

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 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

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.

గుండె వైఫల్యంలోండె వైఫల్యంలో తీసుకునే ఉప్పును పరిమితం చేసుకోవడం ఎందుకు ముఖ్యమైన విషయం?

అధికమైన ఉప్పు (సోడియమ్) శరీరంలో ఎక్కువ ద్రవాలని నిలిచిపోయేలా చేస్తుంది, ఇది గుండె వైఫల్య లక్షణాలను విషమింపజేస్తాయి.



మీ భోజనంలో ఉప్పును పరిమితంగా తీసుకోవడం ద్రవాలను పేరుకుపోవడాన్ని (ఎడెమా) నిరోధించడంలో సహాయపడుతుంది మరియు లక్షణాలను తేలికపరుస్తుంది.

మీ రోజువారీ ఉప్పు పరిమితిని గురించి మీ డాక్టరును సలహా అడగండి.

ఎలా ప్రారంభించాలి?

గుండెకు ఆరోగ్యకరమైన ఆహారాలను పరిమితంగా లేదా ఆంక్షలు పెట్టబడిన ఉప్పుతో (సోడియమ్) భుజించడం ఎల్లప్పుడూ అంత తేలికయిన పని కాదు. మీరు ఇలా మొదలుపెట్టవచ్చును -



సహజంగా ఉప్పు తక్కువ ఉన్న ఆహారాన్ని ఎంచుకోవాలి



సరైన వంట విధానాన్ని ఎంచుకోవాలి



ఉప్పు తక్కువగా ఉన్న ఆహారాన్ని భుజించడం మరియు దానిని ఇష్టపడడం నేర్చుకోవాలి.

ఆహార లేబుళ్ళను చదవాలి

సాల్ట్ పేకరును ముట్టుకోవదు

మీ భోజనంలో ఉప్పును పరిమితం చేసుకోవడానికి ఉన్న విధానాలు ఏమిటి?

వేటిని చేర్చుకోవాలి



సలాడ్లు మరియు తీపి పదార్థాల (డిజర్ట్) కొరకు తాజా పండ్లను మరియు కూరగాయలను ఉపయోగించాలి.



ప్రాసెస్ చేయబడినవి మరియు పొగతో వండిన వాటికి బదులుగా తాజా మాంసం, కోడి మరియు చేపలను భుజించాలి.



ఉప్పు వేయని అల్పాహారాలు మరియు కాయలను భుజించాలి. మూలికలు, మసాలా దినుసులు, వెల్లుల్లి, అల్లం మీ ఆహారంలో తిరగమోతలో ఉపయోగించాలి.

మానుకోవలసినవి



ఊరగాయ పచ్చళ్ళు, చట్నీ, ఉపయోగించడానికి సిద్ధంగా ఉండే సాస్లు మరియు కెప్‌ఆప్‌లు మరియు అప్పడాలు, చిప్స్, బ్రెడ్, బిస్కట్లు లాంటి ప్రాసెస్ చేయబడిన ఆహారాలకు దూరంగా ఉండాలి



వండేటప్పుడు, తిరగమోతలలో, చపాతి పిండిలో, బియ్యం మరియు సలాడ్లలో ఉప్పు వేయడం మానుకోవాలి.



వండడానికి సిద్ధంగా ఉన్న పాస్టా, మరియు నూడుల్స్‌ను, ప్రాసెస్ చేయబడిన చీజ్‌ను వెన్న లేదా ఇతర ఉప్పు కలిపిన పాల ఉత్పాదనలను వాడడం మానుకోవాలి.



ఎమ్‌ఎస్‌జి (మోనో సోడియమ్ గ్లూటామేట్) కలిగిన ఆహారాన్ని మరియు ప్రాసెస్ చేయబడిన లేదా క్యానులలో ఉంచబడిన ఆహారాన్ని తినడం మానుకోవాలి.

References:

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