From the makers of

In HF patients

Azmarda®

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

GOOD PEOPLE for GOOD HEALTH

THE ONLY* ONE:

INNOVATIVE DRUG DESIGN AND CO-CRYSTAL LATTICE ENGINEERING

In patients with HF

Rx

Azmarda®

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

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

- Global standards of quality[1]
- Significant future risk reduction[1,#]
- Robust clinical evidence:[1]
  • Efficacy • Safety • Stability

Abbreviated Prescribing Information
Azmarda®

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

Azmarda® 50: Pack of 14 tablets (Alu-Alu strips of 2 x14)
Azmarda® 100: Pack of 14 tablets (Alu-Alu strips of 2 x14)
Azmarda® 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.
Images are for representation purposes only.

References

*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

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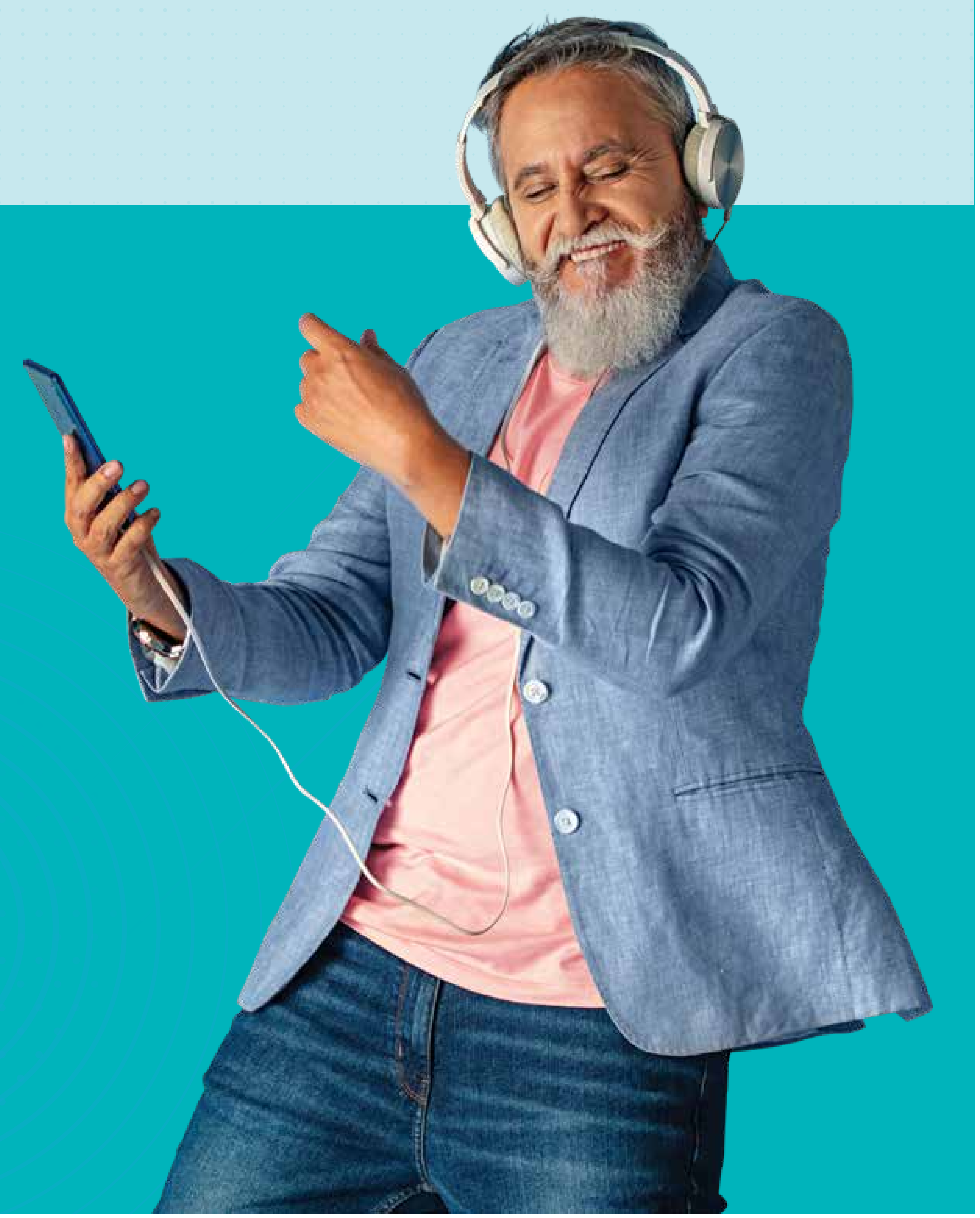
Intake of Potassium in Heart Failure



GOOD PEOPLE *for* GOOD HEALTH

Intake of Potassium in Heart Failure

- Potassium is a mineral that is crucial for normal cell function in the body, including the heart.
- The right level of potassium is the key.
- An abnormal level of potassium can interfere with proper rhythmic beating of the heart.

A high potassium level (Hyperkalaemia) can be just as harmful as a low level (Hypokalaemia).

What causes hypokalaemia and hyperkalaemia in heart failure?

Hypokalaemia

- Increased potassium excretion (medicines like diuretics)
- Insufficient potassium intake

You may need to increase your dietary potassium intake.

Hyperkalaemia

- ACE inhibitors, ARBs, & aldosterone antagonists increase potassium level.
- Other conditions like diabetes and kidney disease

You may need to lower your dietary potassium intake.

Keep a watch on your potassium levels

- Regularly discuss with your doctor about your blood potassium level and how much potassium containing food you should eat.
- Mild cases may be easy to treat.
- If your potassium level is very high, or if there are significant changes in an ECG, emergency treatment may be required.

What should I do if my blood potassium level is high?

Avoid potassium-rich foods.

Read food labels carefully and avoid foods high in potassium.

Soak or boil vegetables and fruits in water before you eat.

Avoid juices from canned or frozen fruits and vegetables.

Potassium rich food to be remembered

- Vegetables: Broccoli, Potato, Avacado, Tomato, leafy greens, Mushroom, Cucumber, Peas, Eggplant
- Fresh fruits: Banana, Orange, Kiwi, Mango, Peach, Papaya
- Coconut water
- Dried fruits: Resins, Prunes, Apricots, Dates
- Protein: Tofu, Fish, Lean Meat
- Dairy: Low fat milk, Yogurt
- Salt substitutes that contain potassium chloride
- Canned juices

Discuss with your doctor about your blood potassium level and intake of potassium.

ACE: Angiotensin Converting Enzyme; ARB: Angiotensin Receptor Blocker

References:.
https://my.clevelandclinic.org/health/articles/17073-heart-failure-diet-potassium
https://www.heart.org/en/health-topics/heart-failure/treatment-options-for-heart-failure/hyperkalemia-high-potassium as accessed on 15 May 2023