



Farxiga[®] (dapagliflozin) – New indication

- On May 5, 2020, the [FDA announced](#) the approval of [AstraZeneca's Farxiga \(dapagliflozin\)](#), to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (New York Heart Association [NYHA] class II-IV) with reduced ejection fraction.
- Farxiga is also approved:
 - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM)
 - To reduce the risk of hospitalization for heart failure in adults with T2DM and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
 - Farxiga is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- Farxiga is the first sodium-glucose co-transporter 2 (SGLT2) inhibitor to be approved to treat adults with NYHA class II-IV heart failure with reduced ejection fraction.
- The approval of Farxiga for the new indication was based on DAPA-HF, a randomized, double-blind, placebo-controlled study in 4,744 patients with heart failure with reduced ejection fraction. The primary composite endpoint was CV death, hospitalization for heart failure or urgent heart failure visit.
 - Farxiga reduced the incidence of the primary composite endpoint with an event rate of 11.6% vs. 15.6% with placebo (hazard ratio 0.74; 95% CI: 0.65, 0.85; $p < 0.0001$).
 - All three components of the primary composite endpoint individually contributed to the treatment effect.
 - The results of the primary composite endpoint were consistent across the subgroups examined, including heart failure patients with and without T2DM.
- The recommended dose of Farxiga for the treatment of heart failure is 10 mg orally once daily.
 - Refer to the Farxiga drug label for dosing for T2DM.



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