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Entresto - Guidelines - HCP

Prescribing information

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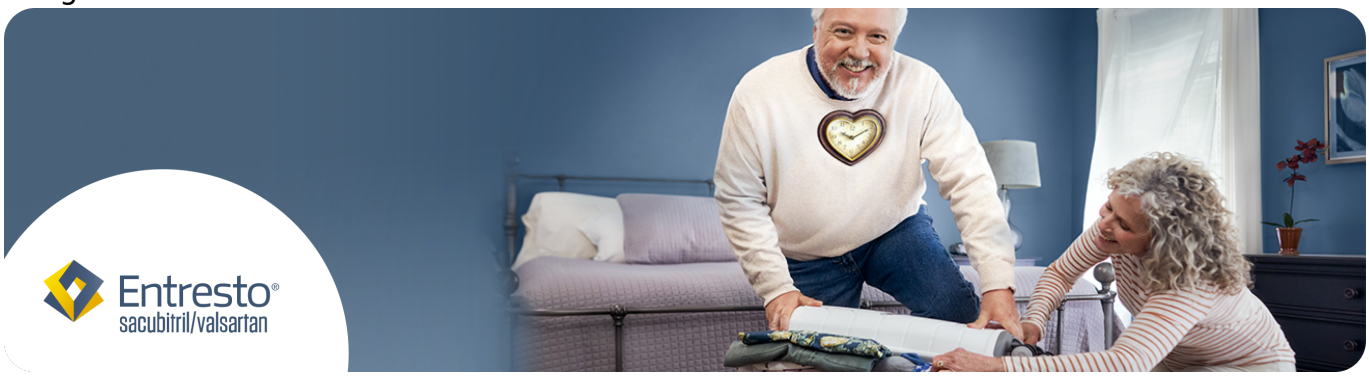

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Entresto®
sacubitril/valsartan

Entresto (sacubitril/valsartan) efficacy and clinical trials

ENTRESTO is indicated in adult patients for the treatment of symptomatic chronic heart failure with reduced ejection fraction.[6]

For further information, please refer to the Entresto Summary of Product Characteristics.[6]

Consider prescribing ENTRESTO as a first-line option as recommended as recommended by the following national[2,3] and international guidelines:[4,5]

CaReMe UK heart failure algorithm

CaReMe UK heart failure algorithm[*2] **recommends treatment with sacubitril/valsartan** or AaCEi or ARBs + beta blocker and an MRA as **first-line treatment** option for **chronic HFrEF** patients where ejection fraction is <35%[†]

Learn more

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2022 ACC/AHA update

In patients with chronic symptomatic HFrEF NYHA class II or III who tolerate an ACEi or ARB, replacement by an ARNi is recommended to further reduce morbidity and mortality.[5]

Learn more

2021 ESC Guidelines

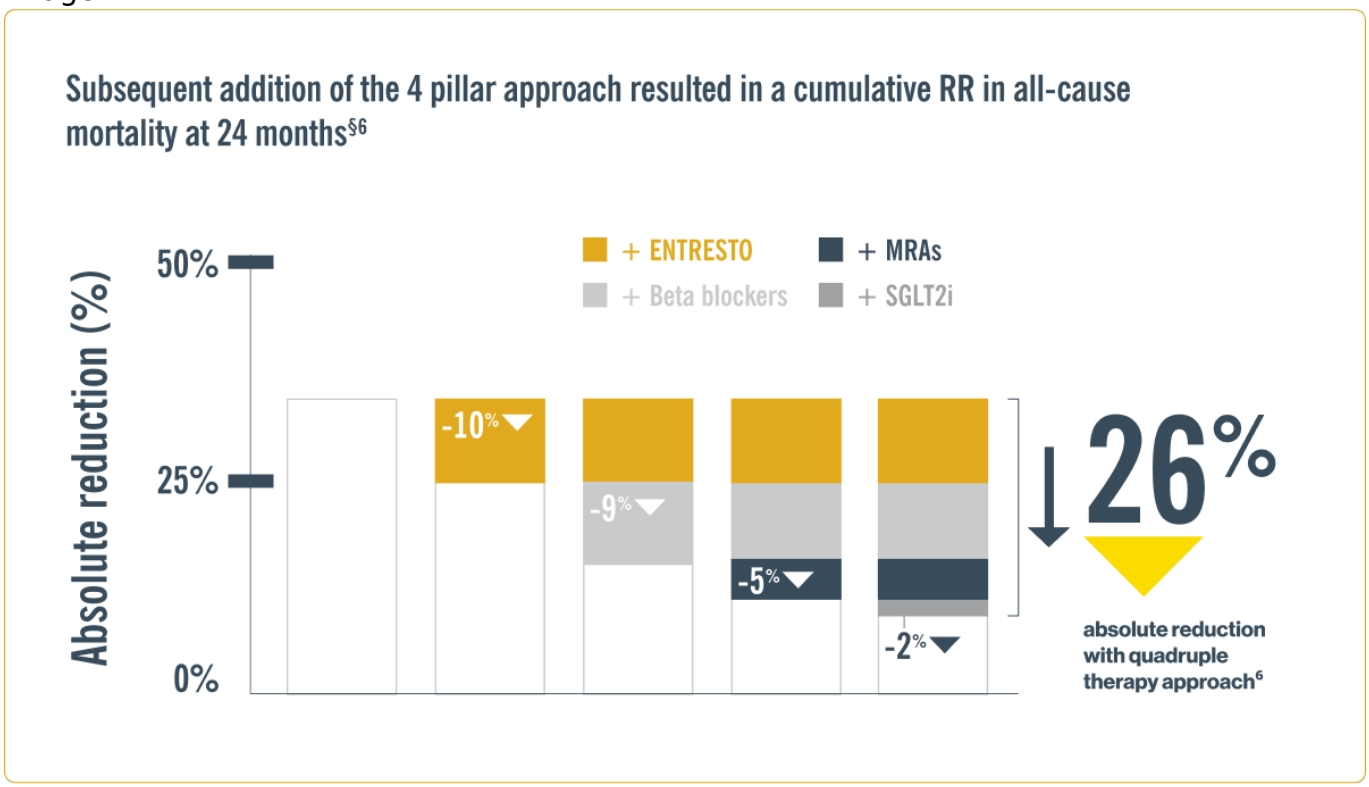
ARNI may be used first line as part of cornerstone HFrEF therapy with a BB, MRA and SGLT2i3 in the 2021 ESC Guidelines for the treatment of chronic HFrEF patients[4]

Learn more

Entresto can help eligible patients with improvements in social and physical activities as well as provide 3x greater improvement in HRQoL (as measured by KCCQ overall summary score) vs enlalapril.*

* LSM estimation (SE) ENTRESTO vs enalapril: 0.80 (SE 0.20) vs -0.39 (SE -0.20). LSM estimates (SE) difference: 1.19 [0.28], P<0.001. Overall score comprising KCCQ measurement differences at pre-determined study KCCQ questionnaire administrations study timepoints of: Months 4, 8,12 ,24 & 36 (from randomisation)

Image



Adapted from Bassi NS, et al. 2020.[6]

Comparisons between drug classes should not be drawn.
This is a decision analytical model study applied on the total US eligible HF population (N=2.1m). The magnitude of mortality reduction for SGLT2i was determined from the DAPA-HF trial.

Treatment should not be initiated if the serum potassium level is >5.4 mmol/l.[1]
Use of sacubitril/valsartan may be associated with an increased risk of hyperkalaemia, although hypokalaemia may also occur. Monitoring of serum potassium is recommended, especially in patients who have risk factors such as renal impairment, diabetes mellitus or hypoaldosteronism or who are on a high potassium diet or on mineralocorticoid antagonists. If patients experience clinically significant hyperkalaemia adjustment of concomitant medicinal products, or temporary down–titration or discontinuation is recommended. If serum potassium level is >5.4 mmol/l discontinuation should be considered.[1]

See Clinical data supporting the recommendation of Entresto in Symptomatic chronic HFrEF patients

CLICK HERE TO FIND OUT

Entresto should not be co-administered with an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB). Due to the potential risk of angioedema when used concomitantly with an ACE inhibitor, it must not be started for at least 36 hours after discontinuing ACE inhibitor therapy[1]

Summary of the safety profile

The most commonly reported adverse events (AEs) during treatment with ENTRESTO were hypotension (17.6%), hyperkalaemia (11.6%) and renal impairment (10.1%). Angioedema was reported in patients treated with sacubitril/valsartan (0.5%).[1]

Common AE:
Anaemia, hypokalaemia, hypoglycaemia, dizziness, headache, syncope, vertigo, orthostatic hypotension, cough, diarrhoea, nausea, gastritis, renal failure (renal failure, acute renal failure), fatigue, asthenia.[1]

Very common AEs:
Hyperkalaemia, hypotension, renal impairment.[1]

Adverse reactions are ranked by System organ class and then by frequency with the most frequent first, using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

Please click here for safety information

*CaReMe UK Partnership is a collaboration between the British Cardiovascular Society, the Renal Association, the Association of British Clinical Diabetologists, the Primary Care

Cardiovascular Society and the Primary Care Diabetes Society.[2]
†Measure serum sodium, potassium and assess renal function before and after starting, and after each dose increment. If eGFR is 30 to 45 ml/min/1.73 m2, consider lower doses or slower titration of ACEI/ARBs/sacubitril/valsartan or MRAs.[2‡]
DISCLAIMER: This is a US guideline and should not be used to guide treatment decisions in the UK.
§Analysis of 2,132,800 patients with HFrEF and NYHA class II-IV heart failure.[6]

ACC, American College of Cardiology; ACEi, angiotensin-converting enzyme inhibitor; AE, adverse event; AHA, American Heart Association; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; BB, beta blocker; CaReMe UK, Cardio-Renal-Metabolic Partnership UK; ESC, European Society of Cardiology; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; HRQoL, health-related quality of life; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; NYHA, New York Heart Association; RAASi, renin-angiotensin-aldosterone system inhibitor; RR, risk reduction; SGLT2i, sodium-glucose co-transporter-2 inhibitor.

References:

1. SMPC GB
2. CaReMeUK-HF-October-2022
3. NHS-Scotland-Heart-Failure-Transition-and-Recovery-Plan-During-COVID-19-May-2020-Final
4. McDonagh et al_Eur Heart J_2021
5. Heidenreich et al_Circulation_2022
6. Bassi et al 2020
7. burnett-et-al-2017-thirty-years-of-evidence-on-the-efficacy-of-drug-treatments-for-chronic-heart-failure-with-reduced
8. Chandra A, et al. JAMA Cardiol 2018
9. lewis-et-al-2017-health-related-quality-of-life-outcomes-in-paradigm-hf

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.

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