

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

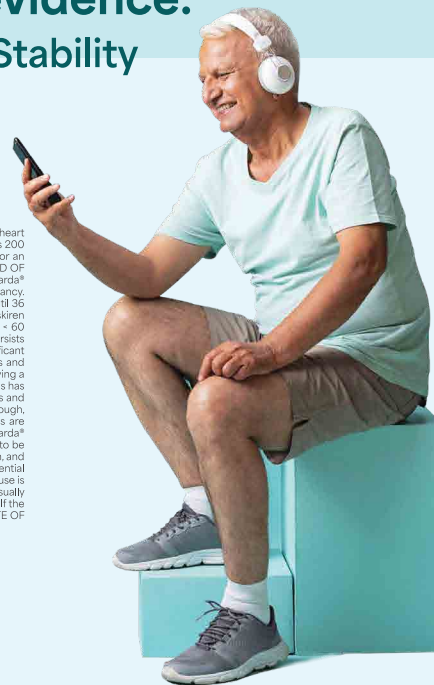


Significant future risk reduction^{1, #}



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 dosage 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

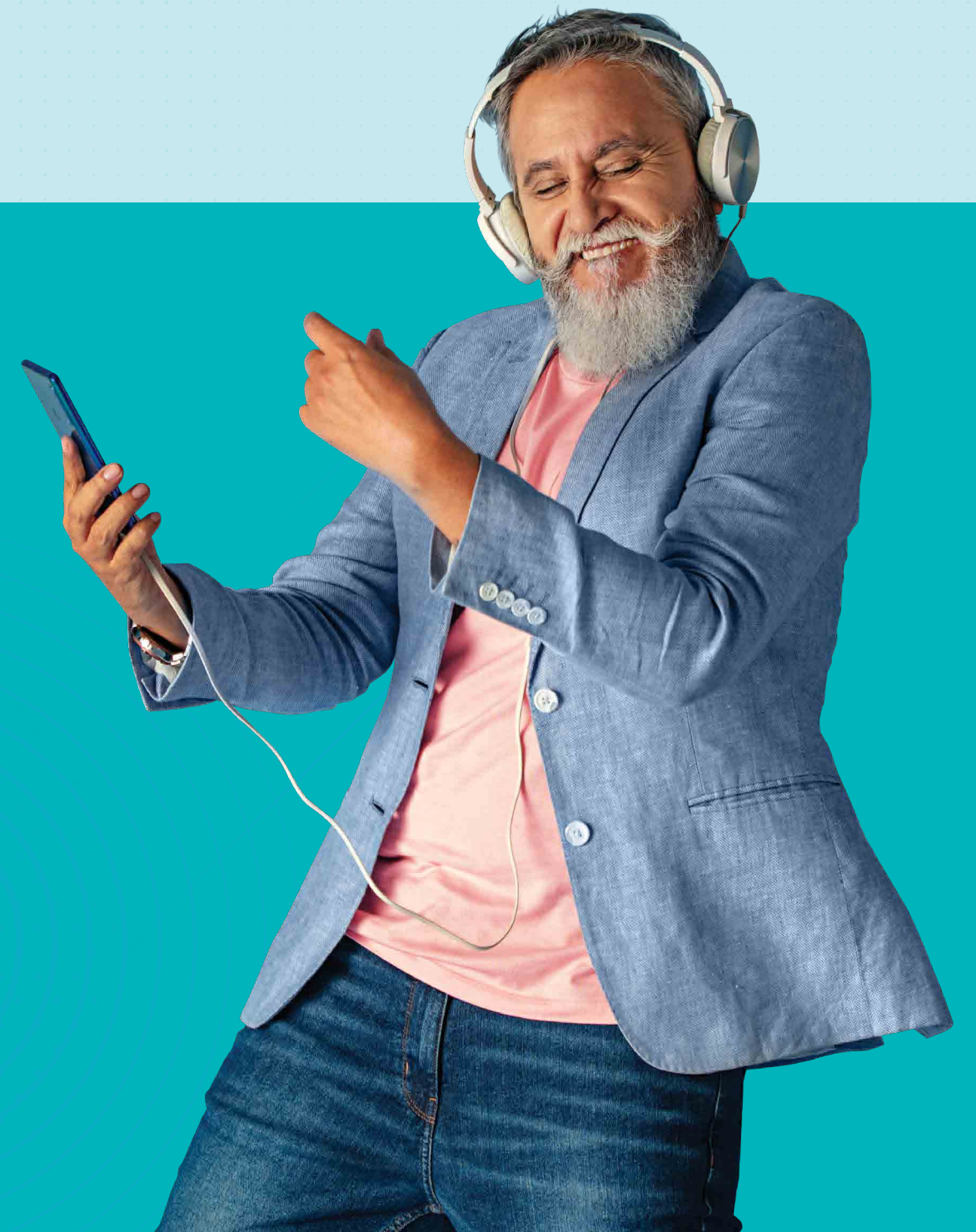
** to reduce the risk of cardiovascular death and hospitalisation for heart failure in adult patients with chronic heart failure.

[#]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.

હાર્ટ ફેલ્ચોરમાં મીઠાંનું સેવન ઓછું કરવું શા માટે અગત્યનું છે?

વધુ પડતું મીઠું (સોડિયમ) શરીરમાં વધુ પ્રવાહી જમા કરે છે જેને લીધે હાર્ટ ફેલ્ચોરનાં લક્ષણો વણસે છે.



તમારા આહારમાં મીઠું ઓછું કરવાથી પ્રવાહીનો ભરાવો (ઓડીમા) થતો ટાળવામાં અને લક્ષણોથી રાહત મેળવવામાં મદદ મળે છે.

તમારે દરરોજ કેટલું મીઠું ભોજનમાં લેવું જોઈએ તેના વિશે તમારા ડૉક્ટરની સલાહ લો.

શરૂઆત કેવી રીતે કરશો?

ઓછું મીઠું (સોડિયમ) ધરાવતો અને હૃદય માટે આરોગ્યપ્રદ આહાર લેવો એ હંમેશા સરળ નથી હોતું.

કુદરતી રીતે ઓછું સોડિયમ ધરાવતો આહાર પસંદ કરો.

રસોઈની ચોચ પદ્ધતિ અપનાવો

ઓછું મીઠું ધરાવતો આહાર ખાતા અને પસંદ કરતા શીખો

ફૂડ લેબલ્સ વાંચો

સોલ્ટ શેકરને મૂર્ખ બનાવો

તમારા આહારમાં મીઠું ઓછું કરવાની કઈ રીતો છે?

શું સામેલ કરશો



સેલેડ્સ અને ડેઝર્ટ્સ માટે તાજાં ફળો અને શાકભાજીનો ઉપયોગ કરો.



પ્રોસેસ કરેલા અને ભૂંજેલાને બદલે તાજું માંસ, ચીકન અને માછલી ખાઓ.



મીઠાં વગરના ફરસાણ અને સૂકો મેવો ખાઓ. તમારા આહારને વધારવા હર્સ, મસાલાં, લસણ, આદૂનો ઉપયોગ કરો.

શું ટાળશો



અથાણાં, ચટણી, રેડી ટુ ચુક સોસ અને કેચઅપ્સ તેમ જ પ્રોસેસ કરેલા આહારો જેમ કે પાપડ, ચિપ્સ, બ્રેડ, બિસ્કિટ્સ ખાવાનું ટાળો.



રસોઈ બનાવતી વખતે, ઉપરથી, રોટલીના લોટમાં, ભાત અને સેલેડમાં મીઠું નાખવાનું ટાળો.



રેડી ટુ ફૂડ પાસ્તા અને નૂડલ્સ, પ્રોસેસ કરેલું ચીઝ, બટર અથવા અન્ય મીઠાંયુક્ત દુધ ઉત્પાદનોનો ઉપયોગ કરવાનું ટાળો.



એમએસજી (મોનો સોડિયમ ગ્લુટામેટ) ધરાવતો આહાર તેમ જ પ્રોસેસ કરેલ અથવા કેનમાં મળતો આહાર લેવાનું ટાળો.

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