

## PATIENT INFORMATION LEAFLET

### LOSARTIL PLUS® 50 mg / 12.5 mg film-coated tablet

It is taken orally

• **Active ingredient:**

It contains 50 mg of losartan potassium and 12.5 mg of hydrochlorothiazide.

• **Excipients:**

Microcrystalline cellulose PH 200, pregelatinized corn starch, colloidal anhydrous silica 200, agglomerate lactose monohydrate 80 (obtained from cow's milk.), magnesium stearate, polyvinyl alcohol, titanium dioxide, PEG 3350, talc, D&C Yellow Aluminum Lacquer 15-20%.

**Please read this INSTRUCTION FOR USE carefully because it contains important information for you.**

- *Keep this leaflet. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *During the use of this medicine, when you go to the doctor or hospital tell your doctor that you are using*
- *Follow exactly what is written in this instruction. Apart from the dose recommended to you about the drug do not take **high or low** doses*

#### **In this Instructions for Use:**

- 1. What is LOSARTIL PLUS and what is it used for?**
- 2. Before you use LOSARTIL PLUS**
- 3. How to use LOSARTIL PLUS?**
- 4. What are the possible side effects?**
- 5. How to store LOSARTIL PLUS**

**Headings are included.**

#### **1. What is LOSARTIL PLUS and what is it used for?**

LOSARTIL PLUS is a combination of losartan, an angiotensin II receptor blocker, and hydrochlorothiazide, a diuretic. Each film-coated tablet contains 50 mg of losartan

potassium and 12.5 mg of hydrochlorothiazide. LOSARTIL PLUS is presented in blister packs containing 28 film-coated tablets.

They are round, convex and light yellow film-coated tablets.

LOSARTIL PLUS is used in the following situations.

- LOSARTIL PLUS is used to reduce high blood pressure of unknown cause (essential hypertension) in patients whose blood pressure cannot be adequately controlled with losartan or hydrochlorothiazide alone.
- LOSARTIL PLUS in patients with high blood pressure (hypertension) and thickened left chamber of the heart (left ventricular hypertrophy).
- LOSARTIL PLUS is used to reduce the risk of stroke (stroke) in patients with high blood pressure (hypertension) and thickened left chamber of the heart (left ventricular hypertrophy), but this benefit does not apply to black patients.

## **2. Before you use LOSARTIL PLUS**

### **DO NOT USE LOSARTIL PLUS in the following conditions**

- If you are allergic (hypersensitive) to losartan, hydrochlorothiazide or any of the ingredients of the drug,
- If you are allergic to sulfonamide-derived drugs (eg other thiazides, some antibacterial drugs such as co-trimoxazole) (consult your doctor if you are not sure what sulfonamide-derived drugs are),
- If you have severe liver dysfunction
- If you have low sodium, high calcium or low potassium levels in your blood that do not improve with treatment.
- If you have gout or hyperuricemia (increased level of uric acid in the blood),
- If you are pregnant,
- if you have severe kidney dysfunction or if your kidneys are unable to produce urine
- If you have diabetes or impaired kidney function and are taking aliskiren to lower your blood pressure.

### **USE LOSARTIL PLUS CAREFULLY in the following situations**

- If you have had swelling in your face, lips, throat and tongue before,
- If you are using a diuretic (diuretic),
- If you are on a salt-restricted diet,

- If you currently have or have had excessive vomiting or diarrhea
  - If you have heart failure
  - If you have liver dysfunction (see Section 2 "DO NOT USE LOSARTIL PLUS in the following conditions")
  - If you have narrowing of the vessels leading to both kidneys (renal artery stenosis) or only one kidney, or if you have recently had a kidney transplant,
  - If there is narrowing of the arteries (atherosclerosis), chest pain (angina pectoris) due to weakening of the heart's functions,
  - If you have aortic or mitral valve stenosis (narrowing of the valves in your heart) or hypertrophic cardiomyopathy (a disease that causes thickening of the heart muscles).
  - If you have diabetes (diabetes),
  - If you have gout or hyperuricemia (increased level of uric acid in the blood),
  - If you have an allergic condition or asthma, or if you have a disease called systemic lupus erythematosus, which causes joint pain, skin rash and fever,
  - If you have high calcium or low potassium levels or are on a low potassium diet,
  - Before the operation or when you need anesthesia (even at the dentist) or if you are going to have a test to check your parathyroid functions, please inform your doctor or the relevant healthcare professional that you are taking losartan potassium and hydrochlorothiazide tablets.
  - If you have a disease called primary hyperaldosteronism (a syndrome associated with increased secretion of aldosterone hormone in this gland as a result of an abnormality in the adrenal gland).
  - If you are taking a medicine called aliskiren to lower your blood pressure.
  - If you have ever had skin cancer or have an unexpected skin lesion during treatment. Treatment with hydrochlorothiazide, especially in high doses, may increase the risk of certain types of skin and lip cancers (non-melanoma skin cancer). Protect your skin from exposure to the sun and UV rays while using LOSARTIL PLUS.
- If these warnings apply to you, even at any time in the past, please consult your doctor.

### **Using LOSARTIL PLUS with food and drink**

LOSARTIL PLUS can be taken on an empty stomach or with food.

It is recommended that you do not drink alcohol while taking these tablets. Alcohol and LOSARTIL PLUS tablets together can increase the effect of each other.

Excessive amounts of salt in the diet may counteract the effect of LOSARTIL PLUS tablets.

**Pregnancy:**

*Consult your doctor or pharmacist before using this medication.*

You should tell your doctor if you are (or may be) pregnant. LOSARTIL PLUS is not recommended during pregnancy. You should not take this medicine if you are pregnant because it can cause serious harm to your baby if used at this stage.

*If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

**Breast-feeding:**

*Consult your doctor or pharmacist before using this medication.*

Tell your doctor if you are breastfeeding or will start breastfeeding. LOSARTIL PLUS is not recommended for women who are breastfeeding, but if you absolutely want to breastfeed, your doctor may choose another treatment for you (especially if your baby is newborn or premature).

**Vehicle and machine use:**

When you are new to treatment with this medicine, you should not do any work that requires special attention (e.g. driving a car or working in dangerous machinery) until you know how the medicine works for you.

**Important information about some of the ingredients of LOSARTIL PLUS**

LOSARTIL PLUS contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicinal product contains less than 1 mmol (39 mg) potassium per dose; so it doesn't actually contain potassium.

**Concomitant use with other drugs**

Diuretic substances such as hydrochlorothiazide contained in LOSARTIL PLUS may interact with other drugs.

Preparations containing lithium should not be given with LOSARTIL PLUS without the close supervision of your doctor.

Potassium supplements, potassium-containing salt preparations or potassium-sparing drugs, other diuretics, some laxatives (e.g. senna and bisacodyl), or glycyrrhizin in licorice root, gout medications (e.g. probenecid, sulfinpyrazone, and allopurinol), drugs used in cardiac arrhythmias, or blood sugar if you are using antidiabetic drugs (oral antidiabetic drugs and insulin), it may be appropriate to take special precautions (such as blood tests).

Aşağıdakileri sıralıyorsanız, ödemeniz önemlidir:

- Other drugs that lower blood pressure,
- Steroids (drugs used in allergy, inflammation and organ transplantation),
- Medicines used in cancer treatment (eg amifostine, cyclophosphamide, methotrexate),
- Pain relievers
- Medicines used to treat tuberculosis (eg rifampicin)
- Medicines used in organ transplantation (eg cyclosporine)
- Drugs used in the treatment of fungal infections
- Arthritis medications (joint inflammation),
- Resins used for high cholesterol (cholestyramine),
- Muscle relaxants (eg tubocurarine),
- Sleeping pills,
- Opioid medicines (pain relievers), such as morphine
- Pressor amines such as adrenaline or other drugs from this group,
- Oral diabetes medications (orally used to treat diabetes) or insulin,
- Epilepsy drugs (eg barbiturates and carbamazepine)
- Drugs used in mood disorders (antipsychotics, eg thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, sultopyrid, amisulpride, tiapiride, pimozide, haloperidol, droperidol)
- Do not use LOSARTIL PLUS if you have diabetes or kidney dysfunction and are using aliskiren to lower your blood pressure.

Please inform your doctor if you are going to have a radiographic procedure where iodinated contrast material will be applied while using LOSARTIL PLUS.

*If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.*

### **3. How to use LOSARTIL PLUS?**

#### **Instructions for proper use and dose / frequency of administration:**

- Always use LOSARTIL PLUS as advised by your doctor. Your doctor will decide the appropriate dose of LOSARTIL PLUS according to your condition and other medicines you use.
- It is important that you continue to take LOSARTIL PLUS for as long as prescribed by your doctor so that your blood pressure control continues properly.
- To control blood pressure during the 24-hour interval, the usual dose of losartan/hydrochlorothiazide in most patients with hypertension is 1 tablet of LOSARTIL PLUS 50mg/12.5mg film-coated tablet daily. This can be increased to two losartan 50mg / 12.5mg hydrochlorothiazide film tablets per day or replaced with 1 tablet of LOSARTIL PLUS 100mg losartan / 25mg hydrochlorothiazide film tablets per day. The maximum daily dose is 2 tablets of 50mg losartan / 12.5mg hydrochlorothiazide or 1 tablet of 100mg losartan / 25mg hydrochlorothiazide.

#### **Application route and method:**

- LOSARTIL PLUS is for oral use only.
- It can be taken on an empty stomach or with food.
- Take the tablets with a sufficient amount of liquid (eg with a glass of water) without chewing.
- Take LOSARTIL PLUS at the same time every day for your convenience and easy recall.

#### **Different age groups:**

##### **Use in children:**

There is no experience with the use of LOSARTIL PLUS in children. Therefore, LOSARTIL PLUS is not recommended for children.

##### **Use in the elderly:**

LOSARTIL PLUS generally works equally well and is tolerated in most elderly patients and younger adult patients. Most elderly patients use the same dose as younger patients.

**Special use cases:****Liver/Kidney failure**

No dosage adjustment is required if you have moderate renal impairment. LOSARTIL PLUS is not recommended if you are on dialysis. Do not use LOSARTIL PLUS if you have severe liver or kidney failure.

*If you have the impression that the effect of LOSARTIL PLUS is too strong or too weak, talk to your doctor or pharmacist.*

**If you use more LOSARTIL PLUS than you should:**

*If you have used more than you should use LOSARTIL PLUS, talk to a doctor or pharmacist.*

Overdose can cause a drop in blood pressure, palpitations, low heart rate, changes in blood composition, and dehydration.

**If you forget to use LOSARTIL PLUS:**

Try to take your medicine as recommended.

If you forget to take a dose of the medicine, do not take this dose and then continue with normal use.

*Do not take a double dose to make up for forgotten doses.*

**Effects that may occur after discontinuation of treatment with LOSARTIL PLUS**

Do not stop your self-treatment without consulting your doctor.

**4. What are the possible side effects?**

Like all medicines, there may be side effects in people who are sensitive to the substances contained in LOSARTIL PLUS.

Side effects are listed as shown in the following categories:

Very common: may occur in at least 1 in 10 patients.

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare: less than 1 in 10,000 patients.

Unknown: Cannot be estimated from available data.

**If any of the following occur, stop using LOSARTIL PLUS and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department.**

**Common :**

- Increase in potassium level (may cause abnormal heart rhythm), decrease in hemoglobin value
- Insomnia, headache, dizziness.
- Cough, upper respiratory tract infection, nasal congestion, sinusitis (sinus inflammation), sinus discomfort,
- Diarrhea, abdominal pain, nausea, indigestion
- Pain or cramps in the muscles, pain in the legs, back pain.
- Fatigue and weakness, chest pain.
- Changes in kidney function, including kidney failure
- Low blood sugar (hypoglycemia), low rate of red blood cells (hematocrit decrease)

**Uncommon :**

- Anemia, red, brownish spots on the skin (sometimes especially on the feet, legs, arms and hips, with joint pain, swelling of the hands and feet and abdominal pain), bruises, decrease in white blood cells, clotting problem, decrease in the number of blood elements that help clotting, appetite loss of blood, increased uric acid level or significant gout, increased blood sugar level, abnormal blood electrolyte levels
- Anxiety, irritability, panic disorder (repeated panic attacks), confusion, depression, abnormal dreams, sleep disturbances, drowsiness, impaired memory
- Sensation of needles or prickles, pain in arms and legs, chills, migraine, fainting
- Blurred vision, burning and stinging sensation in the eyes, conjunctivitis (inflammation of the eye), worsening of visual function, seeing things around yellow
- Ringing, buzzing, grunting and clicking sounds in the ears, dizziness
- Drop in blood pressure and accompanying changes in posture (feeling swaying and weak when standing up), angina (chest pain), abnormal heartbeat, cerebrovascular trauma (transient ischemic attack or “mini-stroke”), heart attack, palpitations
- Inflammation of blood vessels with skin rash or sores
- Sore throat, breathlessness, bronchitis (inflammation of the airways to the lungs), pneumonia (inflammation of the lungs), water in the lungs (making it difficult to breathe), nosebleeds, runny nose, difficulty breathing, constipation, constipation



resistant to treatment, gas, stomach upset, stomach upset spasm, vomiting, dry mouth, inflammation of the salivary glands, toothache,

- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas
- Urticaria, itching, dermatitis, rash, redness of the skin, sensitivity to light, dry skin, hot flashes, sweating, hair loss
- Pain in the arms, shoulders, hips, knees and other joints, swelling, stiffness, muscle weakness in the joints
- Frequent urination, including at night, impaired kidney function including kidney inflammation, urinary tract infection, sugar in the urine
- Decreased sexual desire, impotence
- Facial swelling, local swelling (edema), fever

**Rare :**

- Sudden hypersensitivity response (anaphylactic reaction), which may cause difficulty breathing and swallowing with hepatitis (liver inflammation), abnormalities in liver function tests, hypersensitivity (hypersensitivity), swelling of the face, lips or throat
- Increase in liver enzymes

**Unknown :**

- Flu-like symptoms
- Unexplained muscle pain (rhabdomyolysis, damage to muscle tissue) with dark (tea-colored) urine
- Decreased sodium level in the blood (hyponatremia)
- Disturbance in the sense of taste (dysgeusia)
- Skin scaling (lupus erythematosus)
- Liver function abnormalities
- Decreased platelet count (thrombocytopenia)
- Dose-dependent orthostatic effects (dizziness, weakness and sometimes blackout when standing up)
- Skin and lip cancer (non-melanoma skin cancer)

*If you experience any side effects not mentioned in this leaflet inform your doctor or pharmacist.*

### **5. How to store LOSARTIL PLUS**

*Keep LOSARTIL PLUS out of the sight and reach of children and in its package.*

Store at room temperature below 25°C.

Do not open the blister pack until you are ready to take the medicine.

#### **Use in accordance with expiration dates.**

*Do not use LOSARTIL PLUS after the expiry date on the package.*

Do not use LOSARTIL PLUS if you notice any defects in the product and/or its packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

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**Manufacturing Site:**

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