

THE ONLY* ONE:

INNOVATIVE DRUG DESIGN AND CO-CRYSTAL LATTICE ENGINEERING

In patients with HF



Azmarda[®]

Sacubitril/Valsartan (50mg/100mg/200mg Tablets)

The **ONE** for **PREDICTABLE** Outcomes



Global standards of quality¹



Significant future risk reduction^{1, #}



Robust clinical evidence:¹

• Efficacy • Safety • Stability



Abbreviated Prescribing Information

Azmarda[®]
COMPOSITION: Tablets - Film-coated tablets containing 50 mg, 100 mg, or 200 mg Sacubitril/Valsartan as sodium salt complex. INDICATIONS: Azmarda[®] is indicated to reduce the risk of cardiovascular death and hospitalisation for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with Left Ventricular Ejection Fraction (LVEF) below normal. DOSAGE AND ADMINISTRATION: Adults - The target dose of Azmarda[®] is 200 mg twice daily. The recommended starting dose of Azmarda[®] is 100 mg twice daily. A starting dose of 50 mg twice daily is recommended for patients not currently taking an Angiotensin-Converting Enzyme (ACE) inhibitor or an Angiotensin II Receptor Blocker (ARB) and should be considered for patients previously taking low doses of these agents. Double the dose every 2-4 weeks to the target of 200 mg twice daily, as tolerated by the patient. METHOD OF ADMINISTRATION: For oral use. May be administered with or without food. CONTRAINDICATIONS: Hypersensitivity to the active substance, Sacubitril/Valsartan, or any of the excipients. Concomitant use with ACE inhibitors - Azmarda[®] must not be administered until 36 hours after discontinuing ACE inhibitors. Known history of angioedema related to previous ACE inhibitor or ARB therapy. Concomitant use with aliskiren in patients with type 2 diabetes and pregnancy. WARNINGS AND PRECAUTIONS: Dual blockade of the Renin-Angiotensin-Aldosterone System (RAAS) - Azmarda[®] must not be administered with an ACE inhibitor due to the risk of angioedema. Azmarda[®] must not be initiated until 36 hours after taking the last dose of ACE inhibitor therapy. If treatment with Azmarda[®] is stopped, ACE inhibitor therapy must not be initiated until 36 hours after the last dose of Azmarda[®]. Azmarda[®] must not be administered with aliskiren in patients with type 2 diabetes. Azmarda[®] should not be co-administered with an ARB due to the ARB-blocking activity of Azmarda[®]. Concomitant use with aliskiren should be avoided in patients with renal impairment (eGFR < 60 mL/min/1.73 m²). Hypotension - If hypotension occurs, dose adjustment of diuretics, concomitant antihypertensive drugs, and treatment of other causes of hypotension (e.g., hypovolaemia) should be considered. If hypotension persists despite such measures, the dosage of Azmarda[®] should be reduced or the product temporarily discontinued. Impaired renal function - Down titration of Azmarda[®] should be considered in patients who develop a clinically significant decrease in renal function. Caution should be exercised when administering Azmarda[®] in patients with severe renal impairment. Hyperkalaemia - Medications known to raise potassium levels (e.g., potassium-sparing diuretics and potassium supplements) should be used with caution. Monitoring of serum potassium levels is recommended, especially in patients with risk factors such as severe renal impairment, diabetes mellitus, hypoadrenism, or receiving a high-potassium diet. Angioedema - If angioedema occurs, Azmarda[®] should be discontinued immediately and appropriate therapy and monitoring should be initiated until complete and sustained resolution of signs and symptoms has occurred. Azmarda[®] must not be used in patients with a known history of angioedema related to previous ACE inhibitor or ARB therapy. Patients with renal artery stenosis - Caution is required in patients with renal artery stenosis and monitoring of the renal function is recommended. PREGNANCY, ADVERSE DRUG REACTIONS: The very common adverse reactions are hyperkalaemia, hypotension, and renal impairment. The common adverse reactions are cough, dizziness, renal failure, diarrhoea, hypokalaemia, fatigue, headache, syncope, nausea, asthma, orthostatic hypotension, and vertigo. The events most commonly associated with dosage adjustments or treatment interruptions are hypotension, hyperkalaemia and renal impairment. INTERACTIONS: Concomitant use contraindicated - The concomitant use of Azmarda[®] with aliskiren in patients with type 2 diabetes is contraindicated, concomitant use of Azmarda[®] with ACE inhibitors is also contraindicated. Concomitant use not recommended - ARB, concomitant use of Azmarda[®] with aliskiren, should be avoided in patients with renal impairment (eGFR < 60 mL/min/1.73 m²). Interactions to be considered - Caution should be taken when used concomitantly with statins, sildenafil, lithium, potassium-sparing diuretics (including mineralocorticoid antagonists, potassium supplements, or salt substitutes containing potassium), and Nonsteroidal Anti-Inflammatory Agents (NSAIDs). SPECIAL POPULATION: Pregnancy - Azmarda[®] must not be used during pregnancy. Breastfeeding - It is not known whether Azmarda[®] is excreted in human milk. Because of the potential risk for adverse drug reactions in breastfed newborns or infants, Azmarda[®] is not recommended during breastfeeding. Geriatric patients - No dosage adjustment is required. Paediatric patients - Azmarda[®] has not been studied. Its use is not recommended. Renal impairment - No dosage adjustment is required in patients with mild to moderate renal impairment. In adult patients with severe renal impairment (eGFR < 30 mL/min/1.73 m²), start Azmarda[®] at half the usually recommended starting dose. Hepatic impairment - No dose adjustment is required in patients with mild hepatic impairment. In adult patients with moderate hepatic impairment (Child-Pugh B classification), start Azmarda[®] at half the usually recommended starting dose. In patients with severe hepatic impairment, the use of Azmarda[®] is not recommended. PACKAGING INFORMATION: For more information, please refer to the full prescribing information. DATE OF PREPARATION: March 2023.

Azmarda[®] 50: Pack of 14 tablets (Alu-Alu strips of 2 x14)
Azmarda[®] 100: Pack of 14 tablets (Alu-Alu strips of 2 x14)
Azmarda[®] 200: Pack of 7 tablets (Alu-Alu strips of 2x7)

* HF- Heart Failure

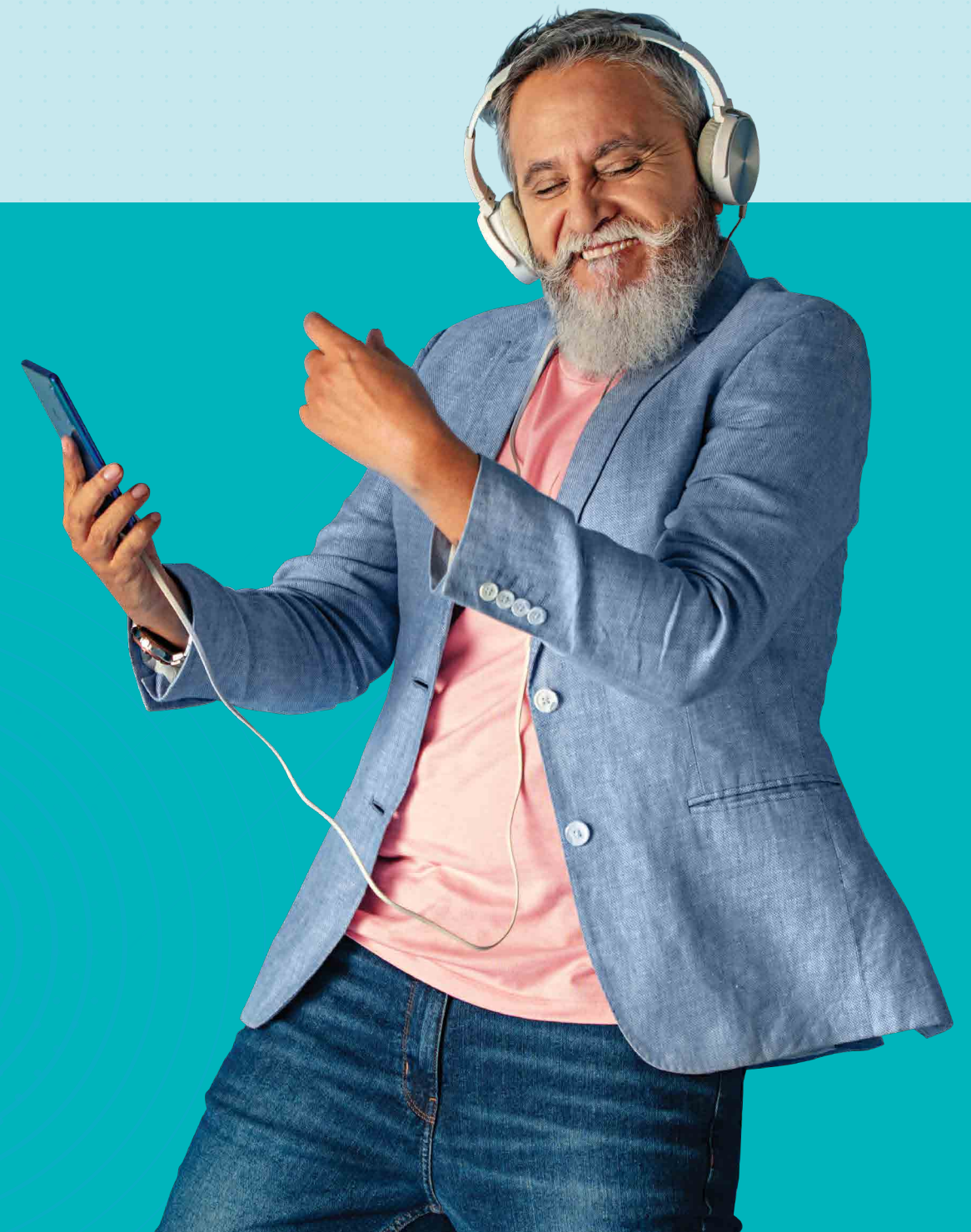
** to reduce the risk of cardiovascular death and hospitalisation for heart failure in adult patients with chronic heart failure.

[#]Imported from the innovator (Novartis). #Significant future risk reduction related to CV/mortality/hospitalisation for HF

1) McMurray et al. N Engl J Med 2014;371(11):993-1004 2) Desai et al. Eur Heart J 2015;36(30):1990-7 3) Packer et al. Circulation 2015;131(1):54-61

2) Source Haddad H et al. The PARASAIL study-Patient reported outcomes from the Canadian real-world experience use of Vymada in patients with heart failure and reduced ejection fraction, European Journal of Heart Failure (2017) 19 (Suppl. S1), 34. Source Canu A et al. Results of a single center experience on 200 consecutive patients treated with Entresto (Vymada), European Journal of Heart Failure (2017) 19 (Suppl. S1), 413

What is Heart Failure?



What is Heart Failure?

Your heart is a pump. It pumps blood, oxygen, and nutrients through your body.



The normal heart
has strong muscular walls that contract to pump blood out to all parts of the body. Heart muscle pumps blood out of the left ventricle.



Heart failure
is a condition that causes the muscle in the heart wall to slowly weaken and enlarge, preventing the heart from pumping enough blood.
In heart failure, weakened heart muscle cannot pump enough blood to meet the needs of your body.

Common causes of heart failure



Severe lung disease



Diseases of heart muscles



Abnormal heart valves



Coronary artery disease



History of heart attack



High blood pressure

What are the common symptoms of heart failure?



Shortness of breath



Excessive coughing



Built up of fluid (oedema)



Fatigue and dizziness



Nausea or lack of appetite



Confusion



Increased heart rate

How to live well with heart failure?

It can be difficult to manage at first, but one can learn to manage the symptoms and live an active life.

What you can do?



Create a heart failure self-care routine.



Follow specific diet and healthy lifestyle.



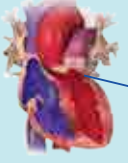
Pay careful attention to your medications.



Learn to track and manage your symptoms.

हार्ट फेल्युअर म्हणजे काय ?

तुमचे हृदय म्हणजे एक पंप आहे. ते तुमच्या शरीरातून रक्त, ऑक्सिजन आणि पोषक द्रव्ये पंप करते.



सामान्य हृदयामध्ये

मजबूत स्नायूंच्या भिंती असतात ज्या शरीराच्या सर्व भागांमधून रक्त बाहेर पंप करण्यासाठी आकुंचन पावतात. हृदयाचे स्नायू डाव्या वेंट्रिकलमधून रक्त पंप करतात.



हार्ट फेल्युअर (हृदय बिघाड)

ही अशी स्थिती आहे ज्यामुळे हृदयाच्या भिंतीतील स्नायू हळुहळू कमकुवत आणि मोठे होतात, ज्यामुळे हृदय पुरेसे रक्त पंप करू शकत नाही.

हार्ट फेल्युअरमध्ये (हृदयबिघाडामध्ये), कमकुवत हृदयाचे स्नायू आपल्या शरीराच्या गरजा पूर्ण करण्यासाठी पुरेसे रक्त पंप करू शकत नाहीत.

हार्ट फेल्युअरची (हृदय बिघाड) सामान्य कारणे



फुफ्फुसांचा गंभीर आजार



हृदयाच्या स्नायूंचे आजार



असामान्य हार्ट वॉल्व्स



हृदयाच्या रक्तवाहिन्यांचा विकार



हृदयविकाराचा इतिहास



उच्च रक्तदाब

हार्ट फेल्युअरची (हृदय बिघाडाची) सामान्य लक्षणे कोणती?



धाप लागणे



जास्त खोकला येणे



द्रव तयार होणे (एडेमा)



थकवा आणि चक्कर येणे



मळमळ किंवा कमी भूक लागणे



गोंधळणे



हार्ट रेटमध्ये वाढ होणे

हार्ट फेल्युअरसह चांगले कसे जगावे?

सुरुवातीला व्यवस्थापन करणे कठीण जाऊ शकते, पण एखादी व्यक्ती लक्षणांवर उपाय घेऊन सक्रिय आयुष्य जगू शकते.

तुम्ही काय करू शकता?



हार्ट फेल्युअर सेल्फ-केअर रूटीन तयार करा.



विशिष्ट आहार आणि निरोगी जीवनशैलीचे अनुसरण करा.



तुमच्या औषधांकडे काळजीपूर्वक लक्ष द्या .



तुमच्या लक्षणांचा मागोवा घेऊन त्यानुसार व्यवस्थापन करा.