

Farxiga[®] (dapagliflozin) – New indication

- On October 21, 2019, [AstraZeneca announced](#) the [FDA approval](#) of [Farxiga \(dapagliflozin\)](#), to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus (T2DM) and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
 - Farxiga is not recommended for patients with T1DM or for the treatment of diabetic ketoacidosis.
- Farxiga is also approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
- The approval of Farxiga for the new indication was based on DECLARE-TIMI 58, a randomized, double-blind, placebo-controlled study in 17,160 patients with T2DM and either established CVD or two or more additional CV risk factors. Patients were randomized to Farxiga or placebo and were followed for a median of 4.2 years. Non-inferiority was tested against the pre-specified risk margin of 1.3 for the hazard ratio (HR) of the composite of CV death, myocardial infarction, or ischemic stroke (MACE) and to test for superiority on the dual primary endpoints: the composite of hospitalization for heart failure or CV death, and MACE, if non-inferiority was demonstrated.
 - The incidence rate of MACE was similar in both treatment arms: 2.3 MACE events per 100 patient-years on Farxiga vs. 2.46 MACE events per 100 patient-years on placebo. The estimated HR of MACE associated with Farxiga relative to placebo was 0.93 (95% CI: 0.84, 1.03).
 - Farxiga was superior to placebo in reducing the incidence of the primary composite endpoint of hospitalization for heart failure or CV death (HR 0.83, 95% CI: 0.73, 0.95). The treatment effect was due to a significant reduction in the risk of hospitalization for heart failure in patients randomized to Farxiga, with no change in the risk of CV death.
- In addition to the new indication approval, warnings for increases in low-density lipoprotein cholesterol, bladder cancer, and macrovascular outcomes were removed from the *Warnings and Precautions* section of the Farxiga label.
- The [Xigduo XR[®] \(dapagliflozin/metformin extended-release\)](#) indication and label was also updated with similar changes as Farxiga.
- The recommended dose of Farxiga to reduce the risk of hospitalization for heart failure is 10 mg orally once daily.
 - Refer to the Farxiga drug label for dosing for improvement in glycemic control.