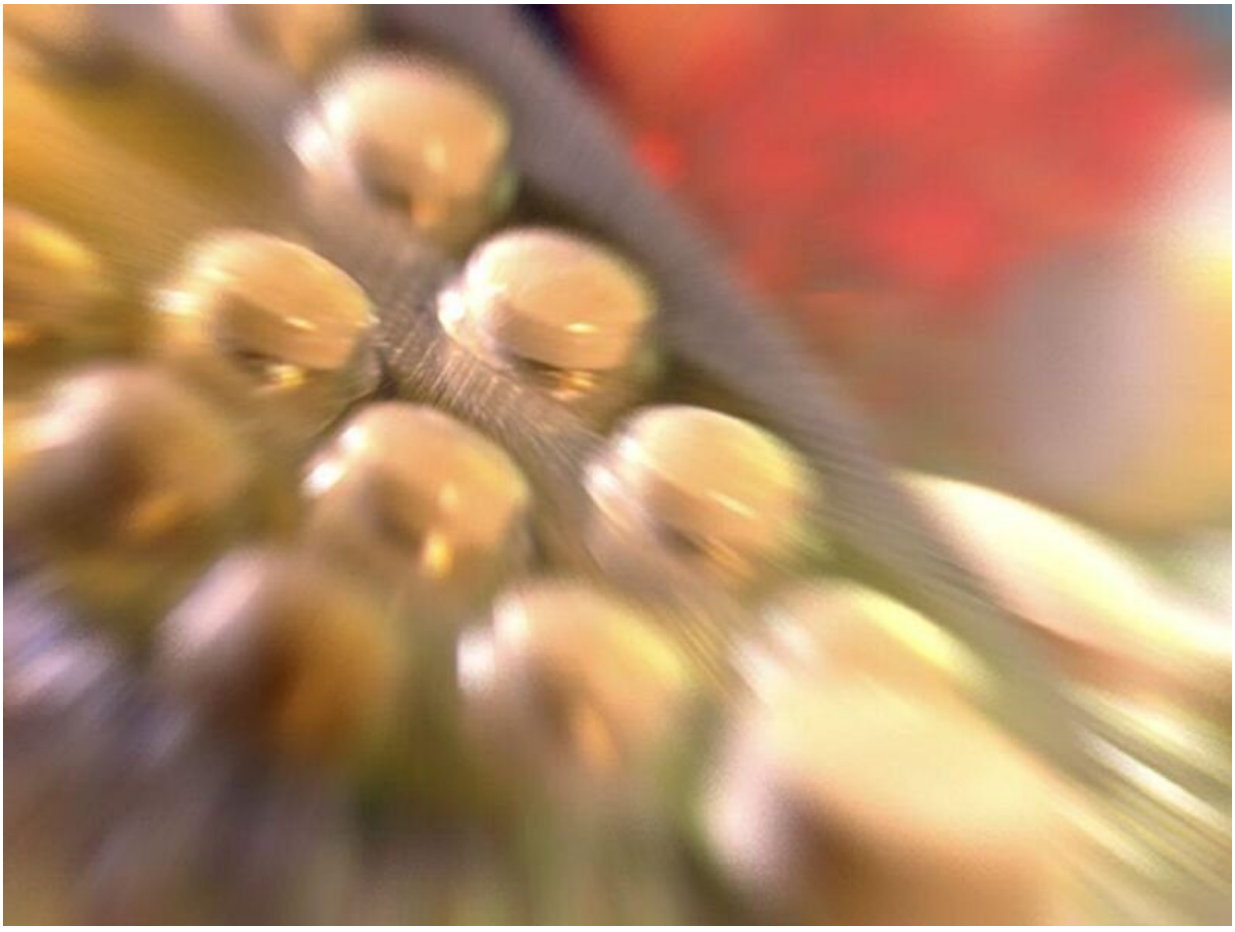
FDA expands approval of jardiance for patients with heart failure

March 1 2022



Approval for Jardiance (empagliflozin) has been expanded to reduce the

risk for cardiovascular death and hospitalization for heart failure in adults, the U.S. Food and Drug Administration announced Thursday.

Jardiance previously received approval in 2014 as a supplement to diet and exercise for improving glucose control in adults with type 2 diabetes. The drug is also approved to reduce the risk for cardiovascular death in adults with both type 2 diabetes and cardiovascular disease and to reduce the risk for death and hospitalization in patients with heart failure and low ejection fraction. Jardiance is now approved for adults with heart failure with an estimated glomerular filtration rate as low as 20 mL/min/1.73 m^2.

The approval was based on data from EMPEROR-Preserved, a phase III randomized, double-blind, international trial. Researchers randomly assigned 5,988 patients with heart failure with left ventricular ejection fraction >40% to 10 mg Jardiance as an adjunct to standard of care (2,997 patients) or placebo (2,991 patients). Among individuals receiving Jardiance for an average of two years, 14% died from cardiovascular causes or were hospitalized for heart failure versus 17% of patients who received placebo.

The most commonly reported adverse events with Jardiance include urinary tract infections and female fungal infections. The FDA notes that Jardiance should not be used in patients with a serious allergic reaction or in patients on dialysis.

"While Jardiance may not be effective in all patients with heart failure, this approval is a significant step forward for patients and our understanding of heart failure," Norman Stockbridge, M.D., Ph.D., of the FDA Center for Drug Evaluation and Research, said in an agency news release.

The approval was granted to Boehringer Ingelheim.

More information: FDA News Release