SAVE LIFE IN HFrEF

FORXIGA is now A CLASS 1A FIRST-LINE THERAPY for all HFrEF patients in ESC 2021 HF guideline[7,††]

- ↓26% **Risk of CV death & Worsening of HF†**
  (HR 0.74 [95% CI, 0.65,0.85]; p<0.001)
- ↓30% **Risk of Worsening of HF*,†**
  (HR 0.70 [95% CI, 0.59, 0.83])
- ↓18% **Risk of CV Mortality***
  (HR 0.82 [95% CI, 0.69, 0.98])
- ↓17% **All-cause Mortality‡,***
  (HR 0.83 [95% CI, 0.71, 0.97])

Consistent Efficacy§ Regardless of¶

- With or without T2DM[2]
- Baseline eGFR[3,**]
- HF background therapy[4]
- LVEF status[6]

Simple and well tolerated[1,5]

- Comparable rate of volume depletion, renal dysfunction, and hypoglycemia vs placebo[1]
- 10 mg once daily[5]
- No dose titration[1,‡‡]
- Initiate treatment if GFR ≥25 mL/min

*Exploratory endpoint
†An episode of worsening heart failure was either an unplanned hospitalization or an urgent visit resulting in intravenous therapy for heart failure[1]
‡Due to the hierarchical testing strategy, all-cause mortality was nominally significant
§Primary endpoint (CV death or worsening of HF†)
¶Post hoc analysis
**Baseline eGFR categories: <60 mL/min/1.73m^2 and ≥60 mL/min/1.73m^2
††In 2021 ESC Guidelines for the treatment of HFrEF, dapagliflozin or empagliflozin are recommended for patients with HFrEF to reduce the risk of HF hospitalization and death (class I, level A).
‡‡In patients with severe hepatic impairment, a starting dose of 5 mg is recommended. If well tolerated, the dose may be increased to 10 mg.

CI=confidence interval. CV=cardiovascular. GFR=glomerular filtration rate. HF=heart failure. HFrEF=HF with reduced ejection fraction. HR=hazard ratio. LVEF=Left ventricular ejection fraction. SGLT2i=sodium-glucose co-transporter-2 inhibitor. SoC=standard of care. T2DM=type 2 diabetes.

References: 1. McMurray JJV et al. N Engl J Med 2019;381:1995–2008. 2. Petrie MC et al. JAMA 2020;323:1353–1368. 3. Jhund PS, et al. Circulation. 2021;143:298-309. 4. Docherty K, et al. Eur Heart J 2020;41:2379–92. 5. Forxiga Hong Kong Prescribing Information. 6. Dewan P, et al. European Journal of Heart Failure 2020;22(7):1247-1258. 7. McDonagh TA, et al. European Heart Journal 2021;00:1-128.

Abbreviated Prescribing Information (API)
FORXIGA (dapagliflozin)
Composition: Dapagliflozin propanediol monohydrate film coated tablet, 5 mg or 10 mg. **Therapeutic Indications:** For the treatment of insufficiently controlled type 2 diabetes mellitus in adults as an adjunct to diet and exercise, either as monotherapy when metformin is considered inappropriate due to intolerance, or in addition to other medicinal products for the treatment of type 2 diabetes. For the treatment of symptomatic chronic heart failure with reduced ejection fraction. For the treatment of chronic kidney disease. **Dosage and Administration:** Type 2 diabetes mellitus: Recommended dose is 10 mg to be taken orally once daily at any time of day with or without food. Tablets are to be swallowed whole. Heart Failure: Recommended dose is 10 mg to be taken orally once daily. Chronic Kidney Disease: Recommended dose is 10mg to be taken orally once daily. In patients with severe hepatic impairment, a starting dose of 5 mg is recommended. **Contraindications:** Hypersensitivity to the active substance or to any of its excipients. **Warnings and Precautions:** Renal function, risk of volume depletion and/or hypotension should be taken into account in patients. Dosage of insulin and sulphonylurea (SU) may need to be readjusted to reduce the risk of hypoglycaemia. May add to the diuretic effect of thiazide and loop diuretics and may increase the risk of dehydration and hypotension. Use with caution in patients with increased risk of diabetic ketoacidosis; on anti-hypertensive therapy with a history of hypotension; elderly (≥ 65 years). Treatment should be temporarily interrupted when volume depleted; when treating pyelonephritis or urosepsis; in patients who are hospitalized for major surgical procedures or acute serious medical illnesses, until ketone values are normal. Should not be initiated in patients with type 1 diabetes; hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption. Additional glucose lowering treatment should be considered for glycaemic control improvementif GFR is persistently below 45 ml/min for the treatment of diabetes; no dose adjustment is required based on renal function for the treatment of heart failure and chronic kidney disease. Due to limited experience, it is not recommended to initiate treatment with dapagliflozin in patients with GFR < 25 mL/min. Discontinue if suspected or diagnosed diabetic ketoacidosis; if Fournier's gangrene is suspected; when pregnancy is detected; while breast-feeding. Limited or no data in cardiac failure NYHA class IV; pregnancy; and paediatric population. **Adverse Reactions:** Very common: hypoglycaemia when used with SU or insulin. Common: vulvovaginitis, balanitis and related genital infections, urinary tract infection, dizziness, rash, back pain, dysuria, polyuria, dyslipidaemia, decreased creatinine renal clearance (during initial treatment), and increased haematocrit. Uncommon: Fungal infection, volume depletion, thirst, constipation, dry mouth, nocturia, vulvovaginal and genital pruritus, increased blood creatinine (during initial treatment), increased blood urea, and decreased weight. Rare: diabetic ketoacidosis (when used in type 2 diabetes). Very rare: necrotising fasciitis of the perineum (Fournier's gangrene), angioedema. Not known: acute kidney injury. **Drug interaction:** Coadministration with rifampicin may reduce dapagliflozin systemic exposure; coadministration with mefenamic acid may increase dapagliflozin systemic exposure. Monitoring glycaemic control with 1,5-AG assay is not recommended in patients taking SGLT2 inhibitors. **Storage:** Store below 30 °C. **Local prescribing information is available upon request. API.HK.FOR.1221**

Please visit contactazmedical.astrazeneca.com, for (1) enquiring Medical Information (MI), (2) reporting Individual Case Safety Report (ICSR) and/or (3) reporting Product Quality Complaint (PQC) to AstraZeneca Hong Kong Limited.

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