

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrENTRESTO®
sacubitril/valsartan film-coated tablets

Read this carefully before you start taking **ENTRESTO®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ENTRESTO**.

Serious Warnings and Precautions

Valsartan should not be used during pregnancy. If you discover that you are pregnant while taking ENTRESTO stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

What is ENTRESTO used for?

ENTRESTO is used to treat heart failure in adults. It has been shown to lower the:

- risk of death that is caused from heart and blood vessel related problems
- need for hospitalisation due to heart failure.

How does ENTRESTO work?

ENTRESTO contains sacubitril and valsartan. These two ingredients work by blocking a specific enzyme and a specific receptor in your body.

ENTRESTO helps treat heart failure by:

- relaxing your blood vessels. This makes it easier for your heart to pump blood around your body.
- helping your body retain less water.

What are the ingredients in ENTRESTO?

Medicinal ingredients: sacubitril and valsartan, as sodium salt complex.

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, low-substituted hydroxypropylcellulose, Macrogol 4000, magnesium stearate (vegetable origin), microcrystalline cellulose, talc and titanium dioxide.

ENTRESTO comes in the following dosage forms:

Film-coated tablet:

24 mg sacubitril/ 26 mg valsartan (violet white). Each tablet contains 24.3 mg sacubitril and 25.7

mg valsartan (as sacubitril valsartan sodium hydrate complex).

49 mg sacubitril/ 51 mg valsartan (pale yellow). Each tablet contains 48.6 mg sacubitril and 51.4 mg valsartan (as sacubitril valsartan sodium hydrate complex).

97 mg sacubitril/ 103 mg valsartan (light pink). Each tablet contains 97.2 mg sacubitril and 102.8 mg valsartan (as sacubitril valsartan sodium hydrate complex).

Do not use ENTRESTO if you:

- are allergic to sacubitril or valsartan or any of the other ingredients in ENTRESTO
- are taking angiotensin converting enzyme (ACE) inhibitors. **You must wait at least 36 hours after your last dose of the ACE Inhibitor before starting ENTRESTO.**
- have had **angioedema**, a swelling of the face, lips, tongue and/or throat, with or without difficulty in breathing:
 - while taking an ACE inhibitor or an ARB in the past
 - due to any other reason. The exception is an allergic reaction to a bee sting, insect or snake bite.

If this occurs, stop ENTRESTO immediately, and contact your doctor.

- have an inherited condition called “hereditary angioedema,” an increased risk of getting an allergic reaction (angioedema) that is passed down through families.
- are taking aliskiren-containing medicines, such as Rasilez, **and** have Diabetes or Kidney disease.
- are pregnant or planning to become pregnant. Taking ENTRESTO during pregnancy can cause injury and even death to your baby.
- are breastfeeding. It is possible that ENTRESTO passes into the breast milk.
- are having symptoms related to low blood pressure
- are 18 years or younger

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ENTRESTO. Talk about any health conditions or problems you may have, including if you:

- have severe kidney disease.
- have severe liver disease
- ever had a reaction called angioedema (swelling of the face, lips, tongue, and/or throat, difficulties in breathing).
- have low blood pressure, or are taking other drugs to lower your blood pressure, such as, a diuretic or water pill.
- are taking any drugs that increase the amount of potassium in your blood (such as potassium supplements, or salt substitutes containing potassium, potassium-sparing drugs, and heparin). Your doctor may check the potassium levels in your blood at regular times while you are taking ENTRESTO
- have one or both of arteries to your kidney that are severely narrowed.

Other warnings you should know about:

Black patients may have a higher risk of **angioedema**.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ENTRESTO:

- ACE inhibitors (such as enalapril, ramipril, lisinopril and fosinopril).
- Drugs used for lowering blood pressure or to treat heart failure:
 - ARB (such as losartan, telmisartan, valsartan and candesartan)
 - Aliskiren-containing drugs
- Drugs used to lower cholesterol levels. These are known as ‘statins’ (such as atorvastatin).
- Sildenafil, a drug used to treat erectile dysfunction
- Drugs that increase the amount of potassium in the blood (such as potassium supplements, or salt substitutes containing potassium, potassium-sparing diuretics or heparin).
- Drugs used to treat inflammation and pain:
 - Non-steroidal anti-inflammatory drugs (NSAIDs)
 - Cox-2 inhibitors (such as celecoxib)
- Lithium, a drug used to treat some types of depression, bipolar or hypomanic disorders.
- Drugs used after organ transplants to protect against transplant rejection (such as cyclosporin)
- Drugs used to treat HIV/AIDS (such as ritonavir)
- Warfarin, a drug used to make blood thinner and less likely to clot.
- Furosemide, a diuretic (water pill) used to reduce the fluid build-up in your body
- Metformin, used to treat diabetes.

Ask your doctor or pharmacist if you are not sure if any of the medicines you take are included in the list above.

How to take ENTRESTO:

If you were taking ACE inhibitors, you **must** wait at least 36 hours after your last dose of the ACE inhibitor before starting ENTRESTO.

Swallow the tablet **whole**. Do **NOT** break the tablet.

Take ENTRESTO:

- exactly as prescribed;
- every 12 hours, at about the same time every day;
- with or without food

Usual Adult Dose:

Recommended starting dose: ENTRESTO 49 mg sacubitril/ 51 mg valsartan twice a day
Maximum daily dose: ENTRESTO 97 mg sacubitril/ 103 mg valsartan twice a day

Your doctor may start you on ENTRESTO 24 mg sacubitril/ 26 mg valsartan twice a day if you:

- have previously taken low doses of an ACE inhibitor or ARB for the treatment of heart failure
- are 75 years of age or older
- have low blood pressure

Your doctor may change your dose depending on how ENTRESTO works for you.

Do not take more than the maximum daily dose.

Do not reduce the dose or stop taking ENTRESTO without consulting your doctor. This could make your disease worse.

Overdose:

If you think you have taken too much ENTRESTO, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. You can take your next dose at the normal time, but do **NOT** double the dose to make up for the missed one.

What are possible side effects from using ENTRESTO?

These are not all the possible side effects you may feel when taking ENTRESTO. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

- low blood pressure
- excessively high level of potassium in the blood, as shown in a blood test
- kidney disorder (signs of renal impairment)
- dizziness
- tiredness (fatigue)
- sudden loss of consciousness
- feeling sick (nausea)
- weakness
- rash
- itchiness

- low blood pressure when switching from sitting or lying down to standing position
- spinning sensation

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON Angioedema: Swollen face, tongue or throat, difficulty breathing			X
Anaphylactic reaction or hypersensitivity: Difficulty breathing or swallowing, rash, itching, hives, dizziness			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

- Store your tablets in the original package. Protect from moisture.
- Do not take this medicine after the expiry date, which is stated on the label.
- Do not store above 30°C.

Keep out of reach and sight of children.

If you want more information about ENTRESTO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#),

(<http://www.hc-sc.gc.ca>); the manufacturer's website (<http://www.novartis.ca>) or by calling 1-800-363-8883

- by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
Novartis Pharmaceuticals Canada Inc.

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