

PATIENT INFORMATION

Valsartan (val-SAR-tan) Tablets, USP

Read the Patient Information that comes with valsartan tablets before you take 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 medical condition or treatment. If you have any questions about valsartan tablets, ask your doctor or pharmacist.

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

Valsartan 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 tablets, tell your doctor right away.

What is valsartan tablet?

Valsartan tablets are prescription medicine called an angiotensin receptor blocker (ARB). It is used in adults to:

- lower high blood pressure (hypertension) in adults and children, 6 to 16 years of age.
- treat heart failure in adults. In these patients, valsartan tablets may lower the need for hospitalization that happens from heart failure.
- improve the chance of living longer after a heart attack (myocardial infarction) in adults.

Valsartan tablets are not for children under 6 years of age or 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. Valsartan tablets can help your blood vessels relax so your blood pressure is lower. Medicines that lower your blood pressure lower your chance 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.

Heart Failure occurs when the heart is weak and cannot pump enough blood to your lungs and the rest of your body. Just walking or moving can make you short of breath, so you may have to rest a lot.

Heart Attack (Myocardial Infarction): A heart attack is caused by a blocked artery that results in damage to the heart muscle.

What should I tell my doctor before taking valsartan tablets?

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

- have any allergies. See the end of this leaflet for a complete list of ingredients in valsartan tablets.
- have a heart condition
- have liver problems
- have kidney problems
- **are pregnant or planning to become pregnant.** See “**What is the most important information I should know about valsartan tablets?**”
- are breast-feeding. It is not known if valsartan passes into your breast milk, or effects your breastfed baby or milk production. Do not breastfeed while you are taking valsartan tablets. Talk with your doctor about the best way to feed your baby if you take valsartan tablets.
- have ever had a reaction called angioedema, to another blood pressure medicine. Angioedema causes swelling of the face, lips, tongue and/or throat, and may cause difficulty breathing.

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Especially tell your doctor if you take:

- other medicines for high blood pressure or a heart problem
- water pills (also called “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
- nonsteroidal anti-inflammatory drugs (like ibuprofen or naproxen)
- 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.
- Lithium, a medicine used in some types of depression

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 tablets?

- Take valsartan tablets exactly as prescribed by your doctor.
- For treatment of high blood pressure, take valsartan tablets one time each day, at the same time each day.
- If your child cannot swallow tablets, or if tablets are not available in the prescribed strength, your pharmacist will mix valsartan tablets as a liquid suspension for your child. If your child switches between taking the tablet and the suspension, your doctor will adjust the dose as needed. Shake the bottle of suspension well for at least 10 seconds before pouring the dose of medicine to give to your child.
- For adult patients with heart failure or who have had a heart attack, take valsartan tablets two times each day, at the same time each day. Your doctor may start you on a low dose of valsartan tablets and may increase the dose during your treatment.
- Valsartan 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. Take the next dose at your regular time.
- If you take too much valsartan tablets, call your doctor or Poison Control Center, or go to the nearest hospital emergency room.

What are the possible side effects of valsartan tablets?

Valsartan tablets may cause the following serious side effects:

Injury or death to an unborn baby. See “**What is the most important information I should know about valsartan tablets?**”

Low Blood Pressure (Hypotension). Low blood pressure is most likely to happen if you also take water pills, are on a low-salt diet, get dialysis treatments, have heart problems, or get sick with vomiting or diarrhea. Lie down, if you feel faint or dizzy. Call your doctor right away.

Kidney problems. Kidney problems may get worse if you already have kidney disease. Some patients will have changes on blood tests for kidney function and may need a lower dose of valsartan 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 tablets.

The most common side effects of valsartan tablets used to treat people with high blood pressure include:

- headache
- dizziness
- flu symptoms
- tiredness
- stomach (abdominal) pain

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

The most common side effects of valsartan tablets used to treat people with heart failure include:

- dizziness
- low blood pressure
- diarrhea
- joint and back pain
- tiredness
- high blood potassium

Common side effects of valsartan tablets used to treat people after a heart attack which caused them to stop taking the drug include:

- low blood pressure
- cough
- high blood creatinine (decreased kidney function)
- rash

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

These are not all the possible side effects of valsartan 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.

How do I store valsartan tablets?

- Store valsartan tablets at room temperature between 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).
- Keep valsartan tablets in a closed container in a dry place.
- Store bottles of valsartan suspension at room temperature less than 86°F (30°C) for up to 30 days, or refrigerate between 35°F - 46°F (2°C - 8°C) for up to 75 days.
- Keep valsartan tablets and all medicines out of the reach of children.

General information about valsartan tablets

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use valsartan tablets for a condition for which it was not prescribed. Do not give valsartan 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 tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about valsartan tablets that is written for health professionals.

For more information about valsartan tablets, ask your pharmacist or doctor, or call Alembic Pharmaceuticals Limited at 1-866-210-9797.

What are the ingredients in valsartan tablets?

Active ingredient: Valsartan

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, pregelatinised starch, poloxamer 188, colloidal silicon dioxide, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol. Additionally Valsartan 40 mg contains Iron Oxide Yellow, Valsartan 80 mg contains Iron Oxide Red, Valsartan 160 mg contains Iron Oxide Yellow, Iron Oxide Red and Valsartan 320 mg contains Iron Oxide Yellow, Iron Oxide Black, Iron Oxide Red.

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

Manufactured by:

Alembic Pharmaceuticals Limited

(Formulation Division),

Panelav 389350, Gujarat, India

Manufactured for:

Alembic Pharmaceuticals, Inc.

750 Route 202, Bridgewater, NJ 08807

USA

Revision: 10/2019

20028540