

**PATIENT INFORMATION**

**ENTRESTO (en-TRESS-toh)  
(sacubitril and valsartan)  
tablets, for oral use**

**ENTRESTO SPRINKLE (en-TRESS-toh SPRINK-el)  
(sacubitril and valsartan)  
oral pellets**

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

ENTRESTO or ENTRESTO SPRINKLE 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. Tell your doctor right away if you become pregnant during treatment with ENTRESTO or ENTRESTO SPRINKLE.

**What is ENTRESTO or ENTRESTO SPRINKLE?**

ENTRESTO or ENTRESTO SPRINKLE is a prescription medicine used to treat:

- adults with long-lasting (chronic) heart failure to help reduce the risk of death and hospitalization. ENTRESTO or ENTRESTO SPRINKLE 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 or ENTRESTO SPRINKLE is safe and effective in children under 1 year of age.

**Do not take ENTRESTO or ENTRESTO SPRINKLE if you:**

- are allergic to any of the ingredients in ENTRESTO or ENTRESTO SPRINKLE. See the end of this Patient Information leaflet for a complete list of ingredients in ENTRESTO or ENTRESTO SPRINKLE.
- 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 or ENTRESTO SPRINKLE for at least 36 hours before or after you take an ACE inhibitor medicine.** Talk with your doctor or pharmacist before taking ENTRESTO or ENTRESTO SPRINKLE if you are not sure if you take an ACE inhibitor medicine.
- have diabetes and take a medicine that contains aliskiren.

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

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

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking ENTRESTO or ENTRESTO SPRINKLE with certain other medicines may affect each other. Taking ENTRESTO or ENTRESTO SPRINKLE 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 or ENTRESTO SPRINKLE?**

- Take ENTRESTO or ENTRESTO SPRINKLE exactly as your doctor tells you to take it.
- Take ENTRESTO or ENTRESTO SPRINKLE 2 times each day. Your doctor may change your dose of ENTRESTO or ENTRESTO SPRINKLE during treatment.
- If you or your child cannot swallow tablets, or if tablets are not available in the prescribed strength, you or your child may take ENTRESTO tablets prepared as a liquid (oral) suspension **or** may take ENTRESTO SPRINKLE.
- If you or your child switches between taking ENTRESTO and the liquid suspension prepared from ENTRESTO tablets, or to ENTRESTO SPRINKLE, your doctor will adjust the dose as needed.
- **If you or your child are prescribed ENTRESTO tablets to be prepared as a liquid suspension:**
  - Your pharmacist will prepare ENTRESTO tablets for you or your child to take as a liquid suspension.
  - Shake the bottle of suspension well before measuring the dose of medicine and before taking or giving the dose.

• **If you or your child are prescribed ENTRESTO SPRINKLE:**

- ENTRESTO SPRINKLE contains oral pellets inside of a capsule that must be opened and sprinkled onto 1 to 2 teaspoonfuls of soft food and taken right away.
  - **Do not** swallow the capsules.
  - **Do not** chew or crush the oral pellets.
  - **See the detailed Instructions for Use information on how to take or give a dose of ENTRESTO SPRINKLE.**
- 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 or ENTRESTO SPRINKLE, call your doctor right away.

**What are the possible side effects of ENTRESTO or ENTRESTO SPRINKLE?**

**ENTRESTO or ENTRESTO SPRINKLE may cause serious side effects, including:**

- See “**What is the most important information I should know about ENTRESTO or ENTRESTO SPRINKLE?**”
- **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 or ENTRESTO SPRINKLE again if you have had angioedema during treatment with ENTRESTO or ENTRESTO SPRINKLE.  
People who are Black and take ENTRESTO or ENTRESTO SPRINKLE may have a higher risk of having angioedema than people who are not Black and take ENTRESTO or ENTRESTO SPRINKLE.  
People who have had angioedema before taking ENTRESTO or ENTRESTO SPRINKLE may have a higher risk of having angioedema than people who have not had angioedema before taking ENTRESTO or ENTRESTO SPRINKLE. See “**Who should not take ENTRESTO or ENTRESTO SPRINKLE?**”
- **Low blood pressure (hypotension).** Low blood pressure is common during treatment with ENTRESTO or ENTRESTO SPRINKLE. Your risk of low blood pressure is greater if you also take water pills (diuretics). Call your doctor if you become dizzy or lightheaded, or you develop extreme tiredness (fatigue).
- **Kidney problems.** Kidney problems are common during treatment with ENTRESTO or ENTRESTO SPRINKLE and can be serious and can lead to kidney failure. Your doctor will check your kidney function during your treatment with ENTRESTO or ENTRESTO SPRINKLE.
- **Increased amount of potassium in your blood (hyperkalemia).** Increased blood potassium levels are common during treatment with ENTRESTO or ENTRESTO SPRINKLE. Your doctor will check your potassium blood level during your treatment with ENTRESTO or ENTRESTO SPRINKLE.

**The most common side effects of ENTRESTO or ENTRESTO SPRINKLE also include** cough and dizziness.

Your doctor may need to lower your dose, temporarily stop treatment, or permanently stop treatment if you develop certain side effects or if you have changes in your kidney function or increased blood levels of potassium during treatment with ENTRESTO or ENTRESTO SPRINKLE.

These are not all of the possible side effects of ENTRESTO or ENTRESTO SPRINKLE. 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 or ENTRESTO SPRINKLE?**

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

**Keep ENTRESTO, ENTRESTO SPRINKLE and all medicines out of the reach of children.**

**General information about the safe and effective use of ENTRESTO or ENTRESTO SPRINKLE.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ENTRESTO or ENTRESTO SPRINKLE for a condition for which it was not prescribed. Do not give ENTRESTO or ENTRESTO SPRINKLE 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 or ENTRESTO SPRINKLE that is written for health professionals.

**What are the ingredients in ENTRESTO or ENTRESTO SPRINKLE?**

**Active ingredients:** sacubitril and valsartan

**ENTRESTO tablets inactive ingredients:** colloidal silicon dioxide, crospovidone, low-substituted hydroxypropylcellulose, magnesium stearate (vegetable origin), microcrystalline cellulose, and talc. Film coat: hypromellose, iron oxide red (E172), polyethylene glycol 4000, talc, and titanium dioxide (E171). 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 (E172). The film-coat for the 49 mg of sacubitril and 51 mg of valsartan tablet contains iron oxide yellow (E172).

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

**ENTRESTO SPRINKLE oral pellets inactive ingredients:** colloidal silicon dioxide, hydroxypropylcellulose, magnesium stearate (vegetable origin), microcrystalline cellulose, and talc. Film-coat: basic butylated methacrylate copolymer, sodium lauryl sulfate, stearic acid, and talc. Capsule shell contains hypromellose and titanium dioxide (E171). The capsule shell for 15 mg of sacubitril and 16 mg of valsartan oral pellets also contains iron oxide yellow (E172). Printing ink: shellac, propylene glycol, iron oxide red (E172), ammonia solution (concentrated), and potassium hydroxide.

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For more information, go to [www.ENTRESTO.com](http://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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