

Entresto®

24/26, 49/51, 97/103

sacubitril/valsartan

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Entresto.

It does not contain all the available information. It does not take the place of talking to your doctor, nurse practitioner or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor, nurse practitioner or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Entresto is used for

Entresto is used to treat a type of long-term heart failure in adults. This

type of heart failure occurs when the heart is weak and cannot pump enough blood to the lungs and the rest of the body. The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling.

Entresto is an angiotensin receptor neprilysin inhibitor (ARNI), which contains sacubitril (a neprilysin inhibitor), and valsartan (an angiotensin receptor blocker or ARB). Entresto works by blocking the effects of neprilysin via sacubitril and angiotensin-II receptor via valsartan. As a result, blood vessels relax and less water is retained by the body which is beneficial to treat heart failure.

Ask your doctor, nurse practitioner or pharmacist if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend this medicine for use in children or adolescents under 18 years old.

Before you take Entresto

When you must not take it

Do not take this medicine if you have ever had an unusual or allergic reaction to sacubitril, valsartan or any other ingredients listed at the end of this leaflet.

Ask your doctor for advice if you think you may be allergic to this medicine.

Your doctor will want to know if you are prone to allergies.

Do not take this medicine if you are taking another medicine for treatment of your high blood pressure or heart failure called an Angiotensin Converting Enzyme (ACE) Inhibitor.

Examples of ACE inhibitors are perindopril (Coversyl, GenRx, Perindo Combi), ramipril (Ramace, Tritace), trandolapril (Gopten, Dolapril, Tarka), lisinopril (Fibsol, Liprace, Prinivil, Zestril), enalapril, Auspril, Enalapril Sandoz, Renitec, Zan-Extra), quinapril (Accupril, Accuretic, Aquinafil, Filpril, Qpril), fosinopril (Monace, Monopril), captopril (Capoten, Zedace) .

Do not start Entresto until 36 hours after taking the last dose of medicines containing ACE inhibitors.

Do not take this medicine if you have ever had a reaction called

angioedema causing swelling of the face, lips, tongue and/or throat, with or without difficulties in breathing while taking an ACE inhibitor or an ARB in the past. Do not take this medicine if you have an inherited condition called "hereditary angioedema", which makes you prone to angioedema.

Do not take this medicine if you have any of the following:

- Type 2 diabetes (high level of sugar in the blood) and high blood pressure which is being treated with a medicine called aliskiren.
- Severe liver disease.

Do not take this medicine if you are pregnant or planning to become pregnant.

Do not take this medicine if you have very low blood pressure (Systolic Blood pressure < 100mmHg). Your doctor will check your blood pressure before you start on Entresto.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor, nurse practitioner or pharmacist:

- If you are already taking any medicines containing an ACE inhibitor, ARB or aliskiren to treat your high blood pressure or heart failure.

Ask your doctor or pharmacist if you are unsure if you are being treated with these other medicines. ACE inhibitors and ARBs are sold under many different brand names in Australia.

- If you have ever experienced angioedema

(swelling of the face, lips, tongue and/or throat, difficulties in breathing).

- If you have low blood pressure or are taking other medicines that reduce your blood pressure such as a diuretic (water pill) or are suffering from vomiting or diarrhoea, especially if you are aged 75 years or more, or if you have kidney disease and low blood pressure.
- If you have severe kidney disease.
- If you have liver disease.
- If you are taking any medicines that increase the amount of potassium in your blood, including potassium supplements, salt substitutes that contain potassium, potassium-sparing medicines, or heparin.
Your doctor may need to check the level of potassium in your blood at regular intervals when you are taking Entresto.
- If your kidney artery has narrowed.

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Tell your doctor if you are pregnant or intend to become pregnant.

Entresto must not be taken during pregnancy. You should stop taking Entresto as soon as you become pregnant during treatment and tell your doctor. The medicine may harm your unborn baby.

Females who might get pregnant should use contraception while taking Entresto and for 1 week after the last dose. You should talk to your doctor about treatment options if you are planning to become pregnant.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Breast-feeding is not recommended during treatment with Entresto.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

You may need to take different amounts of your medicines or to take different medicines while you are taking Entresto. Your doctor and pharmacist have more information.

This is particularly important with the following medicines:

- ACE inhibitors. You must not take Entresto at the same time as an ACE inhibitor. If you were taking an ACE inhibitor, wait 36 hours after taking your last dose of ACE inhibitor before starting Entresto.
If you stop taking Entresto, wait 36 hours after taking your last dose of Entresto before starting an ACE inhibitor.
- Other medicines used to treat heart failure or lower blood pressure such as ARBs or aliskiren.
- Statins, such as atorvastatin, which are medicines used to lower high cholesterol levels.
- Sildenafil, a medicine used to treat erectile dysfunction or lung hypertension
- Medicines that increase the amount of potassium in the blood, including potassium supplements, salt substitutes containing potassium, and heparin. Your doctor may check the level of potassium in your blood periodically.
- Certain painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may check your kidney function when starting or adjusting treatment.
- Lithium, a medicine used to treat some types of depression.

- Frusemide, a medicine for fluid retention.
- Metformin, a medicine for diabetes.
- Some antibiotics (rifampicin group), cyclosporin (a drug used to protect against transplant rejection), or ritonavir (an anti-retroviral drug used to treat HIV/AIDS infection). These drugs may increase the effect of valsartan.

Ask your doctor, nurse practitioner or pharmacist if you are not sure whether you are taking any of the medicines listed above.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take Entresto

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor, nurse practitioner or pharmacist for help.

How much to take

The usual recommended target dose of Entresto is 97 mg/103 mg twice a day (one tablet in the morning and one tablet in the evening).

You will usually start by taking 24 mg/26 mg or 49 mg/51 mg twice a day. Your doctor will decide your exact starting dose based on which medicines you have been taking previously.

Your doctor will then adjust the dose depending on how you respond to the treatment until the best dose for you is found.

Do not exceed the dose prescribed by your doctor.

How to take it

Entresto is for oral use (taken by mouth) only.

Swallow Entresto tablets whole. The coated tablet should not be broken or divided into parts.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Entresto can be taken with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

Do not stop taking Entresto unless your doctor tells you to.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then take the next tablet at the usual time.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number: 13 11 26) (in Australia) / National Poisons Centre (telephone 0800 POISON

or 0800 764 766) (in New Zealand), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have accidentally taken too much Entresto. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

You may need urgent medical attention.

While you are taking Entresto

Things you must do

If you experience swelling of the face, lips, tongue and/or throat and difficulty in breathing, stop taking Entresto and contact your doctor immediately.

If you become pregnant while taking this medicine, stop taking Entresto and tell your doctor immediately.

Entresto must not be taken if you are pregnant. The medicine may harm your unborn baby.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do regular checks to help prevent you from having side effects from the medicine or developing serious complications.

Tell your doctor if you become ill or experience extra stress, injury, fever, infection or need surgery.

Make sure you keep enough medicine to last over weekends and holidays.

Remind your doctor and pharmacist that you are taking Entresto if you are about to be started on any new medicine.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Entresto.

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Side effects

Tell your doctor, pharmacist or nurse practitioner as soon as possible if you do not feel well while you are taking Entresto even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects.

You may not experience any of them.

Ask your doctor, pharmacist or nurse practitioner if you have any questions about these side effects.

Stop taking Entresto and tell your doctor immediately or go to Accident and Emergency if you experience any of the following which may signs of an allergic reaction called angioedema:

- swollen face, tongue, lips or throat,
- difficulty in swallowing,
- rash, itching, hives, dizziness and difficulties in breathing.

Tell your doctor if you notice any of the following side effects and they worry you:

- low blood pressure (dizziness, light-headedness)
- your blood test shows an abnormal (high or low) level of potassium
- kidney problems (signs of renal impairment)

- cough
- dizziness
- diarrhoea
- low level of red blood cells (shown in a blood test)
- tiredness (fatigue)
- severe kidney disorder (severe renal failure)
- headache
- fainting
- weakness
- feeling sick (nausea)
- low blood pressure or dizziness when switching from sitting or lying down to a standing position
- gastritis (stomach pain, nausea)
- spinning sensation
- low level of sugar in the blood (shown in a blood test)

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects (e.g. potassium levels in your blood) can only be found by laboratory testing.

After using Entresto

Storage

Keep your medicine in the original container until it is time to take it.

Store it in a cool dry place where the temperature stays below 25°C.

Protect from moisture.

Do not store Entresto or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any tablets you have left over.

Product description

What it looks like

Entresto is supplied as film-coated tablets and is available in 3 different strengths of 24 mg/26 mg, 49 mg/51 mg and 97 mg/103 mg:

- 24 mg/26 mg: violet-white, ovaloid biconvex film-coated tablets with bevelled edges, unscored, debossed with "NVR" on one side and "LZ" on the other side.
- 49 mg/51 mg: are pale yellow ovaloid biconvex film-coated tablets with bevelled edges, unscored, debossed with "NVR" on one side and "L1" on the other side.
- 97 mg/103 mg: light pink ovaloid biconvex film-coated tablets with bevelled edges, unscored, debossed with "NVR" on one side and "L11" on the other side.

Entresto is packed in blister packs containing 14 or 56 tablets per carton.

Some pack sizes may not be marketed.

Ingredients

The active substances of Entresto are sacubitril and valsartan as a sodium salt complex.

Each tablet also contains the following inactive ingredients:

- microcrystalline cellulose
- hydroxypropylcellulose
- crospovidone
- magnesium stearate (of vegetable origin)
- colloidal anhydrous silica

- purified talc

The film-coating on the tablets contains:

- hypromellose
- macrogol 4000
- purified talc
- titanium dioxide
- iron oxide red
- iron oxide black (in the 24 mg/26 mg and 97 mg/103mg tablets only)
- iron oxide yellow (in the 49 mg/51mg tablets only)

Entresto does not contain lactose, gluten, tartrazine or any other azo dyes.

Sponsor

Entresto is supplied in Australia by:

NOVARTIS Pharmaceuticals
Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1 800 671 203

Web site: www.novartis.com.au

Entresto is supplied in New Zealand by:

Novartis New Zealand Limited
109 Carlton Gore Road

Newmarket

Auckland 1023

Telephone 0800 354 335

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