

Jardiance® (empagliflozin) – Expanded indication

- On February 24, 2022, the [FDA announced](#) the approval of [Boehringer Ingelheim and Eli Lilly's Jardiance \(empagliflozin\)](#), to reduce the risk of cardiovascular (CV) death and hospitalization for heart failure (HHF) in adults with heart failure.
 - Jardiance was previously approved to reduce the risk of CV death plus HHF in adults with heart failure and reduced ejection fraction. This approval expands the use of Jardiance to include patients with preserved ejection fraction.
- Jardiance 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 CV death in adults with T2DM and established CV disease.
- The approval of Jardiance for the expanded indication was based on EMPEROR-Preserved, a randomized, double-blind, placebo-controlled study in 5,988 patients with chronic heart failure New York Heart Association (NYHA) Class II-IV with left ventricular ejection fraction (LVEF) > 40%. Patients received Jardiance 10 mg orally once daily or placebo, as an adjunct to standard of care therapy. The primary endpoint was the time to first event of either CV death or HHF. First and recurrent HHF was assessed as a key secondary endpoint.
 - Jardiance was superior in reducing the risk of the primary composite endpoint compared with placebo, mostly through a reduction in HHF.
 - Jardiance reduced the risk of first and recurrent HHF.

	Placebo	Jardiance	Hazard ratio vs. placebo (95% CI)	p-value
	Number of patients (%)			
CV death or HHF	511 (17.1%)	415 (13.8%)	0.79 (0.69, 0.90)	0.0003
CV death	244 (8.2%)	219 (7.3%)	0.91 (0.76, 1.09)	--
HHF	352 (11.8%)	259 (8.6%)	0.71 (0.60, 0.83)	--
	Number of events			
First and recurrent HHF	541	407	0.73 (0.61, 0.88)	0.0009

- The recommended dose of Jardiance for its various uses is 10 mg once daily in the morning, taken with or without food.
 - For additional glycemic control, the dose may be increased to 25 mg in patients tolerating Jardiance.