

## Farxiga<sup>®</sup> (dapagliflozin), Xigduo<sup>®</sup> XR (dapagliflozin/metformin) – Expanded indication

- On June 12, 2024, [AstraZeneca announced](#) the FDA approval of [Farxiga \(dapagliflozin\)](#) and [Xigduo XR \(dapagliflozin/metformin\)](#), as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.
  - Farxiga and Xigduo XR were previously approved for this indication in adults only.
- Farxiga is also approved to reduce the risk of:
  - Sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.
  - Cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure.
  - Hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors.
- The approval of Farxiga and Xigduo XR for the expanded indication was based on a placebo-controlled, double-blind, randomized study in 157 patients aged 10 to 17 years with inadequately controlled type 2 diabetes mellitus. Patients were randomized to Farxiga or placebo as add-on to metformin, insulin or a combination of metformin and insulin.
  - At week 26, the change from baseline in HbA1c was -0.6 with Farxiga vs. +0.4 with placebo (difference -1.0, 95% CI: -1.6, -0.5; p < 0.001).
- Xigduo XR carries a boxed warning for lactic acidosis.
- In adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus, the recommended starting dosage of Farxiga is 5 mg orally once daily to improve glycemic control. For additional glycemic control, the dosage can be increased to 10 mg orally once daily.
  - The starting dosage for Xigduo XR should be individualized based upon the patient's current regimen.
  - Refer to the Farxiga and Xigduo XR drug labels for complete dosing and administration recommendations, including for Farxiga's other approved indications.