Jardiance®
(empagliflozin) tablets
10 mg/25 mg

JARDIANCE INITIATION GUIDE
FOR CARDIOLOGISTS

INDICATION AND LIMITATIONS OF USE

JARDIANCE is indicated to reduce the risk of cardiovascular (CV) death in adults with type 2 diabetes mellitus and established CV disease.

JARDIANCE is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: History of serious hypersensitivity to empagliflozin or any of the excipients in JARDIANCE; severe renal impairment, end-stage renal disease, or dialysis.

Please see additional Important Safety Information on the following pages. Please see JARDIANCE Prescribing Information and Medication Guide.

Starting patients on JARDIANCE

10 MG

The recommended dose of JARDIANCE is 10 mg once daily, taken orally in the morning, with or without food.

25 MG

In patients who tolerate JARDIANCE 10 mg, the dose can be increased to 25 mg once daily.

CV=cardiovascular; eGFR=estimated glomerular filtration rate.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS

Hypotension: Empagliflozin causes intravascular volume contraction and symptomatic hypotension may occur. Before initiating JARDIANCE, assess and correct volume status in the elderly, and in patients with renal impairment, low systolic blood pressure, or on diuretics. Monitor for hypotension.

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

Important Dosing Considerations

- In patients with volume depletion, correcting this condition prior to initiation of JARDIANCE is recommended
- *Dosing in patients with renal impairment:*
  - *Assessment of renal function is recommended prior to initiation of JARDIANCE and periodically thereafter*
  - *Should not be initiated if eGFR is <45 mL/min/1.73 m^2*
  - *Should be discontinued if eGFR is persistently <45 mL/min/1.73 m^2*
  - *Reduction in risk of CV death was consistently observed among patients, including those with eGFR <60 mL/min/1.73 m^2*
- A lower dose of insulin or insulin secretagogues (eg, sulfonylureas) may be required to reduce the risk of hypoglycemia when JARDIANCE is used in combination with these agents
- JARDIANCE is contraindicated in patients with a history of serious hypersensitivity to empagliflozin or any of the excipients in JARDIANCE; severe renal impairment, end-stage renal disease, or dialysis

NO DOSE ADJUSTMENT NEEDED IN PATIENTS WITH eGFR ≥45 mL/min/1.73 m^2

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.

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When not to use JARDIANCE

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Before initiating JARDIANCE

Evaluate renal function.

Assess and correct volume status. Coadministration with diuretics may enhance the potential for volume depletion.

Consider risk factors for ketoacidosis or acute kidney injury.

When initiating JARDIANCE

Monitor renal function during therapy.

Monitor and temporarily discontinue in situations known to predispose to ketoacidosis or acute kidney injury.

If ketoacidosis, acute kidney injury, or necrotizing fasciitis of the perineum is suspected, discontinue JARDIANCE and treat promptly.

Encourage patients to stay hydrated, as JARDIANCE could cause increased urination and dehydration due to its mechanism of action.

Monitor for signs and symptoms of hypotension, UTIs, and GMIs.

The most common adverse reactions associated with JARDIANCE (5% or greater incidence) were UTIs and female GMIs. Emphasize the importance of maintaining genital hygiene as a key to prevention for men and women.[1,2]

GMI=genital mycotic infection; UTI=urinary tract infection.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Acute Kidney Injury and Impairment in Renal Function: Empagliflozin causes intravascular volume contraction and can cause renal impairment. Acute kidney injury requiring hospitalization and dialysis have been identified in patients taking SGLT2 inhibitors, including empagliflozin; some reports involved patients younger than 65 years of age. Before initiating JARDIANCE, consider factors that may predispose patients to acute kidney injury. Consider temporary discontinuation in settings of reduced oral intake or fluid losses. Monitor patients for signs and symptoms of acute kidney injury. If it occurs, discontinue JARDIANCE and treat promptly.

Empagliflozin increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Before initiating JARDIANCE, evaluate renal function and monitor thereafter. More frequent monitoring is recommended in patients with eGFR <60 mL/min/1.73 m^2. Discontinue JARDIANCE in patients with a persistent eGFR <45 mL/min/1.73 m^2.

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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 have occurred in both females and males. 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: Discontinue JARDIANCE, treat promptly, and monitor until signs and symptoms resolve.

Increased Low-Density Lipoprotein Cholesterol (LDL-C): Monitor and treat as appropriate.

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.

USE IN SPECIAL POPULATIONS

Pregnancy: JARDIANCE is not recommended, especially 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.

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Please see additional Important Safety Information on the preceding pages.
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References: 1. Urinary Tract Infection. Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP). www.cdc.gov/antibiotic-use/community/for-patients/common-illnesses/uti.html#prevention. Accessed April 22, 2019. **2.** What Are Yeast Infections? Urology Care Foundation. www.urologyhealth.org/urologic-conditions/yeast-infections. Accessed April 22, 2019.

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MORE DOSING INFORMATION IS AVAILABLE AT

JARDIANCEhcp.com

Boehringer Ingelheim

Lilly