Pr forxiga (dapagliflozin)

FOUR INDICATIONS[1]

In adults with CHRONIC KIDNEY DISEASE

TO REDUCE THE RISK OF SUSTAINED EGFR DECLINE, ESKD, AND CV AND RENAL DEATH

NEW!

FORXIGA is indicated to reduce the risk of sustained eGFR decline, ESKD, and CV and renal death in adults with CKD.

FORXIGA 10 mg

Once daily
With or without food

In adults with TYPE 2 DIABETES MELLITUS and CARDIOVASCULAR RISK FACTORS or ESTABLISHED CV DISEASE

AS ADD-ON COMBINATION TO REDUCE THE RISK OF HOSPITALIZATION FOR HEART FAILURE (hHF)

FORXIGA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of hHF in adults with T2DM and CV risk factors or established CV disease.

FORXIGA 10 mg

Once daily
With or without food

In adults with TYPE 2 DIABETES MELLITUS

TO IMPROVE GLYCEMIC CONTROL

FORXIGA is indicated in monotherapy for use as an adjunct to diet and exercise to improve glycemic control in adult patients with T2DM for whom metformin is inappropriate due to contraindications or intolerance.

FORXIGA is also indicated in adult patients with T2DM to improve glycemic control in add-on combination with metformin, a sulfonylurea, metformin and a sulfonylurea, sitagliptin (alone or with metformin) or insulin (alone or with metformin), when metformin alone or the existing therapy listed above, along with diet and exercise, does not provide adequate glycemic control.

Recommended starting dose:
FORXIGA 5 mg

If additional glycemic control is needed:
FORXIGA 10 mg

Once daily
With or without food

In adults for the treatment of HEART FAILURE WITH REDUCED EJECTION FRACTION

AS ADD-ON COMBINATION TO REDUCE THE RISK OF CV DEATH, hHF AND URGENT HEART FAILURE VISIT IN PATIENTS WITH HFrEF

FORXIGA is indicated in adults, as an adjunct to standard of care therapy, for the treatment of HFrEF to reduce the risk of CV death, hHF and urgent HF visit.

FORXIGA is the first and only SGLT2i with an indication in HFrEF[2]*

FORXIGA 10 mg

Once daily
With or without food

Convenient, once-daily dosing[1†]

Based on eGFR (mL/min/1.73 m²), the dosage recommendations are:

- **eGFR 25 to <45:** FORXIGA is likely to be ineffective in improving glycemic control in adults with T2DM with an eGFR <45 mL/min/1.73m². Therefore, FORXIGA is not recommended for use to improve glycemic control in T2DM patients with an eGFR persistently <45 mL/min/1.73 m².
- **eGFR <25:** Initiation of treatment with FORXIGA is not recommended in patients with an eGFR <25 mL/min/1.73 m².
- **On dialysis:** FORXIGA is contraindicated in patients on dialysis.

Other dosing considerations:

- Assess renal function prior to initiation of FORXIGA therapy and regularly thereafter.
- Assess volume status and, if necessary, correct volume depletion prior to initiation of FORXIGA therapy.
- **Concomitant use with insulin or an insulin secretagogue** (e.g., sulfonylurea): When FORXIGA is used as add-on therapy with insulin or an insulin secretagogue (e.g., sulfonylurea), a lower dose of insulin or the insulin secretagogue may be considered to reduce the risk of hypoglycemia.

* Comparative clinical significance has not been established.
† Please see the FORXIGA Product Monograph for complete dosing and administration information.
CKD: chronic kidney disease; CV: cardiovascular; eGFR: estimated glomerular filtration rate; ESKD: end-stage kidney disease; ESRD: end-stage renal disease; HF: heart failure; HFrEF: heart failure with reduced ejection fraction; hHF: hospitalization for heart failure; SGLT2i: sodium-glucose co-transporter 2 inhibitor; T2DM: type 2 diabetes mellitus.

Other considerations for special populations

Renal impairment: The glucose-lowering efficacy of FORXIGA is dependent on renal function and declines with decreasing renal function. Monitoring of renal function is required prior to initiation of FORXIGA therapy and regularly thereafter. In patients with eGFR less than 60 mL/min/1.73 m², more frequent monitoring of renal dysfunction is recommended.

Hepatic impairment: No dosage adjustment for FORXIGA is required for patients with mild or moderate hepatic impairment. FORXIGA exposure is increased in patients with severe hepatic impairment.

Please consult the Product Monograph at www.azinfo.ca/forxiga/pm367 for warnings, precautions, adverse reactions, drug interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling 1-800-668-6000.

REFERENCES
1. FORXIGA Product Monograph. AstraZeneca Canada Inc. August 6, 2021.
2. AstraZeneca data on file.

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AstraZeneca