Jardiance®
(empagliflozin) tablets
10 mg

IN ADULT PATIENTS WITH HFrEF*

NOW APPROVED

to reduce the risk of CV death plus hospitalization for heart failure

STRONG EFFICACY DATA
Proven 25% RRR (HR=0.75 [95% CI: 0.65-0.86]; 5.3% ARR) in CV death and hHF along with standard of care†

CONSISTENT SAFETY PROFILE
Established across multiple trials and indications

SIMPLE DOSING
Single, once-daily oral 10-mg dose with no titration

Learn more at JARDIANCEhcp.com

EMPOWERED BY YOU.
POWERED BY JARDIANCE.

SGLT2is—now recommended as a first-line therapy by the ACC ECDP[1]

INDICATIONS AND LIMITATIONS OF USE

JARDIANCE is indicated:

- to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction.
- to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

JARDIANCE is not recommended in patients with type 1 diabetes mellitus. It may increase their risk of diabetic ketoacidosis.

JARDIANCE is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR <30 mL/min/1.73 m^2. JARDIANCE is likely to be ineffective in this setting based upon its mechanism of action.

Please see reverse side for additional Important Safety Information.

Please see accompanying Prescribing Information, including Medication Guide for JARDIANCE.

*Left ventricular ejection fraction 40% or less.

†EMPEROR-Reduced trial design: A randomized, double-blind, placebo-controlled trial examining the efficacy and safety of JARDIANCE 10 mg (n=1863) plus heart failure standard of care treatments (including ACEi/ARBs, ARNis, MRAs, beta blockers, and diuretics) was evaluated vs placebo added to heart failure standard of care treatments (n=1867). The trial included 3730 patients who had chronic heart failure (New York Heart Association functional class II-IV) with reduced ejection fraction and a left ventricular ejection fraction of 40% or less. The primary composite endpoint was time to first occurrence of cardiovascular death or hospitalization for heart failure.

ACC=American College of Cardiology; ACEi=angiotensin-converting enzyme inhibitor; ARB=angiotensin II receptor blocker; ARNi=angiotensin receptor-neprilysin inhibitor; ARR=absolute risk reduction; CV=cardiovascular; ECDP=Expert Consensus Decision Pathway; HFrEF=heart failure with reduced ejection fraction; hHF=hospitalization for heart failure; MRA=mineralocorticoid receptor antagonist; RRR=relative risk reduction; SGLT2i=sodium glucose co-transporter-2 inhibitor.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: Hypersensitivity to empagliflozin or any of the excipients in JARDIANCE, reactions such as angioedema have occurred; patients on dialysis.

WARNINGS AND PRECAUTIONS

Ketoacidosis: Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been identified in patients with type 1 and type 2 diabetes mellitus receiving SGLT2 inhibitors, including empagliflozin. Fatal cases of ketoacidosis have been reported in patients taking empagliflozin. Patients who present with signs and symptoms of metabolic acidosis should be assessed for ketoacidosis, even if blood glucose levels are less than 250 mg/dL. If suspected, discontinue JARDIANCE, evaluate, and treat promptly. Before initiating JARDIANCE, consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation in situations known to predispose to ketoacidosis. For patients who undergo scheduled surgery, consider temporarily discontinuing JARDIANCE for at least 3 days prior to surgery.

Volume Depletion: Empagliflozin can cause intravascular volume depletion which may manifest as symptomatic hypotension or acute transient changes in creatinine. Acute kidney injury requiring hospitalization and dialysis has been reported in patients with type 2 diabetes receiving SGLT2 inhibitors, including empagliflozin. Before initiating, assess volume status and renal function in patients with impaired renal function (eGFR <60 mL/min/1.73 m^2), elderly patients or patients on loop diuretics. In patients with volume depletion, correct this condition. After initiating, monitor for signs and symptoms of volume depletion and renal function.

Urosepsis and Pyelonephritis: Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been identified in patients receiving SGLT2 inhibitors, including empagliflozin. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate for signs and symptoms of urinary tract infections and treat promptly.

Hypoglycemia: The use of JARDIANCE in combination with insulin or insulin secretagogues can increase the risk of hypoglycemia. A lower dose of insulin or the insulin secretagogue may be required.

Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Serious, life-threatening cases requiring urgent surgical intervention have occurred in both females and males. Serious outcomes have included hospitalization, multiple surgeries, and death. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment and discontinue JARDIANCE.

Genital Mycotic Infections: Empagliflozin increases the risk for genital mycotic infections, especially in patients with prior infections. Monitor and treat as appropriate.

Hypersensitivity Reactions: Serious hypersensitivity reactions have occurred with JARDIANCE (angioedema). If hypersensitivity reactions occur, discontinue JARDIANCE, treat promptly, and monitor until signs and symptoms resolve.

MOST COMMON ADVERSE REACTIONS (≥5%): Urinary tract infections and female genital mycotic infections.

DRUG INTERACTIONS: Coadministration with diuretics may enhance the potential for volume depletion. Monitor for signs and symptoms.

USE IN SPECIAL POPULATIONS

Pregnancy: JARDIANCE is not recommended during the second and third trimesters.

Lactation: JARDIANCE is not recommended while breastfeeding.

Geriatric Use: JARDIANCE is expected to have diminished efficacy in elderly patients with renal impairment. Renal function should be assessed more frequently in elderly patients. The incidence of volume depletion-related adverse reactions and urinary tract infections increased in patients ≥75 years treated with empagliflozin.

CL-JAR-100092 08.18.2021

Reference: 1. Maddox TM, Januzzi JL, Allen LA, et al. 2021 Update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2021. doi: 10.1016/j.jacc.2020.11.022.

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