Patient Information HYZAAR[®] (HY-zar) (losartan potassium and hydrochlorothiazide tablets) 50/12.5 mg, 100/12.5 mg, 100/25 mg Rx only

Read the Patient Information that comes with HYZAAR[®] 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 HYZAAR?

• HYZAAR 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 HYZAAR tell your doctor right away.

What is HYZAAR?

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

- lower high blood pressure (hypertension). HYZAAR is 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). HYZAAR may not help Black patients with this problem.

HYZAAR has 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 HYZAAR can help your blood vessels relax so your blood pressure is lower. The hydrochlorothiazide ingredient in HYZAAR 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 HYZAAR?

Do not take HYZAAR if you:

- are allergic to any ingredients in HYZAAR. See a complete list of ingredients in HYZAAR 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 HYZAAR?

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 HYZAAR?"
- are breastfeeding or plan to breastfeed. HYZAAR can pass into your milk and may harm your baby. You and your doctor should decide if you will take HYZAAR 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.

HYZAAR 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 HYZAAR?

- Take HYZAAR exactly as prescribed by your doctor. Your doctor may change your dose if needed.
- HYZAAR 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 HYZAAR, 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 HYZAAR.

What are the possible side effects of HYZAAR?

HYZAAR 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 HYZAAR?"
- 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 HYZAAR.

- 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 HYZAAR can cause eye problems that, if left untreated, may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting HYZAAR. Tell your doctor right away if you have:
 - $\circ \quad \text{decrease in vision} \quad$
 - o eye pain
- Sensitivity of the skin to the sun and risk of skin cancer.

The most common side effects of HYZAAR 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 HYZAAR?

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

General information about HYZAAR

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use HYZAAR for a condition for which it was not prescribed. Do not give HYZAAR 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 HYZAAR. 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 HYZAAR?

Active ingredients: losartan potassium, hydrochlorothiazide

Inactive ingredients:

microcrystalline cellulose, lactose hydrous, pregelatinized starch, magnesium stearate, hydroxypropyl cellulose, hypromellose, titanium dioxide. HYZAAR 50/12.5 and HYZAAR 100/25 also contain D&C yellow No. 10 aluminum lake.

HYZAAR 50/12.5, HYZAAR 100/12.5, and HYZAAR 100/25 may also contain carnauba wax.

For patent information: www.organon.com/our-solutions/patent/

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Revised: 3/2023

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