TRIM SIZE: 8.5" X 11"

FARXIGA is the **FIRST** and **ONLY** SGLT2i with FDA approvals in patients across the heart failure risk continuum[1-4]

- **to help prevent hHF in patients with T2D and multiple CV risk factors or eCVD**
- **to treat HFrEF patients, with or without T2D, by reducing the risk of CV death or hHF**

farxiga® (dapagliflozin) 10mg tablets

Visit Farxiga-hcp.com

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
- to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular (CV) disease or multiple CV risk factors

FARXIGA is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION

Contraindications

- Prior serious hypersensitivity reaction to FARXIGA
- Patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2) being treated for glycemic control without established CV disease or multiple CV risk factors
- Patients on dialysis

Warnings and Precautions

- **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
- **Ketoacidosis in Diabetes Mellitus** has been reported in patients with type 1 and type 2 diabetes receiving FARXIGA. 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
- **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

CV=cardiovascular; eCVD=established cardiovascular disease; FDA=Food and Drug Administration; hHF=hospitalization due to heart failure; HF=heart failure; HFrEF=heart failure with reduced ejection fraction; NYHA=New York Heart Association; SGLT2i=sodium-glucose cotransporter 2 inhibitor; T2D=type 2 diabetes.

References: 1. FARXIGA® (dapagliflozin) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2020. **2.** Jardiance® (empagliflozin) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2020. **3.** Invokana® (canagliflozin) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; 2020. **4.** Steglatro™ (ertugliflozin) [package insert]. Whitehouse Station, NJ: Merck & Co, Inc; 2020.

Please see accompanying US Full Prescribing Information for FARXIGA.

AstraZeneca