

IMPORTANT FACTS ABOUT ENTRESTO®

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 while taking ENTRESTO, tell your doctor right away.

What is ENTRESTO?

ENTRESTO is a prescription medicine used to reduce the risk of death and hospitalization in people with certain types of long-lasting (chronic) heart failure. ENTRESTO is usually used with other heart failure therapies, in place of an angiotensin-converting enzyme (ACE) inhibitor or other angiotensin II receptor blocker (ARB) therapy.

Heart failure occurs when the heart is weak and cannot pump enough blood to your lungs and the rest of your body. It is not known if ENTRESTO is safe and effective in children.

Who should not take ENTRESTO?

Do not take ENTRESTO if you:

- are allergic to sacubitril or valsartan or any of the ingredients in ENTRESTO. See the end of the 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 ACE inhibitor or 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

What should I tell my doctor before taking ENTRESTO?

Before you take ENTRESTO, tell your doctor about all of your medical conditions, including if you: have kidney or liver problems or a history of hereditary angioedema; 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; or 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.

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 while taking 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.** 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.

The most common side effects were low blood pressure, high potassium, cough, dizziness, and kidney problems.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

This information is not comprehensive. To learn more, talk to your health care provider or pharmacist, visit www.entresto.com to obtain the FDA-approved product labeling, or call 1-888-ENTRESTO.

ENTRESTO and the ENTRESTO logo are registered trademarks of Novartis AG.

