

**Losartan  
Potassium/Hydrochlorothiazide  
tablets USP 50mg/12.5  
mg/100mg/12.5mg/100mg/25mg  
Taj Pharma**

(Losartan Potassium and Hydrochlorothiazide)

**Package leaflet: Information for the user**

**Read all of this leaflet carefully before you start taking this medicine.**

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
4. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

- What Losartan Potassium/Hydrochlorothiazide is and what it is used for
- Before you take Losartan Potassium/Hydrochlorothiazide
- How to take Losartan Potassium/Hydrochlorothiazide
- Possible side effects
- How to store Losartan Potassium/Hydrochlorothiazide
- Further information

**1. What Losartan  
Potassium/Hydrochlorothiazide  
is and what it is used for**

Losartan Potassium/Hydrochlorothiazide is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide).

Losartan Potassium/Hydrochlorothiazide is indicated for the treatment of essential hypertension (high blood pressure).

**2. Before you take Losartan  
Potassium/Hydrochlorothiazide**

**Do not take Losartan  
Potassium/Hydrochlorothiazide**

- if you are allergic (hypersensitive) to losartan and/or hydrochlorothiazide or any of the other ingredients of Losartan Potassium/Hydrochlorothiazide,
- if you are more than 3 months pregnant (it is also better to avoid Losartan Potassium/Hydrochlorothiazide in early pregnancy – see “Pregnancy and breast-feeding”),
- if you have severely impaired liver function; cholestasis and biliary obstructive disorders
- if you have severely impaired kidney function (i.e. creatinine clearance <30 ml/min) or your kidneys are not producing any urine,
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment,
- if you are suffering from gout.

**Take special care with Losartan  
Potassium/Hydrochlorothiazide**

- if you have previously suffered from swelling of the face, lips, throat or tongue
- if you take diuretics (water pills)
- if you are on a salt-restricted diet,
- if you have or have had severe vomiting and/or diarrhoea,
- if you have heart failure,
- if you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning,
- kidney, or you have recently had a kidney transplant,
- if you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function),
- if you have ‘aortic or mitral valve stenosis’ (narrowing of the valves of the heart) or ‘hypertrophic cardiomyopathy’ (a disease causing thickening of heart muscle),
- if you are diabetic,

- if you have had gout,
- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus).
- if you have high calcium or low potassium levels or you are on a low potassium diet,
- if you need to have an anaesthetic (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 losartan potassium and hydrochlorothiazide tablets,
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion, of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).

You must tell your doctor if you think you are (or might become) pregnant. Losartan Potassium/Hydrochlorothiazide 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 pregnancy section).

#### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Diuretic agents such as the hydrochlorothiazide contained in Losartan

Potassium/Hydrochlorothiazide may interact with other medicines. Preparations containing lithium should not be taken with Losartan

Potassium/Hydrochlorothiazide without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt

substitutes or potassium-sparing medicines, other diuretics (“water tablets”), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins). 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, drugs for treatment of fungal infections, or arthritis medicines, resins used for high cholesterol, such as colestyramine, medicines which relax your muscles, sleeping tablets, opioid medicines such as morphine, ‘pressor amines’ such as adrenaline or other drugs from the same group; (oral agents for diabetes or insulins).

Please also inform your doctor when it is planned to apply iodine contrast media about taking Losartan Potassium/ Hydrochlorothiazide.

#### **Taking Losartan**

##### **Potassium/Hydrochlorothiazide with food and drink**

You are advised not to drink alcohol whilst taking these tablets: alcohol and Losartan Potassium/Hydrochlorothiazide tablets may increase each other’s effects.

Dietary salt in excessive quantities may counteract the effect of Losartan Potassium/Hydrochlorothiazide tablets.

Losartan Potassium/Hydrochlorothiazide tablets may be taken with or without food.

##### **Pregnancy and breast-feeding**

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

##### Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Losartan Potassium/Hydrochlorothiazide before you become pregnant or as soon as you know you

are pregnant and will advise you to take another medicine instead of Losartan

Potassium/Hydrochlorothiazide. Losartan Potassium/Hydrochlorothiazide is not recommended during pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

#### Breastfeeding

Tell your doctor if you are breast -feeding or about to start breast-feeding. Losartan Potassium/Hydrochlorothiazide 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**

Losartan Potassium/Hydrochlorothiazide is not recommended for use in children below the age of 18 years due to a lack of data on safety and efficacy.

#### **Use in elderly patients**

Losartan Potassium/Hydrochlorothiazide works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

#### **Driving and using machines**

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

#### **Important information about some of the ingredients of Losartan**

##### **Potassium/Hydrochlorothiazide**

This product 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.

### **3. How to take Losartan Potassium/Hydrochlorothiazide**

Always take Losartan

Potassium/Hydrochlorothiazide exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of Losartan Potassium/Hydrochlorothiazide depending on your condition and whether you are taking other medicines. It is important to continue taking Losartan Potassium/Hydrochlorothiazide for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

Losartan Potassium/Hydrochlorothiazide is available in three strengths: Losartan

Potassium/Hydrochlorothiazide 50 mg/12.5 mg film-coated tablets, Losartan

Potassium/Hydrochlorothiazide 100 mg/12.5 mg film-coated tablets, and Losartan

Potassium/ Hydrochlorothiazide 100 mg/25 mg film-coated tablets.

#### High Blood Pressure

The usual dose of Losartan

Potassium/Hydrochlorothiazide for most patients with high blood pressure is 1 tablet of Losartan Potassium/Hydrochlorothiazide 50 mg/12.5 mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of Losartan

Potassium/Hydrochlorothiazide 50 mg/12.5 mg film-coated tablets or changed to 1 tablet daily of Losartan Potassium/Hydrochlorothiazide 100 mg/25 mg film-coated tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan

Potassium/Hydrochlorothiazide 50 mg/12.5 mg

film-coated tablets or 1 tablet daily of Losartan Potassium/Hydrochlorothiazide 100 mg/25 mg film-coated tablets.

Losartan Potassium/Hydrochlorothiazide 100 mg/12.5 mg (losartan 100 mg/HCTZ 12.5 mg) film-coated tablets are available for those patients titrated to 100 mg of losartan who require additional blood pressure control.

**If you take more Losartan Potassium/Hydrochlorothiazide than you should**

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly.

Overdosage can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration. **If you forget to take Losartan**

**Potassium/Hydrochlorothiazide**

Try to take Losartan Potassium/Hydrochlorothiazide daily as prescribed. However, if you miss a dose, do not take an extra dose.

Just resume your usual schedule.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Losartan Potassium/Hydrochlorothiazide can cause side effects, although not everybody gets them. The frequency of side effects is classified in following categories

<b>Very common</b>	affects more than 1 user in 10
<b>Common</b>	affects 1 to 10 users in 100

<b>Uncommon</b>	affects 1 to 10 users in 1,000
<b>Rare</b>	affects 1 to 10 users in 10,000
<b>Very rare</b>	affects less than 1 user in 10,000
<b>Not known</b>	frequency cannot be estimated from available data

If you experience a severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing), stop taking Losartan Potassium/Hydrochlorothiazide tablets and tell your doctor immediately or go to the casualty department of your nearest hospital.

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.

The following side effects have been reported: *Common (affecting less than one person in 10 but more than one person in 100):*

- Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder,
- Diarrhoea, 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 haemoglobin levels.

*Uncommon (affecting less than one person in 100 but more than one person in 1,000):*

- Anaemia, 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, clotting problems and bruising,
- Loss of appetite, increased uric acid levels or frank 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,

- Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting,
  - Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow,
  - Ringing, buzzing, roaring or clicking in the ears,
  - Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up, angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, “mini-stroke”), heart attack, palpitations,
  - Inflammation of blood vessels, which is often associated with a skin rash or bruising,
  - Sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion,
  - Constipation, wind, stomach upsets, stomach spasms, 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 infection, sugar in the urine,
  - Decreased sexual appetite, impotence,
  - Swelling of the face, fever.
- Rare (more than 1 out of 10,000 patients and less than 1 out of 1,000 patients)*
- Hepatitis (inflammation of the liver), abnormal liver function tests.

*Not known (frequency cannot be estimated from available data)*

- Rhabdomyolysis

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. How to Store**

Keep out of the reach and sight of children.

Do not use Losartan

Potassium/Hydrochlorothiazide after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original blister in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Further Information**

### **What Losartan**

#### **Potassium/Hydrochlorothiazide contains**

The active substances are losartan potassium and hydrochlorothiazide.

a) Each film-coated tablet contains:

Losartan potassium USP	50mg
Hydrochlorothiazide USP	12.5mg
Excipients	q.s.

Colour: Yellow Oxide of Iron & Titanium Dioxide USP.

b) Each film-coated tablet contains:

Losartan potassium USP	100mg
Hydrochlorothiazide USP	12.5mg
Excipients	q.s.

Colour: Yellow Oxide of Iron & Titanium Dioxide USP.



c) Each film-coated tablet contains:  
Losartan potassium USP           100mg  
Hydrochlorothiazide USP        25mg  
Excipients                            q.s.  
Colour: Yellow Oxide of Iron & Titanium  
Dioxide USP.

The other ingredients are: Pregelatinised  
maize starch; microcrystalline cellulose;  
lactose monohydrate; magnesium stearate,  
hypromellose; macrogol; talc; titanium  
dioxide .

### **What Losartan**

### **Potassium/Hydrochlorothiazide looks like and contents of the pack**

Losartan Potassium/Hydrochlorothiazide tablets  
are white, oval, biconvex, film-coated tablets.

Al/PVC/Blister Packing.

*Pack sizes:* 7, 14, 28, 30, 50, 90, 100 and 500  
film-coated tablets

Not all pack sizes may be marketed.

### **7. Manufactured In India By: TAJ PHARMACEUTICALS LTD.**

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