

THE ONLY* ONE:

INNOVATIVE DRUG DESIGN AND CO-CRYSTAL LATTICE ENGINEERING

In patients with HF



Rx

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 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

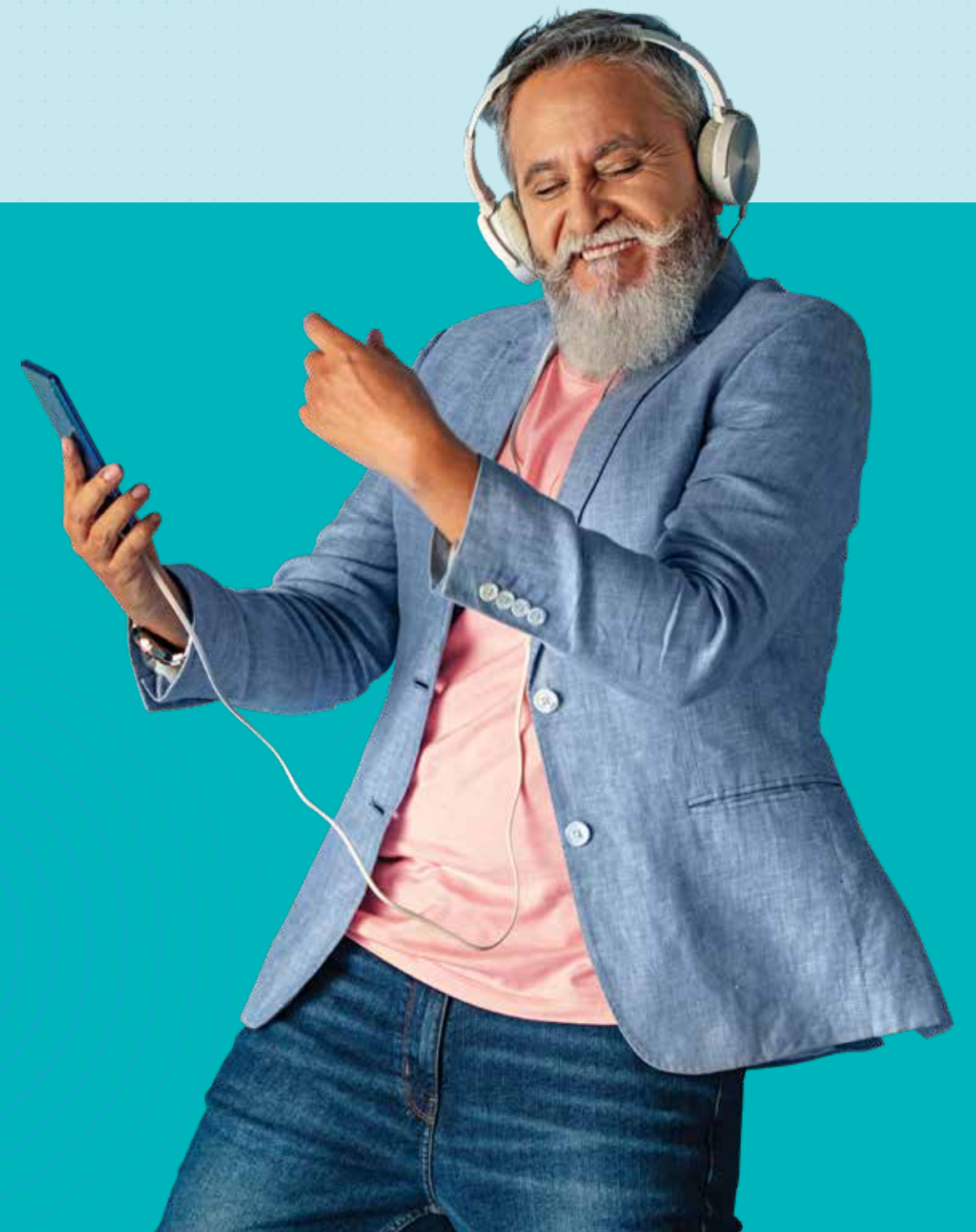
** to reduce the risk of cardiovascular death and hospitalisation for heart failure in adult patients with chronic heart failure.

[#]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

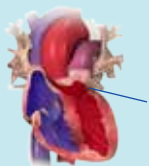
2) Source Haddad H et al. The PARASAIL study-Patient reported outcomes from the Canadian real-world experience use of Vymada in patients with heart failure and reduced ejection fraction, European Journal of Heart Failure (2017) 19 (Suppl. S1), 34. Source Canu A et al. Results of a single center experience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

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.



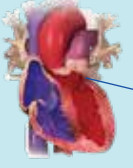
Pay careful attention to your medications.



Learn to track and manage your symptoms.

గుండె వైఫల్యం అంటే ఏమిటి?

మీ గుండె ఒక వంపు. అది రక్తాన్ని, ఆక్సిజెన్‌ను మరియు పోషకపదార్థాలను శరీరం అంతటాకి పంపు చేస్తుంది.



సాధారణ గుండె

బలమైన కండరాల గోడలు కలిగి ఉంటుంది, ఇవి శరీరం అన్ని భాగాలకు రక్తాన్ని పంపు చేయడానికి సంకోచిస్తుంది. గుండె కండరం ఎడమ వెంట్రికల్ బయటికి రక్తాన్ని పంపు చేస్తుంది.



గుండె వైఫల్యం

అనేది గుండె గోడలోని కండరం నిదానంగా బలహీనపడడానికి మరియు వ్యాప్తి చెందడానికి దారితీసేలా చేస్తుంది, తగినంత రక్తాన్ని గుండె పంపు చేయకుండా ఇది నిరోధిస్తుంది.

గుండె వైఫల్యం సంభవించినప్పుడు, బలహీనపడిన గుండె కండరం మీ శరీరపు అవసరాలను నెరవేర్చే తగినంత రక్తాన్ని పంపు చేయలేదు.

గుండె వైఫల్యానికి సాధారణ కారణాలు



తీవ్రమైన ఊపిరితిత్తి వ్యాధి



కఠినమైన ఆర్థ్రై వ్యాధి



గుండె కండరాల వ్యాధులు



గుండె పోటు ఉన్న చరిత్ర కలిగి ఉండడం



అసాధారణమైన గుండె వాలులు



అధిక రక్తపోటు

గుండె వైఫల్యపు సాధారణ లక్షణాలు ఏమిటి?



శ్వాస అందకపోవడం



అధికంగా దగ్గడం



ద్రవాలు పేరుకుపోవడం (ఎడెమా)



బడలిక మరియు కళ్ళు తిరగడం



వికారం లేదా ఆకలి లేకపోవడం



అయోమయం



పెరిగిన గుండె సూచి

గుండె వైఫల్యం చెందుతుంటే హాయిగా జీవించడం ఎలా?

మొదట్లో దీనిని సంబాళించడం కష్టం కావచ్చును, కాని లక్షణాలను సంబాళించడాన్ని మరియు చురుకైన జీవితాన్ని గడపడాన్ని ఎవరైనా నేర్చుకోవచ్చును.

మీరు ఏమి చేయగలరు?



గుండె వైఫల్యానికి స్వయం సంరక్షణ కు సంబంధించి నిత్యపరిపాటి కార్యక్రమాన్ని కల్పించుకోవచ్చును



నిర్దిష్టమైన ఆహారం మరియు ఆరోగ్యరమైన జీవనశైలిని అనుసరించాలి



మీ మందుల పట్ల జాగ్రత్తగా శ్రద్ధ వహించాలి



మీ లక్షణాలు గమనించడం మరియు వాటితో వ్యవహరించడం నేర్చుకోవాలి.