FOR TODAY FOR TOMORROW

START TODAY BETTER OUTCOME TOMORROW

DECLARE TIMI-58

Largest CVOT of SGLT2i with the **broadest** population from multiple risk factors to established ASCVD[1]

Reduction in cardiorenal events observed in T2DM patients[1]

↓17% (95% CI, 0.73-0.95; P=0.005) CV death or hospitalisation for HF*

↓24% (95% CI, 0.67-0.87) Cardiorenal composite endpoint†

↓47% (95% CI, 0.43-0.66) Renal-specific composite endpoint†

Reassured safety profile of Forxiga®[1]

* hHF alone was a separate, nominally significant exploratory endpoint in the DECLARE trial – the primary endpoint composite of CV death/hHF was driven by hHF.
† Nominally significant, prespecified exploratory outcome.

ASCVD=atherosclerotic cardiovascular disease. CV=cardiovascular. CVOT=cardiovascular outcome trial. hHF=hospitalisation for heart failure. HF=heart failure. HFrEF=heart failure with reduced ejection fraction. SGLT2i=sodium-glucose cotransporter 2 inhibitors. T2DM=type 2 diabetes mellitus.

Reference: 1. Wiviott SD, et al. N Engl J Med 2019;380:347-57.

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**

XIGDUO XR API
Presentation: dapagliflozin propanediol monohydrate/metformin hydrochloride extended-release tablets. **Indications:** (1) An adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate. (2) In adults with type 2 diabetes mellitus and established cardiovascular disease or risk factors for cardiovascular disease to reduce the risk of hospitalization for heart failure. **Dosage and Administration:** One tablet to be swallowed whole, once daily with evening meal. For initial therapy, dapagliflozin 10 mg and metformin extended-release 500 mg to be taken once daily, with metformin extended-release titratable to 2000 mg once daily. For add on combination therapy, dapagliflozin 10 mg and metformin extended-release at the dose already being taken, or the nearest therapeutically appropriate dose taken once daily. The maximum dose is dapagliflozin 10 mg/metformin extended-release 2000 mg once daily. If no adequate strength of XIGDUO XR is available, individual mono-components should be used instead. **Contraindications:** Hypersensitivity to dapagliflozin, metformin HCl or excipients. Diabetic ketoacidosis, diabetic pre-coma. eGFR persistently <45 mL/min/1.73². Acute conditions that potentially alter renal function such as: dehydration, severe infection, shock, or intravascular administration of iodinated contrast agents. Acute or chronic diseases which may cause tissue hypoxia such as: cardiac or respiratory failure, pulmonary embolism, recent MI, shock, acute significant blood loss, sepsis, gangrene, pancreatitis. During or immediately following surgery where insulin is essential, elective major surgery. Hepatic impairment. Acute alcohol intoxication. Alcoholism. Pregnancy and lactation. **Precautions:** Lactic acidosis. Renal impairment. Hepatic impairment. Intravascular administration of iodinated contrast materials. Acute hypoxic conditions. Surgery. Risk of volume depletion or hypotension. Urinary tract infections. Vitamin B12 deficiency. Excessive alcohol intake. Ketoacidosis. Risk of hypoglycemia. Concomitant insulin, sulphonylurea or ethanol. Pregnancy and lactation. Elderly. **Interactions:** Rifampicin. Mefenamic acid. Cationic drugs (e.g. amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin). Frusemide. Nifedipine. **Undesirable effects:** Dapagliflozin: Hypoglycaemia. Genital infection. Diabetic ketoacidosis. Metformin: Mild gastrointestinal symptoms (such as diarrhoea, nausea, vomiting, abdominal pain and loss of appetite). Taste disturbance. **Full local prescribing information is available upon request. API.HK.XIG.0621**

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.

HK-7728 7/9/2022 4IC_2422

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forxiga® (dapagliflozin)

ONCE-DAILY xigduo XR (dapagliflozin/metformin HCl extended release) tablets