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Valsartan

Pronunciation: val-sar-tan
Generic name: valsartan
Brand name: <u>Diovan</u>
Dosage form: oral tablet

Drug class: Angiotensin receptor blockers

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What is valsartan?

Valsartan is an angiotensin II receptor blocker (ARB) that may be used to treat high blood pressure or reduce the risk of being admitted to the hospital if you have heart failure. Specifically, valsartan is FDA-approved to:

- Lower high blood pressure in adults and children aged 1 year and older, either alone or in combination with other blood pressure medicines
- Decrease the need for hospitalization because of heart failure in adults with heart failure
- Increase the chance of living longer after a heart attack (myocardial infarction) in adults with certain types of heart failure.

Valsartan should not be used to treat high blood pressure in children less than 1 year of age and it is not known if it is safe and effective in children with certain kidney problems.

Valsartan works by blocking angiotensin II, a powerful blood pressure regulator that narrows blood vessels (vasoconstriction), affects the production and release of aldosterone, stimulates the heart, and promotes sodium reabsorption by the kidneys. Valsartan blocks angiotensin II from binding to the AT_1 receptor in many tissues such as blood vessel smooth muscle and the adrenal gland, lowering blood pressure.

Valsartan was FDA-approved on December 23, 1996, as the brand name Diovan. Generic valsartan has been approved since June 2014.

Valsartan side effects

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

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

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

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

The most common side effects of valsartan when used to treat people after a heart attack that cause them to stop taking it include:

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

Serious side effects and warnings

Valsartan can cause the following serious side effects.

Harm or death to an unborn baby. Talk to your healthcare provider about other ways to lower your blood pressure if you plan to become pregnant. If you become pregnant during treatment with valsartan, stop taking it and tell your healthcare provider right away.

Low blood pressure (hypotension). Your blood pressure may fall while taking valsartan, especially when you first start taking it, and can cause you to feel lightheaded. Lie down, if you feel lightheaded, dizzy, or faint. Call your healthcare provider right away. Feeling lightheaded is most likely to happen if you:

- take water pills such as furosemide or HCTZ
- are dehydrated (decreased body fluids) due to vomiting and diarrhea
- are on a low-salt diet
- you sweat excessively
- get dialysis treatments
- have heart problems
- do not drink enough liquids.

Kidney problems. Valsartan may worsen kidney problems in people who already have kidney disease or heart problems. Your doctor may do blood tests to check for this.

Increased potassium in your blood. Some people may develop high levels of potassium in their blood during treatment with valsartan. Your doctor may do a blood test to check your potassium levels as needed

These are not all of the possible side effects of valsartan. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

• Valsartan side effects (more detail)

Before taking

Before taking valsartan, tell your healthcare provider about all of your medical conditions including, if you:

- have heart problems
- have kidney problems
- take other medications that may affect your blood pressure or potassium levels
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

Pregnancy

Valsartan can cause harm or death to an unborn baby. Talk to your healthcare provider about other ways to lower your blood pressure if you plan to become pregnant. Before taking valsartan your healthcare provider may ask you to complete a pregnancy test. While taking valsartan, you should use effective contraception.

If you become pregnant during treatment with valsartan, stop taking it and tell your healthcare provider right away

Breastfeeding

It is not known if valsartan passes into your breast milk. You should not breastfeed during treatment with valsartan. Talk with your healthcare provider about the best way to feed your baby during treatment.

Valsartan pregnancy and breastfeeding warnings (more detail)

How should I take valsartan?

Take valsartan exactly as prescribed by your healthcare provider.

- Valsartan is usually taken 1 time daily for high blood pressure and 2 times daily for heart failure or post-MI.
- The dosage may be increased up to the maximum dosage range if required and if tolerated.

Valsartan suspension for children

Your pharmacist will mix valsartan as a liquid suspension for your child, if:

- the child is 1 to 5 years of age, or
- your child is older than 5 years of age and cannot swallow tablets, or
- if tablets are not available in the prescribed strength needed for your child.

If your child switches between taking the tablet and the suspension, your healthcare provider 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.



Dosage

Valsartan dosage for high blood pressure

Adults

- Starting dose: valsartan 80 160 mg once daily
- Dose range: valsartan 80 320 mg once daily

Children

- Starting dose: valsartan 1 mg/kg once daily (maximum of 40 mg/day)
- Dose range: valsartan 1 4 mg/kg once daily (maximum of 160 mg/day)

Valsartan dosage for heart failure

Adults

- Starting dose: valsartan 40 mg twice daily
- Dose range: valsartan 40 160 mg twice daily

Valsartan dosage for post MI

Adults

- Starting dose: valsartan 20 mg twice daily
- Dose range: valsartan 20 160 mg twice daily



What happens if I miss a dose?

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.

What happens if I overdose?

If you take too much valsartan, call your healthcare provider, or go to the nearest hospital emergency room.

What should I avoid while taking valsartan?

Do not become pregnant or breastfeed while taking valsartan.

Lightheadedness can occur when taking valsartan, especially during the first days of therapy. Tell your healthcare provider and stop taking valsartan if it makes you feel faint. Be careful when rising from sitting or lying down to standing.

Keep up your fluid intake. Not enough fluids, excessive perspiration, diarrhea, or vomiting can lead to an excessive fall in blood pressure.

Do not use salt substitutes while taking valsartan without consulting their healthcare provider.

Do not stop taking valsartan without talking to your healthcare provider.

Why have valsartan lawsuits been filed?

In 2018, it became public knowledge that some batches of valsartan had been contaminated with two carcinogenic substances, N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA).

The source of the contamination was traced to two manufacturers: Zhejiang Huahai Pharmaceutical Co. Ltd. in China and Hetero Labs in India. These companies produced the affected batches specifically for the U.S. market, likely beginning in 2012 when the drug's patent expired. This timeframe coincides with the introduction of generic versions of the medication in the U.S., which became available in 2014.

The FDA estimates that the risk of developing cancer in people who took the highest dose of NDMA-contaminated medicine for 4 years is approximately 1 in 8000 (an extra 1 person out of 8000 would develop cancer).

But when people who had taken the contaminated valsartan and who were later diagnosed with one of several types of cancer became aware of the carcinogenic substances present in it, they began filing lawsuits. These lawsuits seek compensation for medical costs, pain, and suffering, while insurers sue to recoup the costs of the unsafe drug.

What other drugs will affect valsartan?

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements. Valsartan may affect the way other medicines work. Especially tell your healthcare provider if you take:

- Other medicines for high blood pressure or a heart problem
- Water pills (also called "diuretics")
- Potassium-containing medicines, potassium supplements, or salt substitutes containing potassium. Your healthcare provider may check the amount of potassium in your blood regularly.
- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Lithium. Your healthcare provider will check the amount of lithium in your blood regularly.

Know the medicines you take. Keep a list of your medicines with you to show to your healthcare provider and pharmacist when a new medicine is prescribed. Talk to your healthcare provider or pharmacist before you start taking any new medicine.



Valsartan drug interactions (more detail)

Storage

Store valsartan at room temperature between 68°F to 77°F (20°C to 25 °C).

Keep the container of valsartan tablets tightly closed and in a dry place to protect from moisture.

Keep out of the reach of children.

Valsartan suspension

Store bottles of valsartan suspension at room temperature less than 86°F (30°C) for up to 30 days or refrigerate between 35°F to 46°F (2°C to 8°C) for up to 75 days.

Valsartan suspension is supplied in a glass bottle with a child-resistant screw-cap closure.

Keep out of the reach of children.

Valsartan ingredients

Ingredients for generic valsartan depend on the manufacturer. Refer to the valsartan package insert for that product.

Available as valsartan 40 mg, valsartan 80 mg, valsartan 160 mg, and valsartan 320 mg.

Diovan

Active ingredient: valsartan

Inactive ingredients: colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, iron oxides (yellow, black, and/or red), magnesium stearate, microcrystalline cellulose, polyethylene glycol 8000, and titanium dioxide

Combination valsartan medicines

Valsartan is available in combination with the following other medications:

- sacubitril as valsartan/sacubitril (Entresto) for heart failure
- HCTZ (hydrochlorothiazide) as valsartan/HCTZ (Diovan HCT) for high blood pressure
- amlodipine as valsartan/amlodipine (Exforge) for high blood pressure
- amlodipine and HCTZ as valsartan/amlodipine/HCTZ (<u>Exforge HCT</u>) for high blood pressure

• nebivolol as <u>valsartan/nebivolol</u> (Byvalson [discontinued]) for high blood pressure.

Who makes valsartan?

The **Diovan brand of valsartan** is made by Novartis Pharmaceuticals Corporation in East Hanover, NJ.

Generic valsartan is made by various manufacturers including Alembic Pharmaceuticals, Dr. Reddy's Labor

Frequently asked questions

- Losartan vs Valsartan What's the difference between them?
- What is the strength of Prexxartan (valsartan) oral solution?

References

- 1. Valsartan Lawsuit (2024 Update). May 6, 2024.
- 2. <u>Diovan Medication Guide</u>
- 3. <u>Diovan Prescribing Information</u>