Patient Information
Losartan potassium and hydrochlorothiazide tablets, USP
50 mg/12.5 mg, 100 mg/12.5 mg and 100 mg/25 mg
(loe sar' tan poe tas' ee um and hye'' droe klor'' oh thye' a zide)
Rx only

Read the Patient Information that comes with losartan potassium and hydrochlorothiazide 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 and hydrochlorothiazide tablets?

- **Losartan potassium and hydrochlorothiazide 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 and hydrochlorothiazide tablets tell your doctor right away.

What are losartan potassium and hydrochlorothiazide tablets?

Losartan potassium and hydrochlorothiazide tablet contains 2 prescription medicines, an angiotensin receptor blocker (ARB) and a diuretic (water pill). It is used to:

- lower high blood pressure (hypertension). Losartan potassium and hydrochlorothiazide tablets are not usually the first medicine used to treat high blood pressure.
- lower the chance of stroke in patients with high blood pressure and a heart problem called left ventricular hypertrophy (LVH). Losartan potassium and hydrochlorothiazide tablets may not help Black patients with this problem.

Losartan potassium and hydrochlorothiazide tablets have not been studied in children less than 18 years old.

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. The losartan ingredient in losartan potassium and hydrochlorothiazide tablets can help your blood vessels relax so your blood pressure is lower. The hydrochlorothiazide ingredient in losartan potassium and hydrochlorothiazide tablets works by making your kidneys pass more water and salt.

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.

Who should not take losartan potassium and hydrochlorothiazide tablets?

Do not take losartan potassium and hydrochlorothiazide tablets if you:

- are allergic to any ingredients in losartan potassium and hydrochlorothiazide tablets. See a complete list of ingredients in losartan potassium and hydrochlorothiazide tablets at the end of this leaflet.
- are not passing urine.
- have diabetes and are taking a medicine called aliskiren to reduce blood pressure.

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

Tell your doctor about all 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 and hydrochlorothiazide tablets?"**
- are breastfeeding or plan to breastfeed. Losartan potassium and hydrochlorothiazide can pass into your milk and may harm your baby. You and your doctor should decide if you will take losartan potassium and hydrochlorothiazide tablets or breastfeed. You should not do both.
- have been vomiting (throwing up), having diarrhea, sweating a lot, or not drinking enough fluids. These could cause you to have low blood pressure.
- have liver problems
- have kidney problems
- have systemic lupus erythematosus (Lupus; SLE)
- have diabetes
- have gout
- have any allergies
- have had skin cancer or if you develop a new skin lesion during the treatment. Treatment with hydrochlorothiazide may increase the risk of some types of skin cancer (non-melanoma skin cancer). Discuss with your doctor how to protect your skin from sun exposure and how often you should undergo skin cancer screening.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.
Losartan potassium and hydrochlorothiazide 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.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take losartan potassium and hydrochlorothiazide tablets?

- Take losartan potassium and hydrochlorothiazide tablets exactly as prescribed by your doctor. Your doctor may change your dose if needed.
- Losartan potassium and hydrochlorothiazide 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 and hydrochlorothiazide, call your doctor or Poison Control Center, or go to the nearest hospital emergency room right away.
- Your doctor may do blood tests from time to time while you are taking losartan potassium and hydrochlorothiazide tablets.

What are the possible side effects of losartan potassium and hydrochlorothiazide tablets?

Losartan potassium and hydrochlorothiazide 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 and hydrochlorothiazide tablets?"**

- **Allergic reaction.** Symptoms of an allergic reaction are swelling of the face, lips, throat, or tongue and may include severe shortness of breath and/or difficulty breathing.Get emergency medical help right away and stop taking losartan potassium and hydrochlorothiazide 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.

- **If you 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.

- **A new or worsening condition called systemic lupus erythematosus (Lupus; SLE)**

- **Eye problems.** One of the medicines in losartan potassium and hydrochlorothiazide tablets can cause eye problems that, if left untreated, may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of startinglosartan potassium and hydrochlorothiazide tablets. Tell your doctor right away if you have:
    - decrease in vision
    - eye pain

- **Sensitivity of the skin to the sun and risk of skin cancer.**

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

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

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 should I store losartan potassium and hydrochlorothiazide tablets?

- Store losartan potassium and hydrochlorothiazide tablets at room temperature at 59°F to 86°F (15°C to 30°C).
- Keep losartan potassium and hydrochlorothiazide tablets in a tightly closed container, and keep losartan potassium and hydrochlorothiazide tablets out of the light.
- **Keep losartan potassium and hydrochlorothiazide tablets and all medicines out of the reach of children.**

General information about losartan potassium and hydrochlorothiazide tablets
Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use losartan potassium and hydrochlorothiazide tablets for a condition for which it was not prescribed. Do not give losartan potassium and hydrochlorothiazide 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 and hydrochlorothiazide tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information that

is written for health professionals.

What are the ingredients in losartan potassium and hydrochlorothiazide tablets?

Active ingredients: losartan potassium, hydrochlorothiazide

Inactive ingredients: hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, and titanium dioxide. Losartan potassium and hydrochlorothiazide tablets, 50 mg/12.5 mg and 100 mg/25 mg also contain iron oxide yellow.

For patent information: https://granulespharma.com/products/losartan-and-hctz-tabs

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Granules India Limited
Hyderabad-500 084, India
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Granules Pharmaceuticals Inc.
Chantilly, VA 20151

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