DAR DRUG ASSESSMENT REPORT **03 / 2023**

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▼ VERQUVO®
VERICIGUAT IN HEART FAILURE
If there is no alternative...

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?
Stimulator of soluble guanylate cyclase.

INDICATION
Symptomatic, chronic heart failure (HF) in adult patients with reduced ejection fraction (EF) who are stabilised after a recent decompensation event requiring intravenous (IV) therapy. In Spain it is funded for patients with EF <40% who are stabilised and euvolemic after a recent decompensation event requiring IV diuretic added to best medical care.

POSOLOGY AND METHOD OF ADMINISTRATION
The recommended starting dose is 2.5 mg vericiguat once daily. The dose should be doubled approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated by the patient. Take with food.

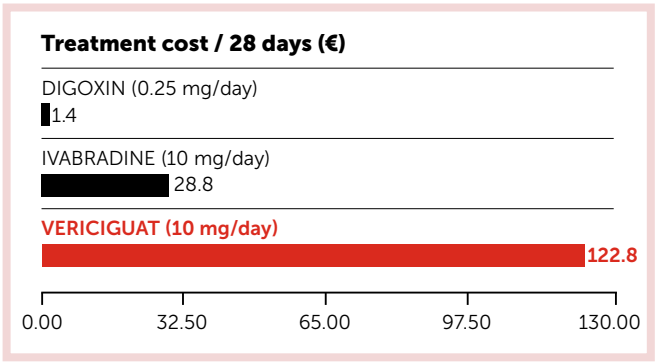
SPECIAL POPULATIONS
Treatment should not be initiated in patients with systolic blood-pressure <100 mmHg. No dose adjustment is required in patients with mild or moderate hepatic impairment or estimated glomerular filtration rate (eGFR) ≥15 mL/min. Treatment is not recommended in patients with eGFR <15 mL/min or on dialysis. Use cautiously in elderly patients as their greater susceptibility to adverse effects and a potential lower effect.

EFFICACY
Vericiguat showed efficacy, compared with placebo, in patients with symptomatic, chronic HF and EF <45% that required a recent hospital admission and intravenous diuretic treatment, in reducing the composite endpoint cardiovascular mortality or hospital admission due to HF (HR 0.90; CI: 95% 0.82 to 0.98). The number of patients needed to treat to prevent one event per year was 24, which implies an annualized absolute risk reduction of 4.2%. The benefit was mostly shown in patients <75 years and in those with a basal NT-proBNP ≤5,314 pg/mL. No statistically significant reduction in cardiovascular mortality or all-cause mortality was demonstrated.

RISKS
Most common adverse events were hypotension, anaemia, dizziness, headache and gastrointestinal disorders.

PLACE IN THERAPEUTICS
Additional therapy for adults with HF and EF <40% who are stabilised and euvolemic after a recent decompensation event requiring IV diuretics and received best medical care (a betablocker, an ACE-I or ARB or sacubitril/valsartan and a sodium-glucose cotransporter 2 inhibitor).

PRESENTATIONS
- Verquvo® 2.5 mg 14 film-coated tablets (61.41€)
- Verquvo® 5 mg 14 film-coated tablets (61.41€)
- Verquvo® 10 mg 14 and 28 film-coated tablets (61.41 and 122.83 €)



Servicio Navarro de Salud Osasunbidea

INTERNATIONAL SOCIETY OF DRUG BULLETINS