**DAR** DRUG ASSESSMENT REPORT **04 / 2023**

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# ▼JARDIANCE®
# EMPAGLIFLOZIN FOR SYMPTOMATIC, CHRONIC HEART FAILURE

## Yes, but... for much selected patients.


IMPORTANT THERAPEUTIC INNOVATION | MODEST THERAPEUTIC INNOVATION | **SOME ADDED VALUE IN SPECIFIC SITUATIONS** | NO THERAPEUTIC INNOVATION | INSUFFICIENT EVIDENCE | + PRODUCT INFORMATION

### WHAT IS IT?
SGLT2 inhibitor.

### INDICATION
Treatment of symptomatic, chronic heart failure (HF) with reduced (HFrEF, EF≤40%), mildly-reduced (HFmrEF, EF 41-49%) and preserved (HFpEF, EF>50%) ejection fraction. In Spain, it is funded for HFrEF patients with increased NT-proBNP levels and not controlled with recommended first-line therapies (ACE inhibitors or ARBs or sacubitril/valsartan with beta-blocker and mineralocorticoid receptor antagonist; unless intolerance or contraindication), as well as in symptomatic HFpEF with increased NT-proBNP levels. It is also labeled for the treatment of type 2 diabetes mellitus.

### POSOLOGY AND METHOD OF ADMINISTRATION
One 10 mg tablet daily with or without food.

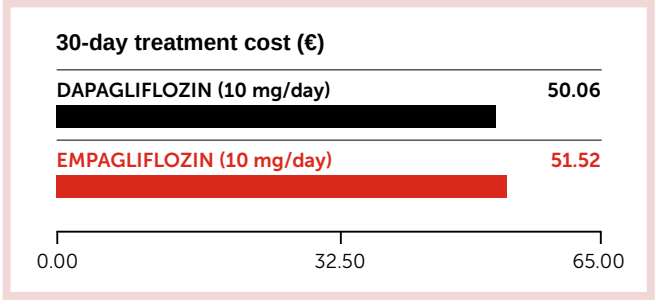
### SPECIAL POPULATIONS
Not recommended in patients with severe hepatic impairment, glomerular filtration rate <20 mL/min/1,73m$^2$, end-stage kidney disease or hemodialysis.

### EFFICACY
In HFrEF, added to standard therapy and compared with placebo, empagliflozin reduced the absolute risk of cardiovascular death or hospitalization due to HF by 5.3% over 18 months, with a NNT of 19 (95%CI: 13 to 37). HR was 0.75 (95%CI 0.65 to 0.86). Of note, there were not statistically significant differences in cardiovascular deaths. In HFpEF, empagliflozin reduced this risk by 3.3% over 26 months, with a NNT of 31 (95%CI 20 to 71). HR was 0.79 (95%CI 0.69 to 0.90). Dapagliflozin demonstrated a lower incidence of cardiovascular deaths in HFrEF. InHFmrEF and HFpEF the benefit of both drugs was due to the reduction of hospital admissions due to HF, without significant differences in cardiovascular mortality. The benefit was shown in patients with and without diabetes. The effect was higher with lower EF levels. Since most patients presented NYHA grade II-III data cannot be applied to patients with NYHA grade IV.

### RISKS
The most relevant adverse effects shown in clinical trials were genitourinary infections and volume depletion. Already known risks of Fournier's gangrene, diabetic ketoacidosis and lower limb amputation should be taken into account.

### PLACE IN THERAPEUTICS
Although there are no direct comparisons, in HFrEF dapagliflozin showed more evidence as it decreased cardiovascular death. Both drugs are labeled for HFrEF and HF with EF >40%, added to standard therapy.

### PRESENTATIONS
Jardiance® 10 mg 30 film-coated tablets (51.52 €)






Servicio Navarro de Salud Osasunbidea

INTERNATIONAL SOCIETY OF DRUG BULLETINS

This information is subject to modifications depending on the evolution of scientific knowledge. Notify the suspicions of adverse reactions in www.notificaram.es **[Evaluated in April 2023]**