

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, sildenafil, 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

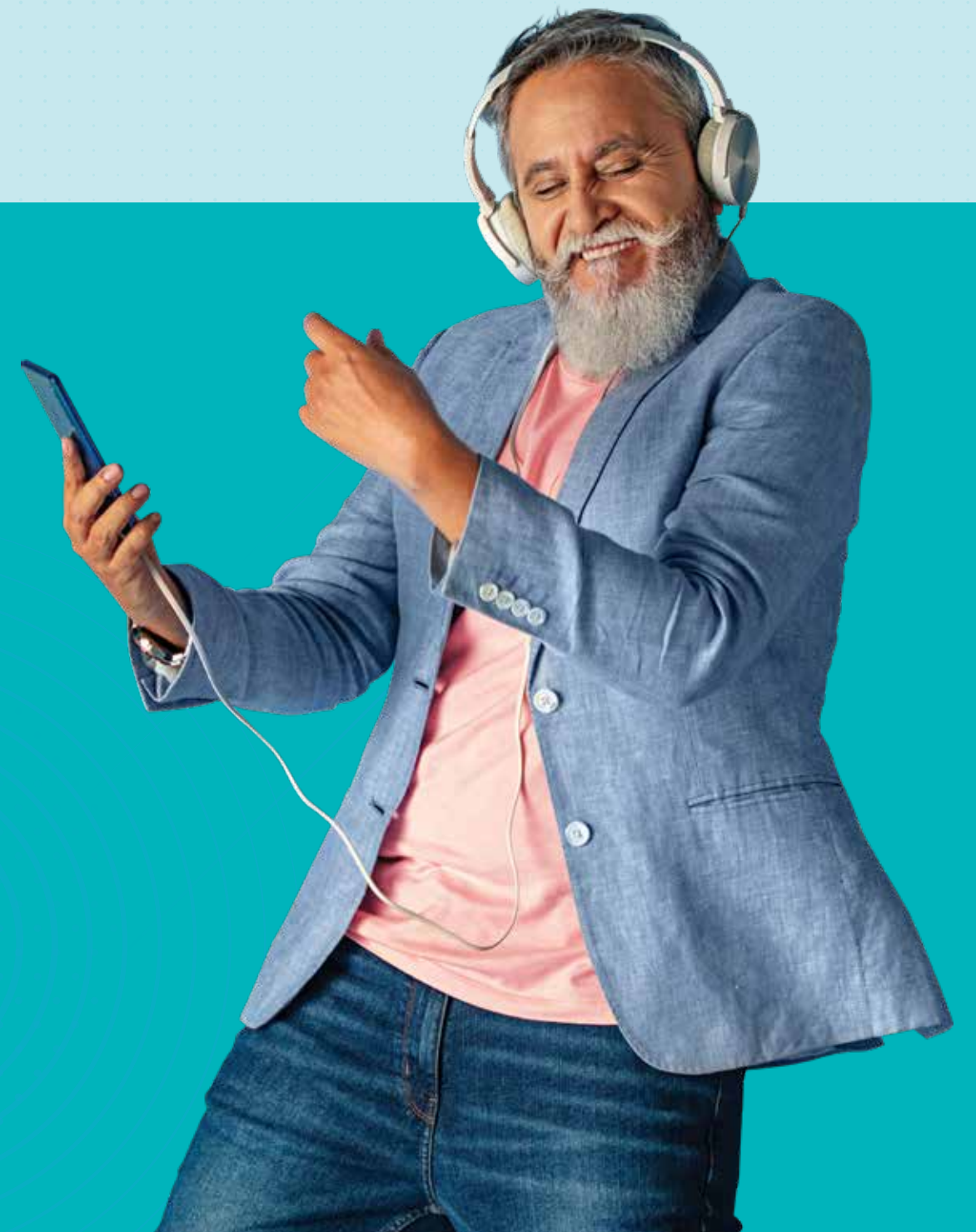
** to reduce the risk of cardiovascular death and hospitalisation for heart failure in adult patients with chronic heart failure.

[#]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

Fluid Intake in Heart Failure



Fluid Intake in Heart Failure

Why fluid restriction is recommended in heart failure?

- In heart failure, your body tends to retain fluids. • Drinking excess fluids can build up extra fluids in your body.
- It can worsen your symptoms of heart failure.

How much fluid is to be restricted?

- Restriction of fluid intake depends on severity of your symptoms.
- Your healthcare provider may recommend limiting your fluid intake or prescribe diuretics.

Limit your fluid intake

- Fluid intake should not be mistaken for water only.
- Following foods and drinks contribute to overall fluid intake.



Dals & Curries



Juices & Water



Coffee & Tea



Ice Cream & Jello



Soups



Coconut Water



Some fruits like
Watermelon, Bannan



Curd, Lassi, Buttermilk

- Considering all foods and drinks, total fluid intake should not exceed 1.5–2L per day.

Tips to limit your daily fluids



Use a small cup to drink your fluids and keep track of your fluid intake.



Count other fluids like soups, fruit juices, sharbat, coffee, tea, coconut water, buttermilk, lassi, soda, curd, dals, curries etc.



Limit your salt and salty foods as these make you thirsty.



If you feel thirsty, try chewing gum or a sugar-free mint, suck on hard candy, a slice of lemon, or small pieces of ice.



Weigh yourself regularly on same scale in the morning to know if there is fluid retention in your body.

Note: Limiting your fluid intake doesn't mean abstaining from drinking.
Adequate hydration is important. Also, be watchful for dehydration.

References:

Adapted from <https://www.heart.org/en/health-topics/heart-failure/treatment-options-for-heart-failure/lifestyle-changes-for-heart-failure> as accessed on 15 May 2023
Adapted from <https://medlineplus.gov/ency/patientinstructions/000112.htm> as accessed on 15 May 2023

ಹೃದಯ ವೈಫಲ್ಯದಲ್ಲಿ ದ್ರವಸೇವನೆ

ಹೃದಯ ವೈಫಲ್ಯದಲ್ಲಿ ದ್ರವಸೇವನೆಗೆ ಯಾಕೆ ನಿರ್ಬಂಧಗಳನ್ನು ತಿಳಿಸಲಾಗುತ್ತದೆ?

- ಹೃದಯ ವೈಫಲ್ಯದಲ್ಲಿ ನಿಮ್ಮ ಹೃದಯ ನೀರನ್ನು ಉಳಿಸಿ ಇಟ್ಟುಕೊಳ್ಳುವ ಪ್ರವೃತ್ತಿ ಹೊಂದಿರುತ್ತದೆ. • ಹೆಚ್ಚು ದ್ರವಸೇವನೆ ಮಾಡಿದರೆ, ನಿಮ್ಮ ದೇಹದಲ್ಲಿ ಹೆಚ್ಚುವರಿ ದ್ರವ ಸಂಗ್ರಹಗೊಳ್ಳಬಹುದು.
- ಅದರಿಂದ ನಿಮ್ಮ ಹೃದಯ ವೈಫಲ್ಯದ ಲಕ್ಷಣಗಳು ಉಲ್ಬಣಿಸಬಹುದು.

ಎಷ್ಟು ದ್ರವವನ್ನು ನಿರ್ಬಂಧಿಸಬೇಕು?

- ದ್ರವಸೇವನೆಯ ಮೇಲಿನ ನಿರ್ಬಂಧವು ನಿಮ್ಮ ಲಕ್ಷಣಗಳ ತೀವ್ರತೆಯನ್ನು ಅವಲಂಬಿಸಿರುತ್ತದೆ.
- ನಿಮ್ಮ ಡಾಕ್ಟರ್‌ರು ದ್ರವಸೇವನೆಯನ್ನು ಸೀಮಿತಗೊಳಿಸಲು ತಿಳಿಸಿದರೆ ಅಥವಾ ಮೂತ್ರವರ್ಧಕಗಳನ್ನು (diuretics) ಆದೇಶಿಸಬಹುದು.

ನಿಮ್ಮ ದ್ರವಸೇವನೆಯನ್ನು ಸೀಮಿತಗೊಳಿಸಿ

- ದ್ರವಸೇವನೆ ಅಂದರೆ ಕೇವಲ ನೀರು ಎಂದು ಭಾವಿಸಬಾರದು.
- ಈ ಕೆಳಗಿನ ಆಹಾರಗಳು ಮತ್ತು ಪಾನೀಯಗಳು ಒಟ್ಟು ದ್ರವಸೇವನೆಗೆ ಕೊಡುಗೆ ಮಾಡುತ್ತವೆ.



ಬೇಳೆಸಾರುಗಳು/ಸಾಂಬಾರ್‌ಗಳು



ಹಣ್ಣಿನ ರಸಗಳು ಮತ್ತು ನೀರು



ಕಾಫಿ ಮತ್ತು ಚಹಾ



ಐಸ್ ಕ್ರೀಮ್ ಮತ್ತು ಜೆಲ್ಲೊ



ಸೂಪ್‌ಗಳು



ಎಳೆನೀರು



ಕೆಲವು ಹಣ್ಣುಗಳು ಅಂದರೆ ಕಲ್ಲಂಗಡಿ



ಮೊಸರು, ಲಸಿ, ಮಜ್ಜೆಗೆ

- ಎಲ್ಲಾ ಆಹಾರಗಳು ಮತ್ತು ಪಾನೀಯಗಳನ್ನು ಸೇರಿಸಿ ಲೆಕ್ಕ ಹಾಕಿದರೆ, ಒಟ್ಟು ದ್ರವಸೇವನೆಯು ದಿನಕ್ಕೆ 1.5-2 ಲೀ.ರನ್ನು ಮೀರಬಾರದು.

ನಿಮ್ಮ ದೈನಂದಿನ ದ್ರವಸೇವನೆಯನ್ನು ಸೀಮಿತಗೊಳಿಸಲು ಸೂಚನೆಗಳು



ನಿಮ್ಮ ದ್ರವಗಳನ್ನು ಕುಡಿಯಲು ಸಣ್ಣ ಕಪ್ ಬಳಸಿ ಮತ್ತು ಕ್ರಮವತ್ತಾಗಿ ನಿಮ್ಮ ದ್ರವಸೇವನೆಯ ಲೆಕ್ಕ ಇಡಿ.



ಸೂಪ್‌ಗಳು, ಹಣ್ಣಿನ ರಸಗಳು, ಶರಬತ್ತು, ಕಾಫಿ, ಚಹಾ, ಎಳೆನೀರು, ಮಜ್ಜೆಗೆ, ಲಸಿ, ಸೋಡಾ, ಮೊಸರು, ಬೇಳೆಸಾರುಗಳು, ಸಾಂಬಾರ್‌ಗಳಂತಹ ಇತರ ದ್ರವಗಳನ್ನೂ ಲೆಕ್ಕ ಹಾಕಿ.



ಉಪ್ಪು ಮತ್ತು ಉಪ್ಪಿನ ಆಹಾರಗಳನ್ನು ಸೀಮಿತಗೊಳಿಸಿ, ಯಾಕೆಂದರೆ ಅವು ನಿಮಗೆ ಬಾಯಾರಿಕೆ ಉಂಟುಮಾಡುತ್ತವೆ.



ನಿಮಗೆ ಬಾಯಾರಿಕೆ ಉಂಟಾದರೆ, ಚೂಯಿಂಗ್ ಗಮ್ ಅಥವಾ ಸಕ್ಕರೆಯಿಲ್ಲದ ಪುಡಿವನ್ನು ಬಳಸಿ ನೋಡಿ, ಗಟ್ಟಿ ಕ್ಯಾಂಡಿ, ನಿಂಬೆಯ ಹೋಳು ಅಥವಾ ಮಂಜುಗಡ್ಡೆಯ ಸಣ್ಣ ತುಂಡುಗಳನ್ನು ಚೇಪಿ.



ನಿಯಮಿತವಾಗಿ ಪ್ರತಿದಿನ ಒಂದೇ ತಕ್ಕಡಿಯಲ್ಲಿ ನಿಮ್ಮ ತೂಕ ನೋಡಿ, ಅದರಿಂದ ನಿಮ್ಮ ದೇಹದಲ್ಲಿ ದ್ರವ ಉಳಿದಿದೆಯಾ ಎಂಬುದು ಗೊತ್ತಾಗುತ್ತದೆ.

ಗಮನಿಸಿ: ದ್ರವಸೇವನೆಯನ್ನು ಸೀಮಿತಗೊಳಿಸುವುದು ಅಂದರೆ ಎನನ್ನೂ ಕುಡಿಯಬಾರದು ಎಂದರ್ಥವಲ್ಲ. ದೇಹದಲ್ಲಿ ಸಾಕಷ್ಟು ದ್ರವ ಇರುವುದು ಮುಖ್ಯವಾದದ್ದು. ಜೊತೆಗೆ, ದೇಹ ನಿರ್ಜಲಗೊಳ್ಳದಂತೆ ಎಚ್ಚರವಹಿಸಿ.

References:

Adapted from <https://www.heart.org/en/health-topics/heart-failure/treatment-options-for-heart-failure/lifestyle-changes-for-heart-failure> as accessed on 15 May 2023