forxiga®
(dapagliflozin)

BRING PROTECTION TO LIFE IN CKD

THE ONLY SGLT2i
Now Approved for Chronic Kidney Disease Treatment*,¶¶,1

39% ↓ **Composite of CKD progression†, ESKD, and renal or CV death‡ vs placebo (NNT=19 patients)**
(HR 0.61; 95% CI, 0.51, 0.72; p<0.001)[2]

31% ↓ **All-cause mortality vs placebo**
(HR 0.69; 95% CI, 0.53, 0.88; p=0.004)[2]

29% ↓ **Composite of CV death or hHF vs placebo**
(HR 0.71; 95% CI, 0.55, 0.92; p=0.009)[2]

Slowed eGFR deterioration
(Between-group change/year in mean eGFR (chronic slope)):
1.9 mL/min/1.73 m² (FORXIGA/placebo)[2]

Consistent Efficacy§
Regardless of T2D status[3], baseline eGFR‖,[2], CKD stage** and aetiology††,[3,4]

Simple and well tolerated
Consistent safety shown in patients with CKD, with or without T2D[2,3].
Similar hypoglycaemia rates¶ and less frequent AKI-related SAEs vs placebo[3,5]

INITIATE TREATMENT§§
GFR ≥25

ONCE DAILY 10 tablet NO TITRATION*

For broad range†† of CKD patients, TREAT EARLY WITH FORXIGA NOW

* FORXIGA is indicated for the treatment of chronic kidney disease in adult patients with or without T2D.
† ≥50% sustained decline in eGFR.
‡ There were comparable rates of the individual component of CV death vs placebo (3.0% vs 3.7%; HR 0.81; 95% CI, 0.58, 1.12).
§ Primary composite endpoint of ≥50% sustained decline in eGFR, reaching ESKD, and renal or CV death. ESKD is defined as the need for maintenance dialysis for at least 28 days and renal transplantation or sustained eGFR <15 mL/min/1.73m² for at least 28 days.
‖ Baseline eGFR categories: <45 mL/min/1.73m² and ≥45 mL/min/1.73m².
¶ Observed only in T2D patients.
** CKD stage groups: Stage 4 and Stage 2/3.
†† Diabetic nephropathy, glomerulonephritides, ischaemic or hypertensive CKD, or CKD of other or unknown cause.
‡‡ 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.
§§ In DAPA-CKD, patients may continue on FORXIGA 10 mg once daily if eGFR falls below 25 mL/min/1.73m².
¶¶ Due to limited experience, it is not recommended to initiate treatment with dapagliflozin in patients with GFR <25 mL/min.

AKI, acute kidney injury; CI, confidence interval; CKD, chronic kidney disease; CV, cardiovascular; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; HF, heart failure; hHF, hospitalization for heart failure; HR, hazard ratio; SAE, serious adverse event; SGLT2i, sodium-glucose co-transporter-2 inhibitor; T2D, type 2 diabetes; UACR, urine albumin-creatinine ratio.

References: 1. FORXIGA Hong Kong Prescribing Information. 2. Heerspink HJL, et al. N Engl J Med. 2020;383:1436-1446. 3. Wheeler DC, et al. Lancet Diabetes Endocrinol. 2021;9:22-31. 4. Chertow GM, et al. J Am Soc Nephrol. 2021;32:2352-2361. 5. Heerspink HJL, et al. Kidney Int. 2021:S0085-2538(21)00865-6.

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 perinaum (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**

Intended for Healthcare professionals only.
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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T2D HF CKD
Bring Protection to Life

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