

Patient Information
ENTRESTO (en-TRESS-toh)
(sacubitril and valsartan) tablets

What is the most important information I should know about ENTRESTO?

ENTRESTO can harm or cause death to your unborn baby. Talk to your doctor about other ways to treat heart failure if you plan to become pregnant. If you get pregnant during treatment with ENTRESTO, tell your doctor right away.

What is ENTRESTO?

ENTRESTO is a prescription medicine used to treat:

- adults with long-lasting (chronic) heart failure to help reduce the risk of death and hospitalization. ENTRESTO works better when the heart cannot pump a normal amount of blood to the body.
- certain children 1 year of age and older who have symptomatic heart failure.

It is not known if ENTRESTO is safe and effective in children under 1 year of age.

Do not take ENTRESTO if you:

- are allergic to any of the ingredients in ENTRESTO. See the end of this Patient Information leaflet for a complete list of ingredients in ENTRESTO.
- have had an allergic reaction including swelling of your face, lips, tongue, throat, or trouble breathing while taking a type of medicine called an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB).
- take an ACE inhibitor medicine. **Do not take ENTRESTO for at least 36 hours before or after you take an ACE inhibitor medicine.** Talk with your doctor or pharmacist before taking ENTRESTO if you are not sure if you take an ACE inhibitor medicine.
- have diabetes and take a medicine that contains aliskiren.

Before taking ENTRESTO, tell your doctor about all of your medical conditions, including if you:

- have a history of hereditary angioedema
- have kidney or liver problems
- are pregnant or plan to become pregnant. See “**What is the most important information I should know about ENTRESTO?**”
- are breastfeeding or plan to breastfeed. It is not known if ENTRESTO passes into your breast milk. You and your doctor should decide if you will take ENTRESTO or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using ENTRESTO with certain other medicines may affect each other. Using ENTRESTO with other medicines can cause serious side effects. Especially tell your doctor if you take:

- potassium supplements or a salt substitute
- nonsteroidal anti-inflammatory drugs (NSAIDs)
- lithium
- other medicines for high blood pressure or heart problems such as an ACE inhibitor, ARB, or aliskiren

Keep a list of your medicines to show your doctor and pharmacist when you get a new medicine.

How should I take ENTRESTO?

- Take ENTRESTO exactly as your doctor tells you to take it.
- Take ENTRESTO 2 times each day. Your doctor may change your dose of ENTRESTO during treatment.
- If your child cannot swallow tablets, or if tablets are not available in the prescribed strength, your pharmacist will prepare ENTRESTO 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 before measuring the dose of medicine to give to your child.
- 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 ENTRESTO, call your doctor right away.

What are the possible side effects of ENTRESTO?

ENTRESTO may cause serious side effects including:

- See “What is the most important information I should know about ENTRESTO?”
- **Serious allergic reactions causing swelling of your face, lips, tongue, and throat (angioedema) that may cause trouble breathing and death.** Get emergency medical help right away if you have symptoms of angioedema or trouble breathing. Do not take ENTRESTO again if you have had angioedema during treatment with ENTRESTO.

People who are Black and take ENTRESTO may have a higher risk of having angioedema than people who are not Black and take ENTRESTO.

People who have had angioedema before taking ENTRESTO may have a higher risk of having angioedema than people who have not had angioedema before taking ENTRESTO. See “Who should not take ENTRESTO?”

- **Low blood pressure (hypotension).** Low blood pressure may be more common if you also take water pills. Call your doctor if you become dizzy or lightheaded, or you develop extreme fatigue.
- **Kidney problems.** Your doctor will check your kidney function during your treatment with ENTRESTO. If you have changes in your kidney function tests, you may need a lower dose of ENTRESTO or may need to stop taking ENTRESTO for a period of time.
- **Increased amount of potassium in your blood (hyperkalemia).** Your doctor will check your potassium blood level during your treatment with ENTRESTO.

These are not all the possible side effects of ENTRESTO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ENTRESTO?

- Store ENTRESTO tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect ENTRESTO tablets from moisture.
- Store bottles of ENTRESTO oral suspension at room temperature less than 77°F (25°C) for up to 15 days. Do not refrigerate ENTRESTO oral suspension.

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

General information about the safe and effective use of ENTRESTO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ENTRESTO for a condition for which it was not prescribed. Do not give ENTRESTO to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or doctor for information about ENTRESTO that is written for health professionals.

What are the ingredients in ENTRESTO?

Active ingredients: sacubitril and valsartan

Inactive ingredients: microcrystalline cellulose, low-substituted hydroxypropylcellulose, crospovidone, magnesium stearate (vegetable origin), talc, and colloidal silicon dioxide. Film coat: hypromellose, titanium dioxide (E 171), Macrogol 4000, talc, iron oxide red (E 172). The film-coat for the 24 mg of sacubitril and 26 mg of valsartan tablet and the 97 mg of sacubitril and 103 mg of valsartan tablet also contains iron oxide black (E 172). The film-coat for the 49 mg of sacubitril and 51 mg of valsartan tablet contains iron oxide yellow (E 172).

Prepared ENTRESTO oral suspension also contains Ora-Sweet SF and Ora-Plus.

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For more information, go to www.ENTRESTO.com or call 1-888-368-7378 (1-888-ENTRESTO).

This Patient Information has been approved by the U.S. Food and Drug Administration.

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