



PROTECT

MEETING SERIES

An update on the evidence for FORXIGA®
(dapagliflozin) in T2D, CKD and HF^{1*}

*FORXIGA® is indicated in adults with T2D and established CVD or risk factors for CVD to reduce the risk of hHF; in adults for the treatment of symptomatic HFrEF, as an adjunct to SoC therapy; to reduce the risk of progressive decline in kidney function in adults with proteinuric CKD (CKD Stage 2,3 or 4 and UACR ≥ 30 mg/g).¹

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SPEAKER

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AGENDA

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PBS Information: FORXIGA: Authority required (STREAMLINED). Type 2 Diabetes. Refer to PBS Schedule for full Authority Required Information. This product is not listed on the PBS for the treatment of Heart Failure or Chronic Kidney Disease.

BEFORE PRESCRIBING PLEASE REVIEW FULL PRODUCT INFORMATION AVAILABLE ON REQUEST FROM ASTRAZENECA ON 1800 805 342 OR www.astrazeneca.com.au/PI

MINIMUM PRODUCT INFORMATION. FORXIGA (dapagliflozin) 10mg tablets. INDICATIONS: Glycaemic control in adults with type 2 diabetes mellitus as: **monotherapy** as an adjunct to diet and exercise where metformin is otherwise indicated but was not tolerated; **initial combination** with metformin, as an adjunct to diet and exercise, to improve glycaemic control when diet and exercise have failed and there are poor prospects for response to metformin monotherapy; in combination with **other anti-hyperglycaemic agents** to improve glycaemic control, when these together with diet and exercise do not provide adequate control. (Refer to full PI for available data on different combinations). **Prevention of hospitalisation for heart failure** in adults with type 2 diabetes mellitus and established cardiovascular disease or risk factors for cardiovascular disease to reduce the risk of hospitalisation for heart failure. **Heart failure in adults for the treatment of symptomatic heart failure with reduced ejection fraction, as an adjunct to standard care of therapy.* **Chronic Kidney Disease to reduce the risk of progressive decline in kidney function in adults with proteinuric chronic kidney disease (CKD Stage 2,3 or 4 and urine ACR ≥ 30 mg/g).* **DOSAGE AND ADMINISTRATION:** Tablets must be taken whole. 10mg once daily at any time of the day regardless of meals. **If eGFR falls below 45 mL/min/1.73 m², additional glucose lowering treatment should be considered in patients with diabetes mellitus. Initiating treatment in patients with eGFR <25 mL/min/1.73 m² is not recommended.* **CONTRAINDICATIONS:** hypersensitivity to any of the ingredients. **PRECAUTIONS:** Not for type 1 diabetes mellitus or diabetic ketoacidosis. **Use in renal impairment – limited experience with initiating treatment in patients with eGFR < 25mL/min/1.73 m²; glucose lowering efficacy is reduced where eGFR is < 45mL/min/1.73 m².* Severe hepatic impairment. Use in patients at risk for volume depletion, and or hypotension; patients for whom dapagliflozin induced blood pressure drop could pose a risk; ketoacidosis **in patients with diabetes mellitus;* surgery; urinary tract infections; necrotising fasciitis of the perineum (Fournier's gangrene); lower limb amputations, counsel patients on routine preventative foot care; use with medications known to cause hypoglycaemia; children; elderly; cardiac failure. Pregnancy (Category D); lactation. Interference with 1,5-anhydroglucitol (1,5-AG) assay; risk of hypoglycaemia while driving or using machinery if used with sulfonylurea or insulin. **INTERACTIONS WITH OTHER MEDICINES:** no clinically meaningful interactions expected (see full PI). **ADVERSE EFFECTS:** Genital infections, urinary tract infections, diabetic ketoacidosis, back pain, polyuria, hypoglycaemia, headache, volume depletion, events related to decreased renal function, ketoacidosis, pyelonephritis, urosepsis, necrotising fasciitis of the perineum (Fournier's gangrene), rash, angioedema, acute kidney injury. **Date of first approval:** 22 October 2012. **Date of revision:** 8 September 2021.

**Please note changes in Product Information.*

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References: 1. FORXIGA® Approved Product Information.

CKD=chronic kidney disease, CV=cardiovascular, CVD=cardiovascular disease, HF=heart failure, HFrEF = heart failure with reduced ejection fraction, hHF=hospitalisation for heart failure, SGLT2i=sodium-glucose co-transporter-2 inhibitor, SoC=standard of care, T2D=type 2 diabetes; UACR=urine albumin-to-creatinine ratio.

FORXIGA® is a registered trademark of the AstraZeneca group of companies. Registered user AstraZeneca Pty. Ltd. ABN 54 009 682 31 1. 66 Talavera Road, Macquarie Park, NSW 2113. www.astrazeneca.com.au. For Medical Information enquiries or to report an adverse event or product quality complaint: Telephone 1800 805 342 or via <https://contactazmedical.astrazeneca.com> or email Medical Information enquiries to medinfo.australia@astrazeneca.com. 001048. Date of preparation: August 2021.

