DAR DRUG ASSESSMENT REPORT **02 / 2023**

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▼FORXIGA® / EDISTRIDE®
DAPAGLIFLOZIN IN CHRONIC KIDNEY DISEASE
Good news for some patients

Lower decline in kidney function and mortality in patients with chronic kidney disease

REPORT [IN SPANISH]

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

WHAT IS IT?
Sodium-glucose cotransporter 2 (SGLT2) inhibitor, already used in type 2 diabetes mellitus and heart failure.

INDICATION
Treatment of chronic kidney disease (CKD) in adults. Funded in patients with estimated glomerular filtration rate (eGFR) between 25-75 mL/min, with or without diabetes, with an albumin-to-creatinine urine ratio (ACR) between 200-5000 mg/g and evidence of ACR increase for at least 3 months, and are not properly controlled with optimised, stable doses of first-line agents: angiotensin-converting enzyme inhibitors (ACE-I) and angiotensin II type 1 receptor blockers (ARB).

POSOLOGY AND METHOD OF ADMINISTRATION
10 mg once daily orally, with or without food.

SPECIAL POPULATIONS
Dapagliflozin is not recommended in patients with eGFR < 25 mL/min. An initial daily dose of 5 mg is recommended in severe hepatic impairment (not commercialized in Spain at present. Available 10 mg tablets must not be crushed).

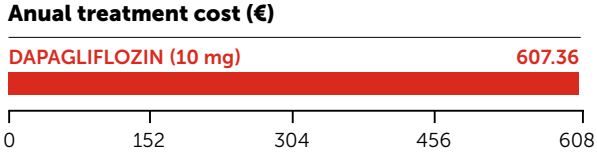
EFFICACY
The combination of dapagliflozin 10 mg daily with an ACE-I or ARB reduced, compared with placebo, a 39% (HR 0.61; CI 95% 0.51 to 0.72) the risk of renal events in the composite endpoint time until apparition of: decrease of the eGFR of at least 50%, advanced CKD (defined as a sustained eGFR value < 15 mL/min, chronic dialysis treatment or kidney transplant) or death related to renal or cardiovascular events, in patients with or without diabetes. The number of patients needed to treat during 2.4 years to prevent a primary event was 19 (CI 95% 15 to 27). Dapagliflozin also showed a lower all-cause mortality (4.7% vs 6.8%, compared with placebo). Forty-eight patients should be treated (CI 95% 29 to 143) to prevent one death. Efficacy was mainly demonstrated in patients with macroalbuminuria in high risk of renal disease progression.

RISKS
The most common adverse events were hypotension, dehydration and hypovolemia. Already-known risks of urinary tract infection, Fournier's gangrene, diabetic ketoacidosis and lower extremities amputation should be taken into account.

PLACE IN THERAPEUTICS
Second-line treatment combined with ACE-I or ARB in patients with CKD, with eGFR 25-75 mL/min, ACR between 200 and 5000 mg/g and evidence of ACR increase for at least 3 months and are not properly controlled with ACE-I or ARB.

PRESENTATIONS
- Forxiga® 10 mg 28 film-coated tablets (46.17€)
- Edistride® 10 mg 28 film-coated tablets (46.17€)

Anual treatment cost (€)



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