

Patient Information

LOSARTAN POTASSIUM (low-SAHR-tan poe-TASS-ee-uhm) TABLETS USP 25 mg, 50 mg, 100 mg

Rx only

Read the Patient Information that comes with losartan potassium tablets before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition and treatment.

What is the most important information I should know about losartan potassium tablets?

- **Losartan potassium tablets can cause harm or death to an unborn baby.**
- Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant.
- If you get pregnant while taking losartan potassium tablets, tell your doctor right away.

What is losartan potassium tablet?

Losartan potassium tablet is a prescription medicine called an angiotensin receptor blocker (ARB). It is used:

- alone or with other blood pressure medicines to lower high blood pressure (hypertension).
- to lower the chance of stroke in patients with high blood pressure and a heart problem called left ventricular hypertrophy. Losartan potassium tablets may not help Black patients with this problem.
- to slow the worsening of diabetic kidney disease (nephropathy) in patients with type 2 diabetes who have or had high blood pressure.

Losartan potassium tablets have not been studied in children less than 6 years old or in children with certain kidney problems.

High Blood Pressure (hypertension). Blood pressure is the force in your blood vessels when your heart beats and when your heart rests. You have high blood pressure when the force is too much. Losartan potassium tablets can help your blood vessels relax so your blood pressure is lower.

Left Ventricular Hypertrophy (LVH) is an enlargement of the walls of the left chamber of the heart (the heart's main pumping chamber). LVH can happen from several things. High blood pressure is the most common cause of LVH.

Type 2 Diabetes with Nephropathy. Type 2 diabetes is a type of diabetes that happens mainly in adults. If you have diabetic nephropathy it means that your kidneys do not work properly because of damage from the diabetes.

Who should not take losartan potassium tablets?

- **Do not take losartan potassium tablets if you are allergic to any of the ingredients in losartan potassium tablets.** See the end of this leaflet for a complete list of ingredients in losartan potassium tablets.
- Do not take losartan potassium tablets if you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.

What should I tell my doctor before taking losartan potassium tablets?

Tell your doctor about all of your medical conditions including if you:

- **are pregnant or planning to become pregnant.** See “What is the most important information I should know about losartan potassium tablets?”
- **are breastfeeding.** It is not known if losartan potassium passes into your breast milk. You should choose either to take losartan potassium tablets or breastfeed, but not both.
- are vomiting a lot or having a lot of diarrhea
- have liver problems
- have kidney problems

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Losartan potassium tablets and certain other medicines may interact with each other. Especially tell your doctor if you are taking:

- potassium supplements
- salt substitutes containing potassium
- other medicines that may increase serum potassium
- water pills (diuretics)
- lithium (a medicine used to treat a certain kind of depression)
- medicines used to treat pain and arthritis, called non-steroidal anti-inflammatory drugs (NSAIDs), including COX-2 inhibitors
- other medicines to reduce blood pressure

How should I take losartan potassium tablets?

- Take losartan potassium tablets exactly as prescribed by your doctor. Your doctor may change your dose if needed.
- Losartan potassium tablets can be taken with or without food.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at your regular time.
- If you take too much losartan potassium tablets, call your doctor or Poison Control Center, or go to the nearest hospital emergency room right away.

What are the possible side effects of losartan potassium tablets?

Losartan potassium tablets may cause the following side effects that may be serious:

- **Injury or death of unborn babies.** See “What is the most important information I should know about losartan potassium tablets?”
- **Allergic reaction.** Symptoms of an allergic reaction are swelling of the face, lips, throat or tongue. Get emergency medical help right away and stop taking losartan potassium tablets.
- **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 well 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

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

- “colds” (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.

How do I store losartan potassium tablets?

- Store losartan potassium tablets at 25°C (77°F); excursion permitted to 15° to 30°C (59° to 86°F).
- Keep losartan potassium tablets in a tightly closed container that protects the medicine from light.
- **Keep losartan potassium tablets and all medicines out of the reach of children.**

General information about losartan potassium tablets

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use losartan potassium tablets for a condition for which it was not prescribed. Do not give losartan potassium tablets to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about losartan potassium tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about losartan potassium tablets that is written for health professionals.

What are the ingredients in losartan potassium tablets?

Active ingredients: losartan potassium

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, pregelatinized starch, magnesium stearate, hydroxypropyl cellulose, hypromellose, titanium dioxide, D&C yellow No. 10 aluminum lake and FD&C blue No. 2 aluminum lake.

Call your doctor for medical advice about side effects. You may report side effects to Alembic Pharmaceuticals Limited at 1-866-210-9797 or FDA at 1-800-FDA-1088.

Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

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