

FDA-Approved Patient Labeling

Patient Information

Valturna[®] (val-tur-na)
(aliskiren and valsartan, USP) Tablets

Read the Patient Information that comes with Valturna 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.

IMPORTANT WARNING: Valturna may harm an unborn baby, causing injury and death. If you get pregnant, stop taking Valturna and call your doctor right away. If you plan to become pregnant, talk to your doctor about other medicines to treat your high blood pressure before taking Valturna.

What is Valturna?

Valturna contains two prescription medicines in one tablet that work together to lower blood pressure. It contains:

- aliskiren (Tekturna), a direct renin inhibitor (DRI)
- valsartan (Diovan), an angiotensin receptor blocker (ARB)

Aliskiren (Tekturna) reduces the effect of renin, and the harmful process that narrows blood vessels. Aliskiren also helps blood vessels relax and widen so blood pressure is lower. Valsartan (Diovan) can help lower your blood pressure by blocking a potent chemical, angiotensin II, that leads to blood vessel constriction and narrowing.

Valturna may be used to lower high blood pressure in adults:

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

Valturna has not been studied in children under 18 years of age.

Your doctor may prescribe other medicines for you to take along with Valturna to treat your high blood pressure.

What is high blood pressure (hypertension)?

Blood pressure is the force that pushes the blood through your blood vessels to all the organs of your body. You have high blood pressure when the force of your blood moving through your blood vessels is too great. One cause of high blood pressure is renin, a chemical in the body that starts a process that makes blood vessels narrow, leading to high blood pressure.

Valturna reduces high blood pressure. 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.

Blood pressure is reduced more with Valturna than when either Tekturna or Diovan is taken by itself.

Who should not take Valturna?

- **If you get pregnant, stop taking Valturna and call your doctor right away. If you plan to become pregnant, talk to your doctor about other treatment options for your high blood pressure.**
- **Do not take Valturna if you are allergic to any of its ingredients. See the end of this leaflet for a complete list of the ingredients in Valturna.**

What should I tell my doctor before taking Valturna?

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

- have kidney problems
- have liver problems
- have ever had a reaction called angioedema, to another blood pressure medicine. Angioedema causes swelling of the face, lips, tongue, throat, arms and legs, and may cause difficulty breathing.
- are pregnant or planning to become pregnant. See IMPORTANT WARNING.
- are breast-feeding. It is not known if Valturna passes into your breast milk.

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

- other medicines for high blood pressure or a heart problem
- water pills (also called “diuretics”)
- medicines for treating fungus or fungal infections
- cyclosporine (a medicine used to suppress the immune system)
- potassium-containing medicines, potassium supplements, or salt substitutes containing potassium
- atorvastatin
- nonsteroidal anti-inflammatory drugs (like ibuprofen or naproxen)

Your doctor or pharmacist will know what medicines are safe to take together. Know your medicines. Keep a list of your medicines and show it to your doctor or pharmacist when you get a new medicine.

How should I take Valturna?

- Take Valturna exactly as prescribed by your doctor. It is important to take Valturna every day to control your blood pressure.
- Take Valturna once each day, about the same time each day.
- Take Valturna the same way everyday, either with or without a meal.
- Your doctor may change your dose of Valturna if needed.
- If you miss a dose of Valturna, 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 Valturna, call your doctor or a Poison Control Center, or go to the nearest hospital emergency room.

What are the possible side effects of Valturna?

Valturna may cause serious side effects:

- **Injury or death to an unborn baby.** See IMPORTANT WARNING.
- **Low blood pressure (hypotension).** Your blood pressure may get too low 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. Drinking alcohol and taking certain medicines (barbiturates or narcotics) can cause low blood pressure to get worse. Lie down if you feel faint or dizzy, and call your doctor right away.

- **Angioedema.** Aliskiren, a component in Valtorna, can cause swelling of the face, lips, tongue, throat, arms and legs, or the whole body. Get medical help right away and tell your doctor if you get any one or more of these symptoms. Angioedema can happen at any time while you are taking Valtorna.

Common side effects of Valtorna include:

- Tiredness
- Sore throat
- Runny nose
- Diarrhea
- Upper respiratory tract infection
- Urinary tract infection
- Flu or flu-like symptoms
- Dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of Valtorna. For a complete list of side effects, ask your doctor or pharmacist.

How do I store Valtorna?

- Store Valtorna tablets at room temperature between 59°F-86°F (15°C-30°C).
- Keep Valtorna in the original prescription bottle in a dry place. Do not remove the desiccant (drying agent) from the bottle.

Keep Valtorna and all medicines out of the reach of children.

General information about Valtorna

Medicines are sometimes prescribed for conditions not listed in the patient information leaflet. Do not take Valtorna for a condition for which it was not prescribed. Do not give Valtorna to other people, even if they have the same condition or symptoms you have. It may harm them.

This leaflet summarizes the most important information about Valtorna. If you have questions about Valtorna talk with your doctor. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

For more information about Valtorna, visit www.valturna.com or call 1-877-282-5887.

What are the ingredients in Valtorna?

Active ingredients: Aliskiren and valsartan

Inactive ingredients: The inactive ingredients for all strengths of the tablets are colloidal silicon dioxide, crospovidone, hydroxypropylcellulose, indigotin blue lake, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, titanium dioxide, and hypromellose

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

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