

ENTRESTO[®] (sacubitril / valsartan)

50 mg, 100 mg, 200 mg Film-coated tablet

Patient Information Leaflet

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SCHEDULING STATUS:

S3

PROPRIETARY NAME and Dosage Form:

ENTRESTO 50 mg film-coated tablets

ENTRESTO 100 mg film-coated tablets

ENTRESTO 200 mg film-coated tablets

Please read all of this leaflet carefully before taking ENTRESTO

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor or your pharmacist.**
- **ENTRESTO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

1. WHAT ENTRESTO CONTAINS

The active ingredient of ENTRESTO 50 mg film-coated tablets is 24 mg sacubitril and 26 mg valsartan. The active ingredient of ENTRESTO 100 mg film-coated tablets is 49 mg sacubitril and 51 mg valsartan. The active ingredient of ENTRESTO 200 mg film-coated tablets is 97 mg sacubitril and 103 mg valsartan.

The other ingredients are:

crospovidone, colloidal silicon dioxide, low-substituted hydroxypropylcellulose, magnesium stearate (vegetable origin), microcrystalline cellulose and talc.

Film-coating excipients: Macrogol 4000, iron oxide red (E 172), hypromellose, talc, titanium dioxide (E 171). For 50 and 200 mg film coatings: iron oxide black (E 172). For 100 mg film coating: iron oxide yellow (E 172).

2. WHAT IS ENTRESTO USED FOR:

ENTRESTO is an angiotensin receptor and neprilysin inhibitor (ARNI), which contains sacubitril (a neprilysin inhibitor), and valsartan (an angiotensin receptor blocker (ARB)). They both help to treat heart failure.

ENTRESTO is used to treat heart failure in adults when other therapies are insufficient.

3. BEFORE USING ENTRESTO

Follow all the doctor's instructions carefully. The instructions may differ from the general information contained in this leaflet.

Do not take ENTRESTO

- **If you have** ever had an unusual or **allergic** reaction to sacubitril or valsartan or any other ingredients of ENTRESTO. If you think you may be allergic, ask your doctor for advice
- **If you are** taking medicines for treatment of your high blood pressure or heart failure called Angiotensin Converting Enzyme (ACE) Inhibitors or ARB's. Do not start ENTRESTO until 36 hours after taking the last dose of these group of medicines (see "Taking other medicines")
- If you ever had a reaction called angioedema (swelling of the face, lips, tongue, and/or throat, difficulties in breathing) when taking an ACE inhibitor or an ARB
- If you are being treated with a medicine called aliskiren to lower your blood pressure (see "Taking other medicines")
- If you are pregnant or planning to become pregnant.
- If you have a single kidney and have narrowing or constriction of the renal artery

- If you have too low a level of potassium or sodium in your blood, or if you have too high a level of calcium in your blood despite treatment;
- If you have porphyria
- If you have a heart condition where you have abnormal narrowing of the aortic valve or a heart condition called hypertrophic obstructive cardiomyopathy where the heart had reduced pumping ability.
- If you have a history of any type of angioedema
- If you use lithium
- If you have severe abnormal kidney functions
- If you use potassium sparing diuretics such as spironolactone, triamterene, amiloride
- If you are already taking any medicines to treat your high blood pressure or heart failure known as an ACE-inhibitor, ARB, or aliskiren.

If any of these apply to you, do not take ENTRESTO and tell your doctor.

Take special care with ENTRESTO

If any of the following apply to you, tell your doctor or pharmacist or healthcare provider before taking ENTRESTO:

- If you have severe kidney disease.
- If you ever had a reaction called angioedema (swelling of the face, lips, tongue, and/or throat, difficulties in breathing).
- If you experience a swelling of the tongue, and/or throat, and difficulties in breathing **stop taking ENTRESTO and contact your doctor immediately.**
- If you have low blood pressure or are taking other medicines that reduce your blood pressure (for example, a diuretic (water pill)) or you are suffering from vomiting or diarrhoea.
- If you are taking any medicines that increases the amount of potassium in your blood (i.e. hyperkalemia). Such medicines include potassium supplements, salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary for your doctor to check the amount of potassium in your blood at regular intervals during ENTRESTO treatment.
- If your kidney artery has narrowed.

Taking ENTRESTO with food

ENTRESTO can be taken with or without food.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ENTRESTO

You must not take ENTRESTO if you are pregnant.

Breast-feeding is not recommended during treatment with ENTRESTO.

Women who might get pregnant (women of child-bearing age)

Women who might get pregnant must use highly effective contraception while taking ENTRESTO.

Taking other medicines with ENTRESTO

Always tell your healthcare professional if you are taking any other medicine, including complementary medicines.

Before you take ENTRESTO, tell your doctor or pharmacist or healthcare provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, because these might interact with ENTRESTO. This includes, in particular:

- Do not take ENTRESTO with ACE inhibitors or ARB's. If you were taking an ACE inhibitor or ARB's, wait 36 hours after taking your last dose of ACE inhibitor or ARB's before starting ENTRESTO (see "Do not take ENTRESTO"). If you stop taking ENTRESTO, wait 36 hours after taking your last dose of ENTRESTO before starting an ACE inhibitor or ARB's.
- Medicines used to lower high cholesterol levels known as 'statins' (e.g. atorvastatin).
- Sildenafil, a medicine used in the treatment of erectile dysfunction or lung hypertension.
- Medicines that increase the amount of potassium in the blood. These include potassium supplements, or salt substitutes containing potassium and heparin. Your doctor may check the amount of potassium in your blood periodically.

- Certain type of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs) or Selective Cyclooxygenase-2 Inhibitors (Cox-2 Inhibitors). If you are taking one of these, your doctor may want to check your kidney function and blood pressure when initiating or modifying the treatment.
- Some antibiotics (rifampicin used for tuberculosis)
- a medicine used to protect against transplant rejection (ciclosporin)
- or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the side effects of ENTRESTO.

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

4. HOW TO TAKE ENTRESTO

Always take ENTRESTO exactly as your doctor has told you. Check with your doctor or pharmacist or healthcare provider if you are not sure.

Do not exceed the recommended dose prescribed by your doctor.

ENTRESTO is for oral use only.

Do not share medicines prescribed for you with any other person.

How much ENTRESTO to take

The usual recommended target dose is 200 mg twice a day (one tablet in the morning and one tablet in the evening).

You will usually start by taking 50 mg or 100 mg twice a day (one tablet in the morning and one tablet in the evening). 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.

If you were taking ACE inhibitors, or ARB's previously, do not take ENTRESTO until 36 hours after your last dose of the ACE inhibitor or ARB's.

When to take ENTRESTO

Taking ENTRESTO at the same time each day will help you to remember when to take your medicine.

How to take ENTRESTO

Take ENTRESTO tablets by mouth.

The coated tablet should not be broken or divided into parts.

How long to take ENTRESTO

Continue taking ENTRESTO every day for as long as your doctor tells you.

If you have questions about how long to take ENTRESTO, talk to your doctor or your pharmacist or healthcare provider.

Older people (aged 65 years age or above)

Patients over the age of 65 years, may have kidney problems, therefore a lower starting dose is recommended.

Children and adolescents (below 18 years)

ENTRESTO is not to be used in children or adolescents (below 18 years).

If you take more ENTRESTO than you should

If you have accidentally taken too many tablets, **talk to your doctor**.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ENTRESTO

If you forget to take a dose, take it as soon as you remember, and then take the next tablet at the usual time. If it is almost time for your next dose, skip the missed dose and continue as usual. Do not take a double dose to make up for the forgotten tablet.

If you stop taking ENTRESTO

Stopping your treatment with ENTRESTO may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

If treatment with ENTRESTO is stopped and you are prescribed an ACE-inhibitor, do not start taking the ACE inhibitor until 36 hours after your last dose of ENTRESTO.

5. POSSIBLE SIDE EFFECTS

ENTRESTO may have side effects.

Not all side effects reported for ENTRESTO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ENTRESTO, please consult your doctor, pharmacist or other healthcare professional.

Some symptoms need immediate medical attention.

Stop taking ENTRESTO and tell your doctor immediately if you experience any of the following symptoms which may be signs of an allergic reaction called "angioedema":

- swollen face, tongue or throat;
- difficulty in swallowing;
- hives and difficulties in breathing.

Frequent:

- Anaemia
- Hypersensitivity

- low blood pressure;
- kidney disorder (signs of renal impairment);
- high level of potassium in the blood as shown in a blood test.
- Hypoglycaemia (low blood sugar)
- Cough
- Dizziness
- Severe kidney disorder (severe renal failure)
- Low level of potassium in the blood (shown in a blood test)
- Diarrhoea
- Tiredness (Fatigue)
- Headache
- Sudden loss of consciousness (fainting)
- Feeling sick (nausea)
- Gastritis
- Pruritus (itchiness)
- Rash
- Weakness
- Dizziness and low blood pressure when switching from sitting or lying down to a standing position
- Spinning sensation (vertigo).
- Dizziness when switching from sitting to standing position (or *vice versa*);

Less frequent:

- Swelling of the face and throat (angioedema).

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

6. STORING AND DISPOSING OF ENTRESTO

Store at or below 25 °C, protect from moisture.

Store in the original package

KEEP OUT OF REACH AND SIGHT OF CHILDREN

7. PRESENTATION OF ENTRESTO

ENTRESTO 50/100/200 mg tablets are packed in PVC/PVDC blister packs with transparent colourless PVC/PVDC film as the forming component and aluminium foil with heat seal lacquer as the backing components.

Pack sizes: 14, 28 or 56 tablets per pack enclosed in a cardboard box with a package insert.

8. IDENTIFICATION OF ENTRESTO

ENTRESTO 50 mg

Violet white ovaloid biconvex film-coated tablet with beveled edges, unscored, debossed with “NVR” on one side and “LZ” on the other side.

ENTRESTO 100 mg

Pale yellow ovaloid biconvex film-coated tablet with beveled edges, unscored, debossed with “NVR” on one side and “L1” on the other side.

ENTRESTO 200 mg

Light pink ovaloid biconvex film-coated tablet with beveled edges, unscored, debossed with “NVR” on one side and “L11” on the other side.

9. REGISTRATION NUMBER

ENTRESTO 50 mg: 50/7.6/1016

ENTRESTO 100 mg: 50/7.6/1017

ENTRESTO 200 mg: 50/7.6/1018

**10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF
CERTIFICATE OF REGISTRATION:**

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

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2090

11. DATE OF PUBLICATION OF THE PATENT INFORMATION LEAFLET:

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