NOVARTIS

VYMADA® (sacubitril / valsartan)

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

Patient Information Leaflet

Document status: Final

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SCHEDULING STATUS: S3

PROPRIETARY NAME and Dosage Form

VYMADA 50 mg film-coated tablets

VYMADA 100 mg film-coated tablets

VYMADA 200 mg film-coated tablets

Please read all of this leaflet carefully before taking VYMADA

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor or your pharmacist.**
- **VYMADA 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 VYMADA CONTAINS

The active ingredient of VYMADA 50 mg film-coated tablets is 24 mg sacubitril and 26 mg valsartan. The active ingredient of VYMADA 100 mg film-coated tablets is 49 mg sacubitril and 51 mg valsartan. The active ingredient of VYMADA 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 VYMADA USED FOR

VYMADA 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.

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

3 BEFORE USING VYMADA

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

Do not take VYMADA

- **If you have** ever had an unusual or **allergic** reaction to sacubitril or valsartan or any other ingredients of VYMADA. 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 VYMADA 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 VYMADA and tell your doctor.

Take special care with VYMADA

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

- 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 VYMADA 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 VYMADA treatment.
- If your kidney artery has narrowed.

Taking VYMADA with food

VYMADA 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 VYMADA

You must not take VYMADA if you are pregnant.

Breast-feeding is not recommended during treatment with VYMADA.

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

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

Taking other medicines with VYMADA

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

Before you take VYMADA, 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 VYMADA. This includes, in particular:

- Do not take VYMADA 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 VYMADA (see "Do not take VYMADA"). If you stop taking VYMADA, wait 36 hours after taking your last dose of VYMADA 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 VYMADA.

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

4 HOW TO TAKE VYMADA

Always take VYMADA 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.

VYMADA is for oral use only.

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

How much VYMADA 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 VYMADA until 36 hours after your last dose of the ACE inhibitor or ARB's.

When to take VYMADA

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

How to take VYMADA

Take VYMADA tablets by mouth.

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

How long to take VYMADA

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

If you have questions about how long to take VYMADA, 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)

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

If you take more VYMADA than you should

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

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

If you forget to take VYMADA

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 VYMADA

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

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

5 POSSIBLE SIDE EFFECTS

VYMADA may have side effects.

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

Some symptoms need immediate medical attention.

Stop taking VYMADA 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 VYMADA

Store at or below 30 °C, protect from moisture.

Store in the original package

KEEP OUT OF REACH AND SIGHT OF CHILDREN

7 PRESENTATION OF VYMADA

VYMADA 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 VYMADA

VYMADA 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.

VYMADA 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.

VYMADA 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

VYMADA 50 mg: 50/7.6/1019

VYMADA 100 mg: 50/7.6/1020

VYMADA 200 mg: 50/7.6/1021

10 NAME AND BUSINESS ADDRESS OF THE HOLDER OF CERTIFICATE OF REGISTRATION

Novartis South Africa (Pty) Ltd

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11 DATE OF PUBLICATION OF THE PAITENT INFORMATION LEAFLET

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