

# INVOKANA® (canagliflozin) real-world evidence: helping people with type 2 diabetes achieve treatment goals

INVOKANA® is the **#1** prescribed SGLT2 inhibitor<sup>1</sup>



INVOKANA® is a once-daily pill that works around the clock to **lower blood glucose (A1C)**



INVOKANA® has been prescribed more than **8 million** times – and counting<sup>1</sup>

## real-world analyses

Recently published retrospective analyses have evaluated INVOKANA® in 20,180 people with type 2 diabetes\*

**lower A1C** ↓

INVOKANA® is associated with **significantly improved A1C** in adults with type 2 diabetes<sup>2,3,4</sup>

Analyses show an average A1C reduction of **0.8 to 1.1%** in patients with mean baseline A1C ranging from 8.5 to 8.9%

In patients with highest baseline A1C (>/=9%), average A1C decreased by **1.8%**



One analysis also shows a large proportion\*† of patients who achieved **A1C** and **blood pressure** goals and a reduction in **body weight** with INVOKANA®<sup>2</sup>

INVOKANA® is not indicated for weight loss or as antihypertensive treatment



The proportions of responders among patients inadequately controlled at baseline, who achieved A1C and blood pressure goals after 3 months, remained stable for **12 months**<sup>2</sup>



Average A1C reductions >1% seen in **Hispanic and Latino American patients**<sup>4</sup>



Approximately **1 in 5 patients discontinued 1 or more other A1C-lowering medications** after initiating treatment with INVOKANA®<sup>3,4\*</sup>††

## clinical studies

Findings are generally consistent with those from INVOKANA® clinical studies involving more than 10,000 patients that show:

- ✓ reductions in A1C and improved glycemic control
- ✓ reduction in body weight and blood pressure
- ✓ treatment was generally well tolerated
- ✓ the most common adverse reactions were genital mycotic infections, urinary tract infections, and increased urination

### WHAT IS INVOKANA®?

INVOKANA® is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. INVOKANA® is not for people with type 1 diabetes or with diabetic ketoacidosis (increased ketones in blood or urine). It is not known if INVOKANA® is safe and effective in children under 18 years of age.

### IMPORTANT SAFETY INFORMATION (continued)

INVOKANA® can cause important side effects, including:

- **Dehydration** (the loss of body water and salt), which may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension). You may be at higher risk of dehydration if you have low blood pressure, take medicines to lower your blood pressure (including diuretics [water pills]), are on a low sodium (salt) diet, have kidney problems, or are 65 years of age or older

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## IMPORTANT SAFETY INFORMATION (continued)

- **Vaginal yeast infection.** Women who take INVOKANA® may get vaginal yeast infections. Symptoms include: vaginal odor, white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese), or vaginal itching
- **Yeast infection of the penis (balanitis or balanoposthitis).** Men who take INVOKANA® may get a yeast infection of the skin around the penis. Symptoms include: redness, itching, or swelling of the penis; rash of the penis; foul-smelling discharge from the penis; or pain in the skin around penis

Talk to your doctor about what to do if you get symptoms of a yeast infection of the vagina or penis.

### Do not take INVOKANA® if you:

- Are allergic to canagliflozin or any of the ingredients in INVOKANA®. Symptoms of allergic reaction may include: rash; raised red patches on your skin (hives); or swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing
- Have severe kidney problems or are on dialysis

**Before you take INVOKANA®, tell your doctor if you** have kidney problems; liver problems; pancreas problems; are on a low sodium (salt) diet; are going to have surgery; are eating less due to illness, surgery, or a very low calorie diet; ever had an allergic reaction to INVOKANA®; drink alcohol very often (or drink a lot of alcohol in short-term); or have other medical conditions.

**Tell your doctor if you are or plan to become pregnant, are breastfeeding, or plan to breastfeed.** It is not known if INVOKANA® will harm your unborn baby. It is also not known if INVOKANA® passes into your breast milk.

**Tell your doctor about all the medicines you take,** including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take diuretics (water pills), rifampin (used to treat or prevent tuberculosis), phenytoin or phenobarbital (used to control seizures), ritonavir (Norvir®, Kaletra® – used to treat HIV infection), or digoxin (Lanoxin® – used to treat heart problems).

### Possible Side Effects of INVOKANA®

INVOKANA® may cause serious side effects, including:

- **Ketoacidosis** (increased ketones in your blood or urine) can happen with INVOKANA®, even if your blood sugar is less than 250 mg/dL. **Stop taking INVOKANA® and call your doctor right away if you get any of the following symptoms: nausea, vomiting, stomach-area pain, tiredness, or trouble breathing**
- **Kidney problems, a high amount of potassium in your blood (hyperkalemia), or low blood sugar (hypoglycemia).** If you take INVOKANA® with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take INVOKANA®
- **Serious Urinary Tract Infections:** may lead to hospitalization and have happened in people taking INVOKANA®. Tell your doctor if you have signs or symptoms of a urinary tract infection such as: burning feeling while urinating, need to urinate often or right away, pain in the lower part of your stomach (pelvis), or blood in the urine. Some people may also have high fever, back pain, nausea, or vomiting

Signs and symptoms of low blood sugar may include: headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, shaking, or feeling jittery.

**Serious allergic reaction.** If you have any symptoms of a serious allergic reaction, stop taking INVOKANA® and call your doctor right away or go to the nearest hospital emergency room.

**Broken Bones (fractures):** Bone fractures have been seen in patients taking INVOKANA®. Talk to your doctor about factors that may increase your risk of bone fracture.

The most common side effects of INVOKANA® include: vaginal yeast infections and yeast infections of the penis; urinary tract infection; or changes in urination, including urgent need to urinate more often, in larger amounts, or at night.

Tell your doctor if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Janssen Scientific Affairs, LLC at 1-800-526-7736.

### Please see full Product Information and Medication Guide.

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**Invokana**<sup>®</sup>  
canagliflozin tablets

Janssen 

\*Baseline and follow-up A1C data were available for 826 of the 4017 patients in the Buysman et al analysis; and for 787 of the 3,846 patients in the Chow et al analysis. Baseline data for A1C, BP, and body weight were available for 11,984, 15,883, and 15,794, respectively, of the 16,163 patients in the Lefebvre et al analysis; the number of patients with follow-up values varied over time in that analysis.

\* \*Results expressed relative to baseline.

\* \* \*Among the subgroup of approximately 80% of patients who initially used INVOKANA® with other A1C-lowering medications.

1 Data on file. Janssen Pharmaceuticals, Inc. Based on IMS Health, NPA Weekly, Total Prescriptions, April 2013 - April 8<sup>th</sup> 2016.

2 Lefebvre P, Pilon D, Robitaille MN, Lefebvre MH, Chow W, Pfeifer M, Duh MS. Real-world glycaemic, blood pressure, and weight control in patients with type 2 diabetes mellitus treated with canagliflozin—an electronic health-record-based study. *Curr Med Res Opin.* 2016 May 11:1-9. [Epub ahead of print].

3 Buysman EK, Chow W, Henk HJ, Rupnow MFT. Characteristics and outcomes of patients with type 2 diabetes mellitus treated with canagliflozin: a real-world analysis. *BMC Endocrine Disorders.* 2015; 15:67.

4 Chow W, Buysman E, Rupnow M, Aguilar R, Henk H. Canagliflozin treatment of Hispanic and non-Hispanic patients with type 2 diabetes in a US managed care setting. *Curr Med Res Opin.* 2015; 32, no. 1 (Jan 2016): 13-22.