Invokana®
canagliflozin tablets

We invite you to join your colleagues and your Janssen Pharmaceuticals, Inc., Sales Representative for

INVOKANA® Can Awaken a Transformation in Type 2 Diabetes Management

OUR GUEST SPEAKER WILL BE

Damon Travis, DO

Physician, Harrisonville Family Medicine
Harrisonville, MO

Dr. Travis is a paid speaker for Janssen Pharmaceuticals, Inc.

Thursday, February 23, 2017 at 6:30 PM

Flame

314 West Walnut, Springfield, MO 65806
Phone: (417) 823-8383

Please RSVP to your Janssen Representative by Thursday, February 16, 2017

Ted Heinzler

Phone: (417) 830-1676 or visit http://www.medforcereg.net/SOMP110428

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INVOKANA® (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA®, such as anaphylaxis or angioedema
- Severe renal impairment (eGFR <30 mL/min/1.73 m^2), end-stage renal disease, or patients on dialysis

Please see Important Safety Information, continued on next page.
Please see accompanying full Prescribing Information and Medication Guide.

Janssen Pharmaceuticals, Inc.

Janssen
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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS and PRECAUTIONS

- **Hypotension:** INVOKANA® (canagliflozin) causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA®, particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m^2), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system, or patients with low systolic blood pressure. Before initiating in patients with ≥1 of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating.
- **Ketoacidosis:** Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in patients with type 1 and 2 diabetes mellitus receiving SGLT2 inhibitors, including INVOKANA®. Fatal cases of ketoacidosis have been reported in patients taking INVOKANA®. Before initiating INVOKANA®, consider factors in patient history that may predispose to ketoacidosis, including pancreatic insulin deficiency, caloric restriction disorders, and alcohol abuse. In patients treated with INVOKANA®, consider monitoring for ketoacidosis and temporarily discontinuing in clinical situations known to predispose to ketoacidosis (eg, prolonged fasting due to acute illness or surgery).
- **Acute Kidney Injury and Impairment in Renal Function:** INVOKANA® causes intravascular volume contraction and can cause renal impairment. Postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, were reported; some reports involved patients younger than 65 years of age. Before initiation, consider factors that may predispose patients to acute kidney injury including hypovolemia, chronic renal insufficiency, congestive heart failure and concomitant medications. Consider temporarily discontinuing INVOKANA® in any setting of reduced oral intake or fluid losses; monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue promptly and institute treatment.

  INVOKANA® increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiation. Renal function should be evaluated prior to initiation and periodically thereafter. Dose adjustment and more frequent renal function monitoring are recommended in patients with an eGFR <60 mL/min/1.73 m^2.
- **Hyperkalemia:** INVOKANA® can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.
- **Urosepsis and Pyelonephritis:** There have been reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors, including INVOKANA®. Treatment with SGLT2 inhibitors increases this risk. Evaluate patients for signs and symptoms and treat promptly.
- **Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** INVOKANA® can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA®.
- **Genital Mycotic Infections:** INVOKANA® increases risk of genital mycotic infections. Patients with history of these infections and uncircumcised males were more likely to develop these infections. Monitor and treat appropriately.
- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema and anaphylaxis, were reported with INVOKANA®; these reactions generally occurred within hours to days after initiation. If reactions occur, discontinue INVOKANA®, treat per standard of care, and monitor until signs and symptoms resolve.
- **Bone Fracture:** Increased risk of bone fracture, occurring as early as 12 weeks after treatment initiation, was observed in patients using INVOKANA®. Consider factors that contribute to fracture risk prior to initiating INVOKANA®.
- **Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C can occur with INVOKANA®. Monitor LDL-C and treat per standard of care after initiating.
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA® or any other antidiabetic drug.

DRUG INTERACTIONS

- **UGT Enzyme Inducers:** Rifampin: Co-administration of INVOKANA® with rifampin decreased INVOKANA® area under the curve (AUC) by 51% and therefore may decrease efficacy. If an inducer of UGT enzymes must be co-administered with INVOKANA®, consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA® 100 mg once daily, have an eGFR ≥60 mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR <60 mL/min/1.73 m^2 who require additional glycemic control.
- **Digoxin:** There was an increase in the AUC and mean peak drug concentration of digoxin (20% and 36%, respectively) when co-administered with INVOKANA® 300 mg. Monitor appropriately.
- **Positive Urine Glucose Test:** Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose test results. Use alternative methods to monitor glycemic control.
- **Interference With 1,5-Anhydroglucitol (1,5-AG) Assay:** Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Based on animal data showing adverse renal effects, INVOKANA® is not recommended during the second and third trimesters of pregnancy. Limited data with INVOKANA® in pregnant women are not sufficient to determine a drug-associated risk for major birth defects or miscarriage. There are risks to mother and fetus associated with poorly controlled diabetes in pregnancy.
- **Nursing Mothers:** There is no information regarding the presence of INVOKANA® in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed infant, advise women that use of INVOKANA® is not recommended while breastfeeding.
- **Pediatric Use:** Safety and effectiveness in patients <18 years of age have not been established.
- **Geriatric Use:** 2034 patients ≥65 years and 345 patients ≥75 years were exposed to INVOKANA® in 9 clinical studies. Patients ≥65 years had a higher incidence of adverse reactions related to reduced intravascular volume (eg, hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years. Smaller reductions in HbA1c relative to placebo were seen in patients ≥65 years (−0.61% with INVOKANA® 100 mg and −0.74% with INVOKANA® 300 mg) compared to younger patients (−0.72% with INVOKANA® 100 mg and −0.87% with INVOKANA® 300 mg).
- **Renal Impairment:** Efficacy and safety were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m^2). These patients had less overall glycemic efficacy and a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m^2); patients treated with 300 mg were more likely to experience increases in potassium. INVOKANA® is not recommended in patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2), with end-stage renal disease, or receiving dialysis.
- **Hepatic Impairment:** INVOKANA® has not been studied in patients with severe hepatic impairment and is not recommended in this population.

OVERDOSAGE

- In the event of an overdose, contact the Poison Control Center and employ the usual supportive measures, eg, remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as needed.

ADVERSE REACTIONS

- The most common adverse reactions associated with INVOKANA® (5% or greater incidence) were female genital mycotic infections, urinary tract infections, and increased urination.

Please see accompanying full Prescribing Information and Medication Guide.

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