PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

VYPORA 24 mg/26 mg (film-coated tablets)

VYPORA 49 mg/51 mg (film-coated tablets)

VYPORA 97 mg/103 mg (film-coated tablets)

Sacubitril and Valsartan

Sugar free

Read all of this leaflet carefully before you start taking VYPORA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VYPORA 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.

What is in this leaflet

1. What VYPORA is and what it is used for

VYPORA 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.

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

2. What you need to know before you take VYPORA

Do not take VYPORA

- If you are hypersensitive (allergic) to sacubitril, valsartan or any of the other ingredients of VYPORA (listed in section 6).
- If you are taking medicines for treatment of your high blood pressure or heart failure called angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB's). Do not start VYPORA until 36 hours after taking the last dose of these group of medicines (see Other medicines and VYPORA).
- 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 have a history of angioedema which is hereditary or for which the cause is unknown (idiopathic).
- 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 has reduced pumping ability.
- If you have a single kidney and have narrowing or constriction of the renal artery.
- If you use potassium-sparing diuretics such as spironolactone, triamterene, amiloride.
- If you have porphyria.
- If you use lithium.
- If you are pregnant or breastfeeding.
- If you have severe kidney function impairment.
- If you have diabetes or impaired kidney function and you are being treated with a medicine called aliskiren to lower your blood pressure (see Other medicines and VYPORA).
- If you have severe liver disease, biliary cirrhosis (a long-term liver disease affecting the bile ducts of the liver) and cholestasis (a condition where the flow of bile from the liver slows down or gets blocked).
- If you have moderate to severe kidney impairment or are elderly and are taking a fluoroquinolone

(an antibiotic) at the same time.

If any of the above applies to you, do not take VYPORA and talk to your doctor.

Warnings and precautions

Take special care with VYPORA:

- If you experience a swelling of the tongue, and/or throat, and difficulties in breathing **stop taking VYPORA and contact your doctor immediately.**
- If you ever had a reaction called angioedema (swelling of the face, lips, tongue and/or throat, difficulties in breathing).
- If you are being treated with an ACE inhibitor as there is an increased risk of angioedema.
- If you are being treated with an ARB or aliskiren (see Do not take VYPORA).
- 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, especially if you are aged 65 years or more, or if you have heart failure, kidney disease and low blood pressure.
- If you are suffering from dehydration or are using medicines called NSAIDs (see Other medicines and VYPORA), as this may affect your kidney function.
- If your potassium blood levels are high, or if you are taking any medicines that increases the amount of potassium in your blood (i.e. hyperkalaemia). Such medicines include potassium supplements, salt substitutes containing potassium, and potassium-sparing diuretics (such as triamterene, amiloride). It may be necessary for your doctor to check the amount of potassium in your blood at regular intervals during VYPORA treatment, especially if you also have other conditions such as:
  - Kidney impairment.
  - Diabetes mellitus.
  - Hypoaldosteronism (a medical condition where your body does not make enough of a hormone called aldosterone).
  - If you are on a high potassium diet.
  - If you are also using medicines called mineralocorticoid antagonists (see Other medicines and VYPORA below).
- If you experience abdominal pain, nausea, vomiting and diarrhoea, tell your health care provider. You may be experiencing intestinal angioedema, a rare condition where the walls of your intestines

swell up due to fluid leaking from blood vessels.

- If your kidney artery has narrowed.
- If you suffer from heart failure classified as NYHA class IV (unable to continue any physical activity without discomfort and may have symptoms even when resting).
- If you have liver impairment (see Do not take VYPORA above).
- If you are taking a fluoroquinolone (an antibiotic) at the same time (see Do not take VYPORA above). This may cause a sudden and rapid decline in kidney function, especially if you already have moderate to severe kidney impairment or are elderly.
- If you experience hallucinations, paranoia or changes in sleeping pattern while taking VYPORA.
- If you are taking statins (medicines to lower your cholesterol) as side effects can increase.

Children and adolescents

The safety and efficacy of VYPORA in paediatric patients aged below 18 years has not been established.

Other medicines and VYPORA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Do not take VYPORA 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 VYPORA (see Do not take PRODUCT NAME). If you stop taking VYPORA, wait 36 hours after taking your last dose of VYPORA before starting an ACE inhibitor or ARB's.
- Do not take VYPORA with aliskiren, a medicine to lower your blood pressure if you have diabetes or impaired kidney function. You may experience a higher frequency of side effects including low blood pressure, high blood potassium levels and decreased kidney function (including acute kidney failure).
- 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-sparing diuretics (e.g. triamterene, amiloride). This is a type of water pill that help

your body get rid of extra fluid without losing too much potassium.

- Mineralocorticoid antagonists (e.g. spironolactone, eplerenone). These medicines help your body get rid of extra salt and water, and keep potassium levels balanced.
- Potassium supplements or salt substitutes containing potassium.

Your doctor may check the amount of potassium in your blood periodically.

- Certain types 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.
- Lithium – a medicine used to treat some types of psychiatric illness.
- Fluoroquinolones (antibiotics).
- Some antibiotics (rifampicin used for tuberculosis).
- A medicine used to protect against transplant rejection (ciclosporin).
- An antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the side effects of VYPORA.

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking VYPORA.

You must not take VYPORA if you are pregnant or breastfeeding.

Women who might get pregnant (women of childbearing age)

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

Driving and using machines

Before you drive a vehicle, use tools or operate machines, or conduct other activities that require concentration, make sure you know how VYPORA affects you. If you feel dizzy or very tired while taking VYPORA, do not drive a vehicle, cycle or use any tools or machines.

VYPORA contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-

free'.

3. How to take VYPORA

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

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

You will usually start by taking a 24 mg/26 mg or 49 mg/51 mg tablet 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 and your blood pressure. Your doctor will then adjust the dose every 3 – 4 weeks depending on how you respond to the treatment until the best dose for you is found.

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

Your doctor will tell you how long your treatment with VYPORA will last. If you have the impression that the effect of VYPORA is too strong or too weak, tell your doctor or pharmacist.

If you take more VYPORA than you should

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

If you experience severe dizziness and/or fainting, tell your doctor as quickly as possible and lie down.

If you forget to take a dose of VYPORA

It is advisable to take your medicine at the same time each day. However, if you forget to take a dose, you should simply take the next one at the scheduled time.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking VYPORA

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

4. Possible side effects

VYPORA can have side effects.

Not all side effects reported for VYPORA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VYPORA, please consult your health care provider for advice.

If any of the following happens, stop taking VYPORA and tell your doctor immediately or go to the casualty department at your nearest hospital:

The following may be signs of an allergic reaction called angioedema:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to VYPORA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Low level of red blood cells, shown in a blood test (anaemia).
- High level of potassium in the blood, shown in a blood test (hyperkalaemia).
- Low level of potassium in the blood, shown in a blood test (hypokalaemia).
- Low level of sugar in the blood, shown in a blood test (hypoglycaemia).
- Dizziness.
- Headache.
- Spinning sensation (vertigo).
- Low blood pressure, which can cause symptoms of dizziness and light-headedness.
- Fainting (syncope).
- Low blood pressure (dizziness, light-headedness) when switching from sitting or lying to standing position (orthostatic hypotension).
- Cough.
- Diarrhoea.
- Feeling sick (nausea).
- Gastritis (stomach pain, nausea).
- Decreased kidney function (renal impairment).
- Acute renal failure (inability of the kidney to work properly.

- Tiredness (fatigue).
- Weakness (asthenia).

Less frequent side effects:

- Hypersensitivity (allergic reaction with rash and itching).
- Low level of sodium in the blood, shown in a blood test (hyponatraemia).
- Seeing, hearing or feeling things that are not there (hallucinations).
- Changes in sleeping pattern (sleep disorder).
- Paranoia (feeling that people are out to get you).
- Dizziness when switching from sitting to standing position (postural dizziness).
- Intestinal angioedema (a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.
- Pruritus (itchiness).
- Rash.
- Swelling of the face and throat (angioedema).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VYPORA.

5. How to store VYPORA

Store all medicines out of reach of children.

- This medicine does not require any special temperature storage conditions.
- Store at or below 25 °C.
- Store in original package.
- Keep the blister strips in the outer carton.
- Protect from light/moisture.
- Do not store in a bathroom.

- Do not use after the expiry date stated on the blister strip/ carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VYPORA contains

- The active substances are sacubitril and valsartan.
- The other ingredients in the tablet core are cellulose microcrystalline, crospovidone, low-substituted hydroxypropylcellulose, magnesium stearate, silica colloidal anhydrous, talc.

  VYPORA 24 mg/26 mg coating contains Opadry II White [hypromellose, macrogol, polydextrose, titanium dioxide (E171)].

  VYPORA 49 mg/51 mg coating contains Opadry II Yellow [hypromellose, iron oxide yellow (E172), macrogol, polydextrose, quinoline yellow aluminium lake (E104), titanium dioxide (E171)].

  VYPORA 97 mg/103 mg coating contains Opadry II Pink [hypromellose, iron oxide red (E172), macrogol, polydextrose, titanium dioxide (E171)].

What VYPORA looks like and contents of the pack

VYPORA 24 mg/26 mg: A white, film-coated, oval, biconvex, bevelled edge tablet debossed with V on one side of the tablet and SV0 on the other side.

VYPORA 49 mg/51 mg: A yellow, film-coated, oval, biconvex, bevelled edge tablet debossed with V on one side of the tablet and SV1 on the other side.

VYPORA 97 mg/103 mg: A pink, film-coated, oval, biconvex, bevelled edge tablet debossed with V on one side of the tablet and SV2 on the other side.

VYPORA is packed in cold form blister pack composed of aluminium foil laminated to oriented polyamide on one side and laminated to PVC on the other side, and hard tempered aluminium foil coated with heat seal lacquer. Pack sizes: 14, 28, 30, 56 or 60 tablets per pack enclosed in a cardboard box with a package insert.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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