Losartan Potassium
• 72000272-00

higher blood pressures, so that even modest reductions of severe hypertension can provide substantial benefit. Relative risk reduction infarction and cardiovascular mortality also have been seen regularly.

**DOSE AND ADMINISTRATION**

• Reduction of the risk of stroke in patients with hypertension

• Usual adult dose: 50 mg once daily. (2.1)

• In clinical trials involving 1024 patients with hypertension, the recommended starting dose of losartan was 50 mg once daily and this dose was increased, if necessary, to 100 mg once daily. The recommended dose range is 50 to 100 mg once daily. The maximum dose of losartan that has been evaluated is 300 mg once daily.

**WARNINGS AND PRECAUTIONS**

• Dual inhibition of the renin-angiotensin system: Increased risk of hyperkalemia, hypotension, and renal impairment. Patients with severe renal impairment (creatinine clearance <15 mL/min) should be initiated on losartan potassium at a dose of 25 mg once daily.

• Hepatic Impairment: Recommended starting dose 25 mg once daily. (2.4, 8.8, 12.3)

**ADVERSE REACTIONS**

• General Disorders and Administration Site Conditions: Malaise.

• Respiratory, thoracic and mediastinal disorders: Dyspnea.

• Nervous system disorders: Somnolence, headache, sleep disorders, paresthesia, migraine.

• Psychiatric disorders: Depression.

• Blood and lymphatic system disorders: Anemia.

• Gastrointestinal disorders: Anorexia.

• General disorders and administration site conditions: Malaria.

• Nervous system disorders: Headache, sleep disorders, paresthesia, migraine.

• Psychiatric disorders: Depression.

• Blood and lymphatic system disorders: Anemia.

**PHARMACOKINETICS**

Losartan does not affect the response to bradykinin, whereas ACE inhibitors increase the response to bradykinin. Aldosterone plasma concentrations fall following losartan administration. In spite of the effect of losartan on aldosterone secretion, very little effect on plasma aldosterone concentrations occurs.

Losartan, the active metabolite of losartan, is orally absorbed, with peak concentrations occurring approximately 4 hours post-dose. Losartan is extensively metabolized in the liver and is secreted into the bile. Losartan is eliminated as the metabolites or unchanged drug in the urine. The mean plasma half-life of losartan is 1 to 2 hours. The average plasma half-life of the metabolites is approximately 9 hours.

Losartan has been shown to be effective in patients with mild, moderate, and severe renal impairment and in patients with hepatic impairment. The pharmacokinetics of losartan are unchanged in patients with mild to moderate renal impairment.

Losartan potassium is a prodrug, the active moiety of losartan. It is rapidly absorbed after oral administration. The absolute bioavailability of losartan is approximately 35%. Losartan is extensively metabolized in the liver and is secreted into the bile. Losartan is eliminated as the metabolites or unchanged drug in the urine. The mean plasma half-life of losartan is 1 to 2 hours.

Losartan is metabolized in the liver by CYP3A4 to its active metabolite, the inactive metabolite is excreted in the bile and feces. Losartan is metabolized to the inactive metabolite and is not further metabolized by the kidney. The inactive metabolite is excreted in the urine and feces. The inactive metabolite is not further metabolized by the kidney.

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The most common side effects of losartan potassium tablets in people with high blood pressure are:

- "cold" (upper respiratory infection)
- dizziness
- stuffy nose
- back pain

The most common side effects of losartan potassium tablets in people with type 2 diabetes with diabetic kidney disease are:

- diarrhea
- tiredness
- low blood sugar
- chest pain
- high blood potassium
- low blood pressure

Tell your doctor if you get any side effect that bothers you or that won’t go away.

This is not a complete list of side effects. For a complete list, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I take losartan potassium tablets?

Store losartan potassium tablets at 59°F to 86°F (15°C to 30°C).

Keep losartan potassium tablets in a tightly closed container that protects the medicine from light.

What are the ingredients in losartan potassium tablets?

Active ingredients: losartan potassium.

Inactive ingredients: croscarmellose sodium, hypromelllose, magnesium stearate, microcrystalline cellulose, potato starch, pregelatinized starch, glycol, talc, and titanium dioxide.


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(PIL 72000273-00; Revised: 06/2016)

2.1 ± 0.70

• If you take too much losartan potassium tablets, call your doctor or

The most common side effects of losartan potassium tablets in people

- Low blood pressure (hypotension): Low blood pressure may cause you to feel faint or dizzy. Lie down if you feel faint or dizzy. Call your doctor right away.

- For people who already have kidney problems, you may see a worsening in how your kidneys work. Call your doctor if you get swelling in your feet, ankles, or hands, or unexplained weight gain.

- High blood levels of potassium

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