

THE ONLY* ONE:

INNOVATIVE DRUG DESIGN AND
CO-CRYSTAL LATTICE ENGINEERING

In patients with HF



Azwarda[®]

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

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



Global standards of quality¹

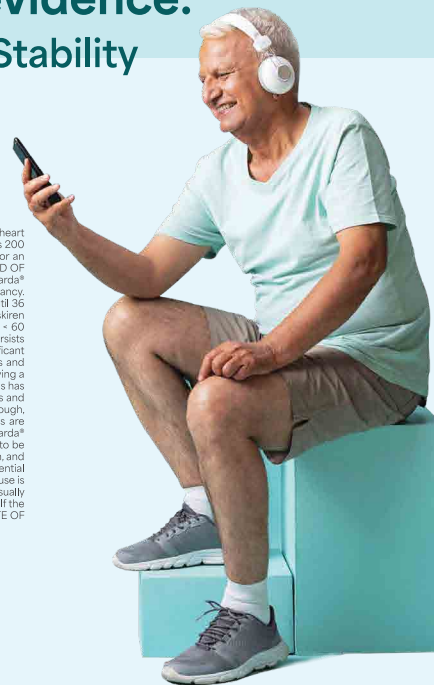


Significant future risk reduction^{1, #}



Robust clinical evidence:¹

• Efficacy • Safety • Stability



Abbreviated Prescribing Information

Azwarda[®]
COMPOSITION: Tablets - Film-coated tablets containing 50 mg, 100 mg, or 200 mg Sacubitril/Valsartan as sodium salt complex. INDICATIONS: Azwarda[®] 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 Azwarda[®] is 200 mg twice daily. The recommended starting dose of Azwarda[®] 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 - Azwarda[®] 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) - Azwarda[®] must not be administered with an ACE inhibitor due to the risk of angioedema. Azwarda[®] must not be initiated until 36 hours after taking the last dose of ACE inhibitor therapy. If treatment with Azwarda[®] is stopped, ACE inhibitor therapy must not be initiated until 36 hours after the last dose of Azwarda[®]. Azwarda[®] must not be administered with aliskiren in patients with type 2 diabetes. Azwarda[®] should not be co-administered with an ARB due to the ARB-blocking activity of Azwarda[®]. 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 Azwarda[®] should be reduced or the product temporarily discontinued. Impaired renal function - Down titration of Azwarda[®] should be considered in patients who develop a clinically significant decrease in renal function. Caution should be exercised when administering Azwarda[®] 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, Azwarda[®] should be discontinued immediately and appropriate therapy and monitoring should be initiated until complete and sustained resolution of signs and symptoms has occurred. Azwarda[®] 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 Azwarda[®] with aliskiren in patients with type 2 diabetes is contraindicated, concomitant use of Azwarda[®] with ACE inhibitors is also contraindicated. Concomitant use not recommended - ARB, concomitant use of Azwarda[®] 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, sildenafl, lithium, potassium-sparing diuretics (including mineralocorticoid antagonists, potassium supplements, or salt substitutes containing potassium), and Nonsteroidal Anti-Inflammatory Agents (NSAIDs). SPECIAL POPULATION: Pregnancy - Azwarda[®] must not be used during pregnancy. Breastfeeding - It is not known whether Azwarda[®] is excreted in human milk. Because of the potential risk for adverse drug reactions in breastfed newborns or infants, Azwarda[®] is not recommended during breastfeeding. Geriatric patients - No dosage adjustment is required. Paediatric patients - Azwarda[®] 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 Azwarda[®] 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 Azwarda[®] at half the usually recommended starting dose. In patients with severe hepatic impairment, the use of Azwarda[®] is not recommended. PACKAGING INFORMATION: For more information, please refer to the full prescribing information. DATE OF PREPARATION: March 2023.

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

* HF- Heart Failure

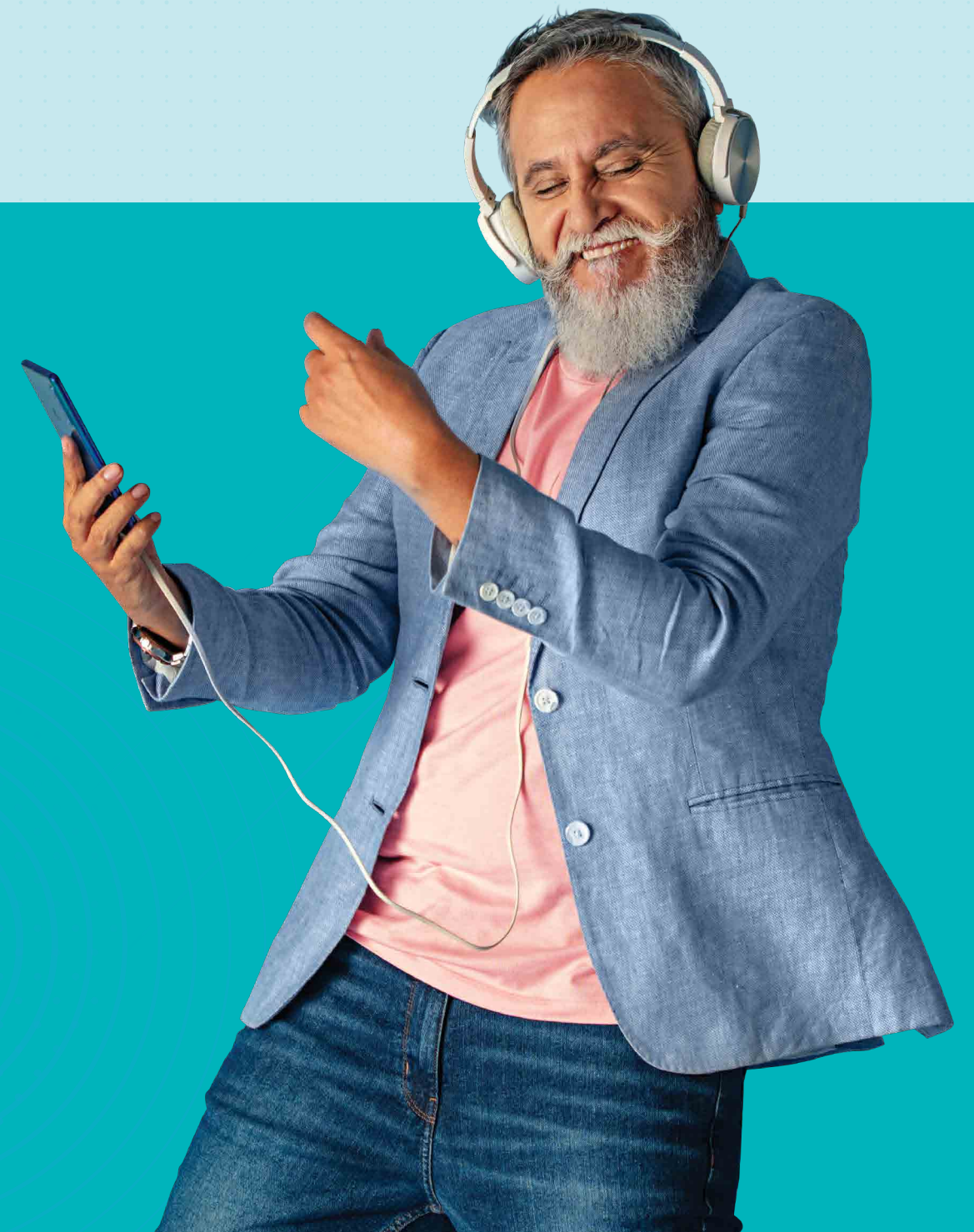
** to reduce the risk of cardiovascular death and hospitalisation for heart failure in adult patients with chronic heart failure.

[#]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

Why Limiting Salt Intake is Important in Heart Failure



Why Limiting Salt Intake is Important in Heart Failure?

Excess salt (sodium) retains more fluid in the body which makes heart failure symptoms worse.



Limiting salt in your diet helps to prevent fluid built-up (oedema) and eases symptoms.

Ask your doctor's advice about your daily salt limit.

How to start?

Eating heart-healthy foods with limited or restricted salt (sodium) is not always easy. You can start with:



Pick the food naturally low in sodium.



Select a right cooking method.



Learn to eat and like the food low in salt.

Read food labels

Ditch the salt shaker

What are the ways to limit salt in your diet?

What to include?



Use fresh vegetables and fruits for salads and desserts.



Eat fresh meat, chicken, and fish instead of processed and smoked one.



Eat unsalted snacks and nuts. Use herbs, spices, garlic, ginger to season your food.

What to avoid?



Avoid pickles, chutney, ready-to-use sauces and ketchups & processed food like papad, chips, bread, biscuits.



Avoid salt while cooking, seasoning, in chapati dough, rice, and salads.



Avoid ready-to-cook pasta and noodles, processed cheese, butter or other salted dairy products.



Avoid food containing MSG (monosodium glutamate) and processed or canned food.

References:

<https://www.webmd.com/heart-disease/heart-failure/low-sodium-eating> as accessed on 15 May 2023

https://www.cardiosmart.org/docs/default-source/assets/worksheet/hf-ap-limitingsalt.pdf?sfvrsn=5b47b777_3 as accessed on 15 May 2023

हार्ट फेल्योर में नमक का सेवन सीमित करना क्यों महत्वपूर्ण है?

अत्यधिक नमक (सोडियम) से शरीर में अधिक द्रव जुटता है जिससे हार्ट फेल्योर के लक्षण बदतर हो जाते हैं



आपके आहार में नमक को सीमित करने से द्रव का जुटना (एडेमा) रोकने और लक्षणों से राहत दिलाने में मदद मिलती है।

अपना दैनिक नमक का सेवन सीमित करने के बारे में अपने डॉक्टर से सलाह लें।

कैसे शुरुआत करें?

सीमित या प्रतिबंधित नमक (सोडियम) से युक्त हृदय के लिए स्वस्थ आहार खाना हमेशा आसान नहीं होता। आप इस तरह से शुरुआत कर सकते हैं:



स्वाभाविक रूप से कम नमक वाले आहार का चयन करें



खाना पकाने की सही पद्धति का चयन करें



कम नमक वाले आहार खाना और चुनना सीखें

फूड लेबल्स पढ़ें

नमक की डिब्बी हटा दें

आपके आहार में नमक सीमित करने के क्या उपाय हैं?

क्या शामिल करें



सलाद और डेज़र्ट्स के लिए ताज़ा सब्जियों और फलों का उपयोग करें



प्रक्रियायित और स्मोकड आहार के बजाय ताज़ा माँस, चिकन और मछली खाएँ



बिना नमकवाले स्नैक्स और नट्स खाएँ। अपने भोजन का स्वाद बढ़ाने के लिए हर्ब्स, मसालों, लहसुन, अदरक का उपयोग करें।

क्या टालें



अचार, चटनी, उपयोग के लिए तैयार सॉसेज और केचप तथा प्रक्रियायित आहार जैसे कि पापड़, चिप्स, ब्रेड, बिस्किट टालें



खाना पकाते समय नमक, सीज़निंग, रोटी की लोई, चावल और सलाद टालें।



रेडी टू कुक पास्ता और नूडल्स, प्रोसेस्ड चीज़, बटर या अन्य नमक युक्त दुग्ध उत्पाद टालें



एमएसजी (मोनो सोडियम ग्लूटामेट) और प्रक्रियायित या डिब्बाबंद आहार टालें

References:

<https://www.webmd.com/heart-disease/heart-failure/low-sodium-eating> as accessed on 15 May 2023

https://www.cardiosmart.org/docs/default-source/assets/worksheet/hf-ap-limitingsalt.pdf?sfvrsn=5b47b777_3 as accessed on 15 May 2023