Losartan Potassium/Hydrochlorothiazide

100 mg/25 mg film-coated tablets

Losartan potassium/Hydrochlorothiazide

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

• 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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

In this leaflet:

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).

Do not take Losartan Potassium/Hydrochlorothiazide

• if you are allergic (hypersensitive) to losartan or to 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 section.)
• if you have severely impaired liver function, cholestasis and biliary obstructive disorders
• if you have severely impaired kidney function (e.g. creatinine clearance <10 ml/min)
• if your kidney is 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.

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 have a salt-restricted diet
• if you have had severe vomiting and/or diarrhoea
• if you have heart failure
• if you have narrow arteries to your kidneys (renal artery stenosis) or you have only one functioning kidney, or you have recently had a kidney transplant
• if you have abnormalities of the arteries (atherosclerosis), aortic stenosis (heart problem due to poor heart function)
• if you are diabetic
• if you have had gout
• if you have or 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 Kathegin function, you must tell your 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 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).

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 consultation by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate if you take lithium tablets, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics (‘water tablets’), some laxatives, medicines for the treatment of gout, medicines to control high urine production 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, design for treatment of fungal infections, or antibiotics medicines, excess used for high cholesterol, inflammatory, medicines which cause your muscles, sleeping tablets, topical medicines such as morphine, ‘pressur arteries’ such as adrenaline or other drugs from the same group, (oral agents for diabetes or insulins).

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

Taking Losartan Potassium/Hydrochlorothiazide with food and drink

This medicinal product may be taken with or without food.

Dietary salt in excess quantities may counteract the effect of Losartan potassium and hydrochlorothiazide tablets.

1. BEFORE YOU TAKE LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE

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

2. HOW TO TAKE LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE

Please avoid not to drink alcohol whilst taking these tablets: alcohol and losartan potassium and hydrochlorothiazide tablets may increase each other’s effects.

Dietary salt in excess quantities may counteract the effect of losartan potassium and hydrochlorothiazide tablets.

Pregnancy and breast-feeding

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 to take another medicine instead of Losartan Potassium/Hydrochlorothiazide. Losartan Potassium/Hydrochlorothiazide is not recommended in early 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.

Breast-feeding

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 so you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

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.

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 sugar, contact your doctor before taking this medicinal product.
4. POSSIBLE SIDE EFFECTS

The frequency of side effects is classified into the following categories:

- **Very common** (affects more than 1 user in 10):
  - Headache
  - Insomnia
  - Dry cough

- **Common** (affects 1 to 10 users in 100):
  - Dizziness
  - Headache
  - Fatigue
  - Back pain
  - Cough

- **Uncommon** (affects 1 to 10 users in 1,000):
  - Dizziness
  - Fatigue
  - Back pain

- **Rare** (affects less than 1 user in 1,000):
  - Dizziness
  - Fatigue
  - Back pain

- **Very rare** (affects less than 1 user in 10,000):
  - Dizziness
  - Fatigue
  - Back pain

Not all pack sizes may be marketed.

Pack size:
8 mm x 15 mm thickness 5.1 – 6.1 mm.

Losartan Potassium/Hydrochlorothiazide 100 mg/25 mg:
yellow, oval, slightly biconvex, film-coated tablets,
tablet dimension in the core – pregelatinised maize starch;
microcrystalline cellulose; lactose monohydrate; magnesium stearate; in the coating:
• The other ingredients are:
  - in the core – pregelatinised maize starch, microcrystalline cellulose, lactose monohydrate; magnesium stearate; in the coating – hypromellose, macrogel, magnesium stearate; sodium chloride (0.17%); sodium hydrogen carbonate;

What Losartan Potassium/Hydrochlorothiazide looks like and contains of the pack
Losartan Potassium/Hydrochlorothiazide 100 mg/25 mg: yellow, oval, slightly biconvex, film-coated tablets, tablet dimension 8 mm x 5 mm.

Pool size:
7, 10, 14, 28, 30, 50, 60, 80, 90 and 98 film-coated tablets in Al/PVC/PVC transparent blister and carton.

Not all pack sizes may be marketed.

Marketing Authorization Holder

RKA, d.d., Novo-mesto, marja_ka_cesta 6, 8011 Novo mesto, Slovenia

Manufacturer

1. RKA, d.d., Novo-mesto, marja_ka_cesta 6, 8011 Novo mesto, Slovenia
2. TAD Pharma GmbH, Heinz-Lohmann-Strasse 5, 27472 Cuxhaven, Germany

Distributed by:

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3. HOW TO TAKE LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE

Keep out of the reach of and sight of children.

Do not use Losartan Potassium/Hydrochlorothiazide after the expiry date which is stated on the carton and blister after EXP.

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

- A new 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 may have been reported:

- Cough, upper airway infection, congestion in the nose, sinus, 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) affects less than 1 user in 10,000 or more than 1 user in 1,000:
  - Anaphylaxis, nausea, vomiting
  - Arthritis, pain in the joints, swelling, redness
  - Anemia
  - Decreased white blood cell count
  - Diarrhoea
  - Fever
  - Headache
  - Insomnia
  - Abnormal liver function tests
  - Conjunctivitis, drying of the eyes
  - Decreased or absent sexual desire
  - Earache

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

- Anaphylactic shock (which 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)

- Anaphylaxis, nausea, vomiting
- Arthritis, pain in the joints, swelling, redness
- Anemia
- Decreased white blood cell count
- Diarrhoea
- Fever
- Headache
- Insomnia
- Abnormal liver function tests
- (Uncommon) affects less than 1 user in 10,000 or more than 1 user in 1,000:
  - Anaphylaxis, nausea, vomiting
  - Arthritis, pain in the joints, swelling, redness
  - Anemia

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 LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE

Keep out of the reach of and sight of children.

Do not use Losartan Potassium/Hydrochlorothiazide after the expiry date which is stated on the carton and blister after EXP.

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