

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, hypoadrenalism, or receiving a high-potassium diet. Angioedema - If angioedema occurs, Azmarda[®] should be discontinued immediately and appropriate therapy and monitoring 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 dosage 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

Daily monitoring tools in Heart Failure



Daily monitoring tools in Heart Failure

7 Things to Track Daily



☐ Daily weight

- Weigh yourself on the same scale every morning



☐ Oedema

- Watch for any swelling on ankles, lower legs and feet



☐ Shortness of breath

- Breathlessness or worsening in your ability to do your regular activities



☐ Blood pressure

- Monitor your blood pressure regularly



☐ Low sodium diet

- Eat food which is low in salt (sodium)



☐ Medication

- Be sure to take medicines as directed
- Report any side effects or other concerns



☐ Adopt heart-healthy habits

- Regular exercise
- Good nutrition
- Avoid alcohol and smoking
- Manage stress

When you are aware of the changes, you are more likely to take action.
Making small changes in your lifestyle and treatment plan can help
you live your longest and healthiest life.

Speak to your doctor and know more about your personalised daily monitoring tools.

References:

Adapted on <https://www.heart.org/en/health-topics/heart-failure/warning-signs-of-heart-failure/managing-heart-failure-symptoms> as on 15 May 2023

Adapted from <https://www.cardiosmart.org/assets/worksheet/your-heart-failure-checklist> as on 15 May 2023

இதயச் செயலிழப்பில் தினசரி கண்காணிப்புக் கருவிகள்

தினமும் கவனிக்க வேண்டிய 7 விஷயங்கள்

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☐ **தினசரி எடை**
 - ஒவ்வொரு நாள் காலையிலும் ஒரே இயந்திரத்தில் உங்களுக்கு நீங்களே எடை பார்த்துக் கொள்ளுங்கள்
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☐ **ஒடிம**
 - கணுக்கால்கள், கீழ்ப்புற கால்கள் மற்றும் பாதங்களை கவனிக்கவும்
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☐ **மூச்சுத் திணறல்**
 - மூச்சுத் திணறல் அல்லது உங்களது வழக்கமான வேலைகளை உங்களால் செய்யும் உங்கள் திறன் மோசமடைதல்
- 
☐ **ரத்த அழுத்தம்**
 - உங்கள் ரத்த அழுத்தத்தை வழக்கமாகக் கண்காணிக்கவும்
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☐ **உப்புக் குறைவாக உள்ள உணவு**
 - குறைவாக உப்புச் சேர்க்கப்பட்ட (சோடியம்) கொண்ட உணவை உட்கொள்ளவும்
- 
☐ **தியானம்**
 - பரிந்துரைத்தபடி மருந்துகளை எடுக்கவும்
 - ஏதாவது பக்க விளைவுகள் அல்லது வேறு சந்தேகங்களை நிவர்த்தி செய்யவும்
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☐ **இதயத்திற்கு ஆரோக்கியமான பழக்கங்களைப் பின்பற்றவும்**
 - வழக்கமாக உடற்பயிற்சி செய்யுங்கள்
 - சிறந்த ஊட்டச்சத்தை எடுத்துக் கொள்ளுங்கள்
 - மது மற்றும் புகைப்பிடித்தலைத் தவிருங்கள்
 - மன அழுத்தத்தைச் சமாளியுங்கள்

மாற்றங்களை நீங்கள் அறியும்போது, நீங்கள் வேலைகளைச் செய்யும் வாய்ப்புள்ளது. உங்கள் வாழ்க்கை முறை மற்றும் சிகிச்சை திட்டத்தில் சிறிய மாற்றங்களைச் செய்வது

நீங்கள் நீண்ட மற்றும் ஆரோக்கியமான வாழ்க்கையை வாழ உதவலாம்.

உங்கள் மருத்துவரிடம் பேசி உங்களுக்கென தனிப்பட்ட முறையில் வடிவமைக்கப்பட்ட தினசரி கண்காணிப்பு கருவிகள் பற்றி அதிகம் தெரிந்துகொள்ளுங்கள்.

References:

Adapted on <https://www.heart.org/en/health-topics/heart-failure/warning-signs-of-heart-failure/managing-heart-failure-symptoms> as on 15 May 2023
Adapted from <https://www.cardiosmart.org/assets/worksheet/your-heart-failure-checklist> as on 15 May 2023