

FDA-Approved Patient Labeling
PATIENT INFORMATION

Valsartan and Hydrochlorothiazide Tablets USP
(val-SAR-tan and HYE-droe-KLOR-oh-THYE-a-zide)

Rx only

Read the Patient Information that comes with valsartan 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. If you have any questions about valsartan and hydrochlorothiazide tablets, ask your doctor or pharmacist.

What is the most important information I should know about valsartan and hydrochlorothiazide tablets?

Valsartan 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 valsartan and hydrochlorothiazide tablets, tell your doctor right away.

What are valsartan and hydrochlorothiazide tablets?

Valsartan and hydrochlorothiazide tablets contains 2 prescription medicines:

1. valsartan, an angiotensin receptor blocker (ARB)
2. hydrochlorothiazide (HCTZ), a water pill (diuretic)

Valsartan and hydrochlorothiazide tablets may be used to lower high blood pressure (hypertension) in adults-

- when 1 medicine to lower your high blood pressure is not enough.
- as the first medicine to lower high blood pressure if your doctor decides you are likely to need more than 1 medicine.

Valsartan and hydrochlorothiazide tablets have not been studied in children under 18 years of age.

Who should not take valsartan and hydrochlorothiazide tablets?

Do not take valsartan and hydrochlorothiazide tablets if you:

- **are allergic to any of the ingredients in valsartan and hydrochlorothiazide tablets.** See the end of this leaflet for a complete list of ingredients in valsartan and hydrochlorothiazide tablets.
- make less urine due to kidney problems
- are allergic to medicines that contain sulfonamides.

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

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

- **are pregnant or plan to become pregnant.** See “**What is the most important information I should know about valsartan and hydrochlorothiazide tablets?**”
- **are breastfeeding.** Valsartan and hydrochlorothiazide passes into breast milk. It is not known if valsartan and hydrochlorothiazide tablets effects your breastfed baby or milk production. Do not breastfeed while you are taking valsartan and hydrochlorothiazide tablets.
- **have liver problems**
- **have kidney problems**
- **have or had gallstones**
- **have Lupus**
- **have low levels of potassium** (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm) or magnesium in your blood
- **have high levels of calcium in your blood** (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching).
- **have high levels of uric acid in the blood.**
- **have ever had a reaction called angioedema to another blood pressure medication. Angioedema causes swelling of the face, lips, tongue, throat and may cause difficulty breathing.**

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Some of your other medicines and valsartan and hydrochlorothiazide tablets could affect each other, causing serious side effects. Especially, tell your doctor if you take:

- other medicines for high blood pressure or a heart problem
- water pills (diuretics)
- potassium supplements. Your doctor may check the amount of potassium in your blood periodically.
- a salt substitute. Your doctor may check the amount of potassium in your blood periodically.
- antidiabetic medicines including insulin
- narcotic pain medicines
- sleeping pills
- lithium, a medicine used in some types of depression (Eskalith[®], Lithobid[®], Lithium Carbonate, Lithium Citrate)
- aspirin or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs), like ibuprofen or naproxen
- digoxin or other digitalis glycosides (a heart medicine)
- muscle relaxants (medicines used during operations)
- certain cancer medicines, like cyclophosphamide or methotrexate
- certain antibiotics (rifamycin group), a drug used to protect against transplant rejection (cyclosporine) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of valsartan.

Ask your doctor if you are not sure if you are taking 1 of these medicines.

Know the medicines you take. Keep a list of your medicines with you to show to your doctor and pharmacist when a new medicine is prescribed. Talk to your doctor or pharmacist before you start taking any new medicine. Your doctor or pharmacist will know what medicines are safe to take together.

How should I take valsartan and hydrochlorothiazide tablets?

- Take valsartan and hydrochlorothiazide tablets exactly as prescribed by your doctor. Your doctor may change your dose if needed.
- Take valsartan and hydrochlorothiazide tablets once each day.
- Valsartan 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 valsartan and hydrochlorothiazide tablets, call your doctor or Poison Control Center, or go to the nearest hospital emergency room.

What should I avoid while taking valsartan and hydrochlorothiazide tablets?

You should not take valsartan and hydrochlorothiazide tablets during pregnancy. See “**What is the most important information I should know about valsartan and hydrochlorothiazide tablets?**”

What are the possible side effects of valsartan and hydrochlorothiazide tablets?

Valsartan and hydrochlorothiazide tablets may cause serious side effects including:

- **Harm to an unborn baby causing injury and even death.** See “**What is the most important information I should know about valsartan and hydrochlorothiazide tablets?**”
- **Low blood pressure (hypotension).** Low blood pressure is most likely to happen if you:
 - take water pills
 - are on a low salt diet
 - get dialysis treatments
 - have heart problems
 - get sick with vomiting or diarrhea
 - drink alcohol

Lie down if you feel faint or dizzy. Call your doctor right away.

- **Allergic reactions.** People with and without allergy problems or asthma who take valsartan and hydrochlorothiazide tablets may get allergic reactions.
- **Worsening of Lupus.** Hydrochlorothiazide, 1 of the medicines in valsartan and hydrochlorothiazide tablets may cause Lupus to become active or worse.
- **Fluid and electrolyte (salt) problems.** Tell your doctor about any of the following signs and symptoms of fluid and electrolyte problems:
 - dry mouth
 - thirst
 - lack of energy (lethargic)
 - weakness
 - drowsiness
 - restlessness
 - confusion
 - seizures
 - muscle pain or cramps
 - muscle fatigue
 - very low urine output
 - fast heartbeat
 - nausea and vomiting

- **Kidney problems.** Kidney problems may become worse in people that already have kidney disease. Some people will have changes on blood tests for kidney function and may need a lower dose of valsartan and hydrochlorothiazide tablets. Call your doctor if you get swelling in your feet, ankles, or hands, or unexplained weight gain. If you have heart failure, your doctor should check your kidney function before prescribing valsartan and hydrochlorothiazide tablets.
- **Skin rash.** Call your doctor right away if you have an unusual skin rash.
- **Eye Problems.** One of the medicines in valsartan and hydrochlorothiazide tablets can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting valsartan and hydrochlorothiazide tablets. Tell your doctor right away if you have:
 - decrease in vision
 - eye pain

Other side effects were generally mild and brief. They generally have not caused patients to stop taking valsartan and hydrochlorothiazide tablets.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of valsartan and hydrochlorothiazide tablets. 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. You may also report side effect to Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

How do I store valsartan and hydrochlorothiazide tablets?

- Store valsartan and hydrochlorothiazide tablets at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep valsartan and hydrochlorothiazide tablets in a closed container in a dry place.

Keep valsartan and hydrochlorothiazide tablets and all medicines out of the reach of children.

General information about valsartan and hydrochlorothiazide tablets

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

This leaflet summarizes the most important information about valsartan and hydrochlorothiazide tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about valsartan and hydrochlorothiazide tablets that is written for health professionals. For more information about valsartan and hydrochlorothiazide tablets, go to www.lupinpharmaceuticals.com or call 1-800-399-2561.

What are the ingredients in valsartan and hydrochlorothiazide tablets?

Active ingredients: Valsartan and hydrochlorothiazide

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, polyethylene glycol, titanium dioxide and additional colorants as below.

80 mg/12.5 mg: iron oxide red and iron oxide yellow

160 mg/12.5 mg: iron oxide red

160 mg/25 mg: iron oxide black, iron oxide red and iron oxide yellow

320 mg/12.5 mg: iron oxide black and iron oxide red

320 mg/25 mg: iron oxide yellow

What is 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. Valsartan and hydrochlorothiazide tablets can help your blood vessels relax and reduce the amount of water in your body so your blood pressure is lower. Medicines that lower blood pressure lower your risk of having a stroke or heart attack.

High blood pressure makes the heart work harder to pump blood throughout the body and causes damage to the blood vessels. If high blood pressure is not treated, it can lead to stroke, heart attack, heart failure, kidney failure, and vision problems.

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Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Goa - 403 722

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