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Farxiga (dapagliflozin) Tablets
Clinical Update

Clinical Update: Farxiga Approved in the US for the Treatment of Heart Failure in Patients with Heart Failure with Reduced Ejection Fraction.
FDA approval date: May 5, 2020

Farxiga (dapagliflozin) is a first-in-class, oral once-daily SGLT2 inhibitor indicated in adults for the treatment of insufficiently controlled T2D as both monotherapy and as part of combination therapy as an adjunct to diet and exercise to improve glycaemic control, with the additional benefits of weight loss and blood-pressure reduction. In the DECLARE CV outcomes trial in adults with T2D, Farxiga reduced the risk of the composite endpoint of hospitalisation for HF or CV death versus placebo, when added to standard of care.

The approval by the Food and Drug Administration (FDA) was based on positive results from the landmark Phase III DAPA-HF trial, which showed Farxiga achieving a statistically significant and clinically meaningful reduction of CV death or hospitalisation for heart failure (HF), compared to placebo. The DAPA-HF (Dapagliflozin And Prevention of Adverse-outcomes in Heart Failure) trial showed that Farxiga, in addition to standard of care, reduced the risk of the composite outcome of CV death or the worsening of HF versus placebo by 26% (absolute risk reduction [ARR] = 5% [event rate/100 patient years: 11.6 vs 15.6, respectively]; $p<0.0001$) in patients with HFrEF. During the trial duration, one CV death or hospitalisation for HF or an urgent visit associated with HF could be avoided for every 21 patients treated with Farxiga. The safety profile of Farxiga in the DAPA-HF trial was consistent with the well-established safety profile of the medicine. The data from the DAPA-HF trial were published in The New England Journal of Medicine.

In October 2019 the US FDA approved Farxiga to reduce the risk of hospitalisation for HF in adult patients with T2D and established CV disease or multiple CV risk factors. The approval was based on the DECLARE-TIMI 58 trial.
Farxiga is also indicated as an adjunct to diet and exercise to improve glycaemic control in adults with T2D.

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