see section 2.5 "Pregnancy and breast-feeding").

Before treatment with **Lotan**, it is important to 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 suffer from excessive vomiting or diarrhea leading 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 **Lotan**?").
- you have a known narrowing or blockage of the blood vessels leading to your kidneys or if you have recently undergone a kidney transplant.
- your liver function is impaired (see sections 2.1 "Do not take **Lotan** if" and 3 "How should you use **Lotan**?").
- you suffer from heart failure, with or without kidney damage, or combined with severe and life-threatening cardiac arrhythmias. Special caution should be exercised when you are being treated with a beta-blocker (β -blocker) concomitantly.
- you have problems with your heart valves or heart muscle.
- you suffer from 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 suffer from primary hyperaldosteronism (a syndrome caused by an impairment of the adrenal gland, and is 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 2.1 "Do not take **Lotan** if".

- you are taking other medicines that may increase the serum potassium levels (also see information in section 2.3 "Taking other medicines").

2.3 Taking other medicines

If you are taking, or have recently taken, 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 such as certain diuretics (amiloride, triamterren, spironolactone), or other medicines that may increase serum potassium levels (e.g., heparin, trimethoprim-containing medicines), whose combination with **Lotan** is not recommended. Be especially cautious if you are taking the following medicines while under treatment with **Lotan**:

- Other blood pressure lowering medicines, as they may further reduce your blood pressure. Blood pressure may also be lowered by one of the following medicines/classes of medicines: tricyclic antidepressants, antipsychotics, baclofen, 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), since they may reduce the blood pressure lowering effect of losartan.

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 2.1 "Do not take **Lotan** if" and section 2.2 "Special warnings regarding use of **Lotan**").

If you have impaired kidney function, concomitant use of these medicines may lead to deterioration in kidney function.

Do not take losartan together with lithium-containing medicines without the close supervision of your doctor. Special precautionary measures (e.g., blood tests) may be appropriate.

2.4 Taking Lotan with food and beverage:

Lotan may be taken with or without food.

2.5 Pregnancy and breast-feeding:

Pregnancy

You must tell your doctor if you think you are pregnant (or might become pregnant). Generally, your doctor will recommend that you stop taking **Lotan** before you become pregnant or as soon as you know that you are pregnant and will recommend that you take another medicine instead of **Lotan**. **Lotan** is not recommended at the beginning of pregnancy and it must not be taken if you are more than 3 months pregnant, since 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** 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 was just born, or was born prematurely.

Consult with your doctor or with a pharmacist before taking this medicine.

2.6 Driving and operating machinery:

No studies on the effects on the ability to drive or operate machinery have been performed.

Lotan is unlikely to affect your ability to drive or operate machinery. 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 to perform such activities.

2.7 Important information about some of the ingredients of Lotan:

Lotan tablets contain lactose (for the lactose content, see section 6). If you have been told by the doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

Lotan tablets contain potassium (for potassium content, see section 6).

3. HOW SHOULD YOU USE LOTAN?

Always take **Lotan** exactly as the doctor has told you. You should check with the doctor or pharmacist if you are uncertain.

Your doctor will determine the dosage and duration of treatment.

Your doctor will determine the appropriate dose of **Lotan**, taking into account your condition and whether you are taking other medicines. It is important to continue taking **Lotan** for as long as your doctor prescribes it for you, in order to maintain control of your blood pressure.

Adult patients with high blood pressure

Treatment usually starts with 50 mg losartan (one **Lotan 50** tablet), 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 (one **Lotan 100** tablet), once daily. If you have the impression that the effect of losartan is too strong or too weak, please speak with your doctor or the pharmacist.

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

Treatment usually starts with 50 mg losartan (one **Lotan 50** tablet), once a day.

Sometimes, in certain patients, it might be necessary to increase the dosage of the medicine to 100 mg losartan (one **Lotan 100** tablet), once daily, according to the effect of the medicine on the blood pressure.

Losartan may be taken together 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 (one **Lotan 12.5** tablet), once a day. Generally, 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 physician. The maximum dose is 150 mg (three **Lotan 50** mg tablets), once daily. In the treatment of heart failure, losartan is usually given in combination with a diuretic (medicine that increases the amount of water that you excrete through your kidneys) and/or digitalis (medicine that helps to strengthen and improve heart activity) and/or a beta-blocker.

Dosage in special patient groups

The doctor may recommend a lower dosage, 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 75 years of age. Losartan should not be used in patients with severe liver impairment (see section 2.1 "Do not take **Lotan** if").

Do not exceed the recommended dosage.

Method of administration

Swallow the tablets whole 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 **Lotan** until your doctor tells you otherwise.

Lotan 12.5: Do not halve the tablet.

Lotan 50, Lotan 100: If necessary, the tablet can be halved for immediate use.

There is no information regarding crushing or chewing the tablet.

If you take more Lotan than you should

Symptoms of overdose are: low blood pressure, accelerated pulse, possible slowing of pulse. If you took an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take Lotan

If you forgot to take the daily dose, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

How can you contribute to the success of the treatment?

It is important to continue taking **Lotan** as long as your doctor prescribes it for you, 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 a medicine. Wear glasses if you need them.

If you have any further questions about use of the medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Lotan** may cause side effects in some users. Do not be alarmed by the list of side effects; you may not suffer from any of them.

Stop using the medicine and refer to the doctor or proceed to the nearest emergency room if the following occurs:

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 that occurs at a frequency of 1-10 patients out of 10,000. You may need urgent medical treatment or hospitalization.

The following side effects have been reported with **Lotan**:

Common (may affect up to one person out of 10): dizziness; low blood pressure (especially after increased loss of water from the body from within blood vessels, e.g., in patients with severe heart failure or under treatment with high dose diuretics); dose-dependent effects of hypotension, such as a drop in blood pressure occurring when rising from a lying or sitting position; weakness; fatigue; too little sugar in the blood (hypoglycemia); too much potassium in the blood (hyperkalemia); 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 (may affect up to one out of 100 people): sleepiness; 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 (may affect up to one out of 1,000 people): hypersensitivity; angioedema; inflammation of blood vessels (vasculitis, including Henoch-Schönlein purpura); numbness or tingling sensation (paraesthesia); fainting (syncope); very rapid and irregular pulse (atrial fibrillation); stroke; inflammation of the liver (hepatitis); elevated levels of alanine aminotransferase (ALT) in the blood, which usually resolves upon discontinuation of treatment

Unknown (frequency cannot be estimated from the existing data): reduced number of thrombocytes; migraine; liver dysfunction; 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); taste disturbance

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.

Additionally, a report can be made to "Unipharm Ltd."

5. HOW SHOULD LOTAN BE STORED?

- Avoid poisoning! This medicine, and 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** after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of the indicated month.

- Store the medicine at a temperature below 25°C and in a place protected from light.

- Do not dispose of medicines in wastewater or household waste. Consult your pharmacist on how to dispose of medicines that are no longer necessary. Taking these measures will help protect the environment.

6. FURTHER INFORMATION

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

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

Lotan 12.5 contains potassium in the following amount: 1.06 mg (0.027 mEq).

Lotan 50 contains potassium in the following amount: 4.24 mg (0.108 mEq).

Lotan 100 contains potassium in the following amount: 8.48 mg (0.216 mEq).

Lotan 12.5 contains lactose in the following amount: 25.1 mg.

Lotan 50 contains lactose in the following amount: 100.4 mg.

Lotan 100 contains lactose in the following amount: 200.8 mg.

What the medicine looks like and contents of the package:

Lotan is packed in trays (blister) inserted into a carton package. Each package has 5, 7, 10, 14, 15, 20, 28 or 30 tablets. Not all package sizes may be marketed. **Lotan 12.5** tablets are white, film-coated, round and biconvex.

Lotan 50 tablets are white, film-coated, round, biconvex, with a score line on one side.

Lotan 100 tablets are white, film-coated, oval, biconvex, with a score line on one side.

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

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

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Lotan 12.5: 137 93 31629 01

Lotan 50: 137 94 31700 01

Lotan 100: 139 36 31707 01

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 **unipharm Ltd.**