# DAR DRUG ASSESSMENT REPORT 04 / 2022

# FORXIGA®/EDISTRIDE® DAPAGLIFLOZIN FOR HEART FAILURE WITH REDUCED EJECTION FRACTION (HFrEF) Another way to reduce the risk of mortality and admissions in HFrEF





IMPORTANT THERAPEUTIC INNOVATION



SOME ADDED VALUE IN SPECIFIC SITUATIONS

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NO THERAPEUTIC INNOVATION

INSUFFICIENT EVIDENCE

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PRODUCT

dtbr

REPORT

More efficient than sacubitril/

valsartan in the

third step of HFrEF treatment.

# WHAT IS IT?

Oral antidiabetic SGLT-2 inhibitor.

# INDICATION

Treatment of symptomatic chronic heart failure with reduced ejection fraction (HFrEF<40%), funded in patients not controlled with first-line therapies (ACE inhibitors or ARBs with beta-blockers) and second-line (mineralcorticoid receptor antagonists [MRAs]). It is also indicated in the treatment of type 2 diabetes mellitus and in chronic kidney disease.

#### **POSOLOGY AND METHOD OF ADMINISTRATION**

One 10 mg tablet daily with or without food. **Special populations:** Not recommended in children under 18 years of age and in patients with a glomerular filtration rate of less than 25 ml/min. In patients with severe liver failure, an initial dose of 5 mg/day is recommended (not currently available in Spain).

#### EFFICACY

Added to standard therapy, it reduced the risk of cardiovascular death or worsening heart failure (urgent visit resulting in intravenous therapy for heart failure) by 4.9% over 18 months (dapagliflozin 16.3% vs. placebo 21.2%), with an NNT of 21 (95% CI: 15 to 38). The benefit was shown in patients with and without type 2 diabetes mellitus. The effect resulted in a worsening measure of functional class. In patients with NYHA grade III-IV, no statistically significant differences were found for the primary outcome. There are no data in NYHA IV.

# RISKS

The most frequent adverse reactions are hypotension, dehydration and hypovolemia. The known risks of urinary tract infections, Fournier's gangrene, diabetic ketoacidosis and lower limb amputation should be taken into account.

# **PLACE IN THERAPEUTICS**

Although there are no direct comparisons with sacubitril/ valsartan, it is a more efficient option than the latter and could be placed as the third treatment step in HFrEF, added to standard therapy.

# PRESENTATIONS

Forxiga<sup>®</sup> 10 mg 28 film-coated tablets (49.19 €) Edistride<sup>®</sup> 10 mg 28 film-coated tablets (49.19 €)

Treatment day/cost (euros)				
SACUB	ITRIL/VALSART	AN (97/103 mg)	6.12	
DAPAG	LIFLOZIN (10 m	g) <b>1.76</b>		
0.00	1.75	I 3.50	I 5.25	7.00



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This information is subject to modifications depending on the evolution of scientific knowledge. Notify the suspicions of adverse reactions in <u>www.notificaram.es</u>