

Give your patients a strong JARDIANCE start

Set your patients up for success by discussing the following information with them when they begin treatment with JARDIANCE.

Why JARDIANCE?



Ensure that your patients understand why you prescribed JARDIANCE. Use this opportunity to remind them that type 2 diabetes can contribute to CV disease and for adults with established CV disease and type 2 diabetes, **JARDIANCE can reduce their risk of a fatal CV event** (see *Clinical Studies section 14.2 of the Prescribing Information for more about JARDIANCE Cardiovascular Outcomes*). **Collaboration with primary care physicians and endocrinologists can help with the treatment of type 2 diabetes.**^{1,2}

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](#).

Dosing and Administration



10 MG

Tell your patients that they will be taking **10 mg of JARDIANCE once a day** and that it should be **taken orally in the morning**. Remind them that it can be **taken with or without food**, so they can take JARDIANCE before or after breakfast (see *section 2 of the Prescribing Information for more about JARDIANCE dosing*).

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

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 m²
 - Should be discontinued if eGFR is persistently <45 mL/min/1.73 m²
 - Reduction in risk of CV death was consistently observed among patients, including those with eGFR <60 mL/min/1.73 m²
- 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

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.

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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.

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 m². Discontinue JARDIANCE in patients with a persistent eGFR <45 mL/min/1.73 m².

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 following pages. Please see JARDIANCE [Prescribing Information](#) and [Medication Guide](#).

Safety and Tolerability



Inform your patients about potential side effects of JARDIANCE, such as urinary tract infections and yeast infections (see *Warnings and Precautions* section 5, *Adverse Reactions* section 6, and *Patient Counseling Information* section 17 of the *Prescribing Information* for more information).

Provide them with the following information about the side effects:



Staying hydrated

Due to the mechanism of action, JARDIANCE could cause increased urination and dehydration. Your patients' blood pressure-lowering medicines or diuretics may need to be reduced in order to lower the risk of dehydration.



Maintaining genital hygiene

The most common side effects of JARDIANCE are urinary tract infections and yeast infections. Proper hygiene is a key to prevention. Inform your patients of symptoms to watch out for so they can recognize a potential infection early and get appropriate treatment.^{3,4}



Diet and exercise

Encourage your patients to maintain a balanced diet and exercise regimen while taking JARDIANCE.

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References: **1.** Masharani U. Diabetes Mellitus & Hypoglycemia. In: Papadakis MA, McPhee SJ, Rabow MW, eds. *Current medical diagnosis & treatment* 2019. New York, NY: McGraw-Hill, 2019. **2.** Das SR, Everett BM, Birtcher KK, et al. *J Am Coll Cardiol*. 2018;72(24):3200-3223. **3.** 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. **4.** What Are Yeast Infections? Urology Care Foundation. www.urologyhealth.org/urologic-conditions/yeast-infections. Accessed April 22, 2019.