
PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

<small>Rx Only</small> LOSARTAN/ HYDROCHLOROTHIAZIDE	50mg/ 12.5mg
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Losartan Potassium and
Hydrochlorothiazide Tablets, USP
Angiotensin II Antagonist

Toll Free No.: 1800 222 434
& 1800 222 825

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Protect Health And Life



PHARMACIST ONLY MEDICINES KEEP OUT OF REACH OF CHILDREN

Rx Only
**LOSARTAN/
HYDROCHLOROTHIAZIDE**

**50mg/
12.5mg**

Losartan Potassium and
Hydrochlorothiazide Tablets, USP

Angiotensin II Antagonist

Losartan potassium/Hydrochlorothiazide 50 mg/12.5 mg
film-coated tablets

Losartan potassium/Hydrochlorothiazide 100 mg/12.5 mg
film-coated tablets

Losartan potassium/Hydrochlorothiazide 100 mg/25 mg
film-coated tablets

Losartan potassium and hydrochlorothiazide

Package leaflet: Information for the user

Read all of this leaflet carefully before you start taking this
medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or
pharmacist.

- This medicine has been prescribed for you only. Do not pass it
on to others. It may harm them, even if their signs of illness are
the same as yours.

- If you get any side effects, talk to your doctor, or pharmacist or
nurse. This includes any possible side effects not listed in this
leaflet. See section 4.

What is in this leaflet:

- 1. What Losartan potassium/Hydrochlorothiazide Tablets is and what it is used for**
- 2. What you need to know before you take Losartan potassium/Hydrochlorothiazide Tablets**
- 3. How to take Losartan potassium/Hydrochlorothiazide Tablets**
- 4. Possible side effects**
- 5. How to store Losartan potassium/Hydrochlorothiazide Tablets**
- 6. Contents of the pack and other information**

The name of your medicine is “Losartan potassium/
Hydrochlorothiazide 50 mg/12.5 mg, 100 mg/12.5 mg & 100 mg/
25 mg film-coated tablets” (referred to as ‘Losartan
potassium/Hydrochlorothiazide Tablets’ or as ‘Losartan
potassium/Hydrochlorothiazide’ throughout this leaflet).

1. What Losartan potassium/Hydrochlorothiazide Tablets 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. What you need to know before you take Losartan potassium/Hydrochlorothiazide Tablets

Do not take Losartan potassium/Hydrochlorothiazide Tablets

- if you are allergic to losartan, hydrochlorothiazide or to any of the other ingredients of this medicine (listed in section 6)
- if you are allergic (hypersensitive) to other sulfonamide-derived substances (e.g. other thiazides, some antibacterial drugs such as co-trimoxazole, ask your doctor if you are not sure)
- if you are more than 3 months pregnant. It is also better to avoid Losartan potassium/Hydrochlorothiazide in early pregnancy (see also pregnancy section) if you have severely impaired liver function
- if you have severely impaired kidney function 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
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

Warnings and precautions

Talk to your doctor or pharmacist before taking 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).
- if 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 under the heading “Do not take Losartan potassium/ Hydrochlorothiazide”.

You must tell your doctor if you think that 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).

Other medicines and Losartan potassium/ Hydrochlorothiazide
Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines.

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 under the headings “Do not take Losartan potassium/ Hydrochlorothiazide ” and “Warnings and precautions”) 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 Tablets with food and drink and alcohol

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

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 in 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 breastfeeding.

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

Use in children and adolescents

There is no experience with the use of Losartan potassium/ Hydrochlorothiazide in children. Therefore, Losartan potassium/Hydrochlorothiazide should not be given to children.

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.

Losartan potassium/Hydrochlorothiazide Tablets contains lactose

Losartan potassium/Hydrochlorothiazide Tablets 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 Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. 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.

This medicinal product is available in three strengths: 50 mg/ 12.5 mg, 100 mg/12.5 mg and 100 mg/25 mg.

High Blood Pressure

The recommended 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 The dosage strength of Losartan potassium/Hydrochlorothiazide 100 mg/12.5 mg is available for those patients titrated to 100 mg of Losartan who required additional blood pressure control.

If you take more Losartan potassium/Hydrochlorothiazide Tablets than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Over dosage can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take Losartan potassium/Hydrochlorothiazide

Tablets

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience the following, stop taking Losartan potassium/Hydrochlorothiazide tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

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.

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 10000 patients and less than 1 out of 1000 patients)

- Hepatitis (inflammation of the liver), abnormal liver function tests **Other side effects with unknown frequency (cannot be estimated from the available data):**
- Unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis)

5. How to store Losartan potassium/Hydrochlorothiazide Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on

the label, carton, bottle. The expiry date refers to the last day of that month.

Store below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Losartan potassium/Hydrochlorothiazide Tablets contains

The active substances are losartan potassium and hydrochlorothiazide.

Losartan potassium/Hydrochlorothiazide 50 mg/12.5 mg tablet contains 50 mg of losartan potassium and 12.5 mg of hydrochlorothiazide (HCTZ) as the active ingredients.

Losartan potassium/Hydrochlorothiazide 100 mg/12.5 mg tablet contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide (HCTZ) as the active ingredients.

Losartan potassium/Hydrochlorothiazide 100 mg/25 mg tablet contains 100 mg of losartan potassium and 25 mg of hydrochlorothiazide (HCTZ) as the active ingredients.

The other ingredients are cellulose microcrystalline, lactose monohydrate, starch pregelatinised, silica colloidal anhydrous, magnesium stearate.

Tablet coat: Hydroxypropyl cellulose (E463), hypromellose 6cp (E464), titanium dioxide (E171), quinoline yellow aluminium lake (E104) [only in 50 mg/12.5 mg & 100 mg/25 mg].

What Losartan potassium/Hydrochlorothiazide Tablets looks like and contents of the pack

Film coated tablets

Losartan potassium/Hydrochlorothiazide 50 mg/12.5 mg Yellow coloured, oval shaped, beveled edge, biconvex film-coated tablets debossed with 'E' on one side and '48' on the other side.

Losartan potassium/Hydrochlorothiazide 100 mg/12.5 mg White, Oval shaped, beveled edge, biconvex film-coated tablets debossed with 'F' on one side and '74' on the other side.

Losartan potassium/Hydrochlorothiazide 100 mg/25 mg Yellow coloured, oval shaped, beveled edge, biconvex film-coated tablets debossed with 'E' on one side and '49' on the other side.

Losartan potassium/Hydrochlorothiazide is available in packs of white opaque PVC/PE/PVDC – Aluminium foil blisters and HDPE bottle packs.

Pack sizes: / **Blister pack:** 14, 28, 30, 50, 56, 60, 90, 98, 100, 280 and 500 film coated tablets

Bottle pack: 14, 30 and 500 film-coated tablets
Not all pack sizes may be marketed.

Shelf life: 36 months Storage: Store in a cool, dry and dark place.

Marketing Authorisation Holder

Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

**Unit No. 214.Old Bake House,
Maharashtra chambers of Commerce Lane,
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at : Ahmedabad - Gujarat, INDIA.

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**PHARMACIST ONLY MEDICINES
KEEP OUT OF REACH OF CHILDREN**

Rx Only
**LOSARTAN/
HYDROCHLOROTHIAZIDE**

**50mg/
12.5mg**

Losartan Potassium and
Hydrochlorothiazide Tablets, USP

Angiotensin II Antagonist

TAJ PHARMA