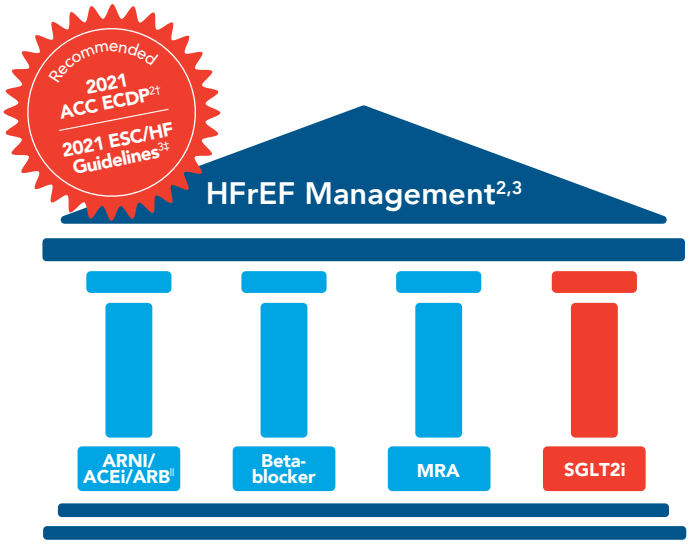
#1 PRESCRIBED SGLT2i FOR HFrEF[1]*

FARXIGA is now recommended as a component of first-line HFrEF therapy[2,3†‡]



Start FARXIGA while titrating the other drugs[2§]

- FARXIGA can be used in patients with eGFR as low as 25 mL/min/1.73 m^2 [4]

*IQVIA database, Longitudinal Access and Adjudication Data, as of [April 2021], for US Cardiology HFrEF total prescriptions for the SGLT2i class, [May 2020 - April 2021].[1]

†SGLT2is are recommended as first-line therapy, as discussed in the 2021 Update to the 2017 ACC Expert Consensus Decision Pathway (ECDP) for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction.[2]

‡SGLT2is are recommended to treat HFrEF in the 2021 ESC/HF Guidelines.[3]

§As recommended by the 2021 ACC ECDP.[2]

‖According to the 2021 ACC ECDP, ARNI is preferred over ACEi/ARB, except in patients for whom ARNI administration is not possible.[2] According to the 2021 ESC HF Guidelines, use of ACEi in patients with HFrEF is a class 1A recommendation, and replacement of ACEi with Sacubitril/Valsartan in patients with HFrEF is a class 1B recommendation. ARBs were not included in the guidelines.[3]

WITH OPTIMAL EFFECTIVE DOSE FROM DAY 1

FARXIGA significantly reduced the primary composite endpoint of CV death or hHF¶ in patients with HFrEF[4,5]

↓26% RRR
P=0.0001
(HR 0.74; 95% CI: 0.65–0.85)
4.9% ARR#

NNT=21

- In a post hoc analysis, FARXIGA demonstrated RRR in the primary composite endpoint in as early as 28 days[6]

DAPA-HF was a Phase 3, randomized, placebo-controlled, HF outcomes trial of 4744 adults with HFrEF (NYHA class II-IV) and LVEF ≤40%, well treated with SoC, with and without T2D. The study assessed whether treatment with FARXIGA reduced the risk of CV events over a median follow-up of 18.2 months.[5]

¶Also include urgent visits for HF.[4]

#Data represented as event rates over a median follow-up of 18.2 months.[5]

INDICATIONS AND LIMITATIONS OF USE for FARXIGA® (dapagliflozin)

FARXIGA is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.

FARXIGA is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

FARXIGA is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m^2. FARXIGA is likely to be ineffective in this setting based upon its mechanism of action.

FARXIGA is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. FARXIGA is not expected to be effective in these populations.

IMPORTANT SAFETY INFORMATION

Contraindications

- Prior serious hypersensitivity reaction to FARXIGA
- Patients on dialysis

Please see additional Important Safety Information on back.
Click here for US Full Prescribing Information for FARXIGA.

farxiga®
(dapagliflozin) 10mg tablets

PROTECT LIFE

FARXIGA helps protect patients with HFrEF from CV death and hospitalization for heart failure, so they can keep living their life[4]

Start FARXIGA today for simple, foundational therapy in your newly diagnosed patients with HFrEF who are on an ACEi/ARB

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- **Ketoacidosis in Diabetes Mellitus** has been reported in patients with type 1 and type 2 diabetes receiving FARXIGA. In placebo-controlled trials of patients with type 1 diabetes, the risk of ketoacidosis was increased in patients who received SGLT2 inhibitors compared to patients who received placebo. Some cases were fatal. Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue FARXIGA, evaluate and treat promptly. Before initiating FARXIGA, consider risk factors for ketoacidosis. Patients on FARXIGA may require monitoring and temporary discontinuation in situations known to predispose to ketoacidosis
- **Volume Depletion:** FARXIGA can cause intravascular volume depletion which may manifest as symptomatic hypotension or acute transient changes in creatinine. Acute kidney injury requiring hospitalization and dialysis has been reported in patients with type 2 diabetes receiving SGLT2 inhibitors, including FARXIGA. Patients with impaired renal function (eGFR less than 60 mL/min/1.73 m^2), elderly patients, or patients on loop diuretics may be at increased risk for volume depletion or hypotension. Before initiating FARXIGA in these patients, assess volume status and renal function. After initiating therapy, monitor for signs and symptoms of hypotension and renal function
- **Urosepsis and Pyelonephritis:** SGLT2 inhibitors increase the risk for urinary tract infections (UTIs) and serious UTIs have been reported with FARXIGA. Evaluate for signs and symptoms of UTIs and treat promptly
- **Hypoglycemia:** FARXIGA can increase the risk of hypoglycemia when coadministered with insulin and insulin secretagogues. Consider lowering the dose of these agents when coadministered with FARXIGA
- **Necrotizing Fasciitis of the Perineum (Fournier's Gangrene):** Rare but serious, life-threatening cases have been reported in patients with diabetes mellitus receiving SGLT2 inhibitors including FARXIGA. Cases have been reported in females and males. Serious outcomes have included hospitalization, surgeries, and death. Assess patients presenting with pain or tenderness, erythema, swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment and discontinue FARXIGA
- **Genital Mycotic Infections:** FARXIGA increases the risk of genital mycotic infections, particularly in patients with prior genital mycotic infections. Monitor and treat appropriately

Adverse Reactions

In a pool of 12 placebo-controlled studies, the most common adverse reactions (≥5%) associated with FARXIGA 5 mg, 10 mg, and placebo respectively were female genital mycotic infections (8.4% vs 6.9% vs 1.5%), nasopharyngitis (6.6% vs 6.3% vs 6.2%), and urinary tract infections (5.7% vs 4.3% vs 3.7%).

Use in Specific Populations

- **Pregnancy:** Advise females of potential risk to a fetus especially during the second and third trimesters
- **Lactation:** FARXIGA is not recommended when breastfeeding

DOSING

To improve glycemic control, the recommended starting dose is 5 mg orally once daily. Dose can be increased to 10 mg orally once daily for additional glycemic control.

For all other indications, the recommended dose is 10 mg orally once daily.

References: 1. Data on file, REF-54141, AstraZeneca Pharmaceuticals LP. **2.** Writing Committee; Maddox TM, Januzzi JL Jr, Allen LA, et al. 2021 update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2021;77(6):772-810. **3.** Metra M. ESC HF guidelines. Presented at ESC-HF 2021 Online Congress; June 29-July 1, 2021. **4.** FARXIGA® (dapagliflozin) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2021. **5.** McMurray JJV, Solomon SD, Inzucchi SE, et al; DAPA-HF Trial Committees and Investigators. Dapagliflozin in patients with heart failure and reduced ejection fraction. *N Engl J Med*. 2019;381(21):1995-2008. **6.** Berg DD, Jhund PS, Docherty KF, et al. Time to clinical benefit of dapagliflozin and significance of prior heart failure hospitalization in patients with heart failure with reduced ejection fraction. *JAMA Cardiol*. 2021;6(5):499-507.

ACC=American College of Cardiology; ACEi=angiotensin-converting enzyme inhibitor; ARB=angiotensin receptor blocker; ARNI=angiotensin receptor-neprilysin inhibitor; ARR=absolute risk reduction; CV=cardiovascular; DAPA-HF=Dapagliflozin And Prevention of Adverse outcomes in Heart Failure; eGFR=estimated glomerular filtration rate; ESC=European Society of Cardiology; FDA=Food and Drug Administration; HF=heart failure; HFrEF=heart failure with reduced ejection fraction; LVEF=left ventricular ejection fraction; MRA=mineralocorticoid receptor antagonist; NNT=number needed to treat; NYHA=New York Heart Association; RRR=relative risk reduction; SGLT2i=sodium-glucose cotransporter 2 inhibitor; SoC=standard of care; T2D=type 2 diabetes; US=United States.

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