

JARDIANCE

A CARDIOLOGIST'S REVIEW OF CV DATA

FEATURED GUEST SPEAKER

Dr. William Thomas Structual Heart Specialist PimaHeart DATE Thursday, November 18, 2021

TIME 6:30 PM MT

Location Locale Italian Restaurant, Tucson, AZ

INVITATION FROM

RSVP BY Wednesday, November 17, 2021

Elizabeth Mosley

520-991-3901

This program is open to healthcare practitioners (HCPs) for whom the information presented is relevant to their practice. Spouses or guests cannot be accommodated.

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INDICATIONS AND LIMITATIONS OF USE

JARDIANCE is indicated:

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

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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 m². JARDIANCE is likely to be ineffective in this setting based upon its mechanism of action.

IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information on the next page and accompanying Prescribing Information, including Medication Guide for JARDIANCE.







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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 m²), 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, lifethreatening 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.

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



