Medication Guide
INVOKANA® (in-vo-KAHN-uh)
(canagliflozin)
tablets, for oral use

What is the most important information I should know about INVOKANA?
INVOKANA can cause serious side effects, including:

- **Diabetic ketoacidosis (increased ketones in your blood or urine) in people with type 1 and other ketoacidosis.** INVOKANA can cause ketoacidosis that can be life-threatening and may lead to death. Ketoacidosis is a serious condition which needs to be treated in a hospital. People with type 1 diabetes have a high risk of getting ketoacidosis. People with type 2 diabetes or pancreas problems also have an increased risk of getting ketoacidosis. Ketoacidosis can also happen in people who: are sick, cannot eat or drink as usual, skip meals, are on a diet high in fat and low in carbohydrates (ketogenic diet), take less than the usual amount of insulin or miss insulin doses, drink too much alcohol, have a loss of too much fluid from the body (volume depletion), or who have surgery or a procedure that requires not having food for a long time (prolonged fasting). Ketoacidosis can happen even if your blood sugar is less than 250 mg/dL. Your healthcare provider may ask you to periodically check ketones in your urine or blood.
- **Stop taking INVOKANA and call your healthcare provider or get medical help right away if you get any of the following. If possible, check for ketones in your urine or blood, even if your blood sugar is less than 250 mg/dL:**
  - nausea
  - vomiting
  - stomach-area (abdominal) pain
  - tiredness
  - trouble breathing
  - ketones in your urine or blood
- **Amputations. INVOKANA may increase your risk of lower limb amputations.**
  You may be at a higher risk of lower limb amputation if you:
  - have a history of amputation
  - have had blocked or narrowed blood vessels, usually in your leg
  - have damage to the nerves (neuropathy) in your leg
  - have had diabetic foot ulcers or sores

Call your healthcare provider right away if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot. Talk to your healthcare provider about proper foot care.

- **Dehydration. INVOKANA can cause some people to become dehydrated (the loss of too much body water). Dehydration may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension). There have been reports of sudden worsening of kidney function in people with type 2 diabetes who are taking INVOKANA.**
  You may be at higher risk of dehydration if you:
  - take medicines to lower your blood pressure, including diuretics (water pill)
  - are on a low sodium (salt) diet
  - have kidney problems
  - are 65 years of age or older

Talk to your healthcare provider about what you can do to prevent dehydration including how much fluid you should drink on a daily basis. Call your healthcare provider right away if you reduce the amount of food or liquid you drink, for example if you cannot eat or you start to lose liquids from your body, for example from vomiting, diarrhea, or being in the sun too long.

- **Genital and urinary tract infections.** INVOKANA can cause serious infections in your genital area or urinary tract that could require hospitalization. **A rare but serious bacterial infection called necrotizing fasciitis can cause damage to the tissue under the skin in the area between and around the anus and genitals (perineum).** This infection may require hospitalization, multiple surgeries, and could lead to death. **Seek medical attention immediately if you have a fever or you are feeling very weak, tired or uncomfortable (malaise), and you develop any of the following symptoms in the area between and around your anus and genitals:**
  - pain or tenderness
  - swelling
  - redness of skin (erythema)

Also tell your healthcare provider if you have any of these signs or symptoms of urinary tract infections or yeast infections:

- **Urinary tract infection:**
  - burning feeling when you urinate
  - need to urinate often or right away
  - pain in the lower part of your stomach (pelvis)
  - blood in your urine

You may also have a fever, back pain, nausea, or vomiting.

- **Vaginal yeast infection:**
  - vaginal odor
  - white or yellowish vaginal discharge (may be lumpy or look like cottage cheese)

- vaginal itching

- **Yeast infection of the skin around the penis (balanitis or balanoposthitis):** If you are uncircumcised, swelling may make it difficult to pull back the skin around the tip of your penis. Other symptoms include:
  - redness, itching, or swelling of the penis
  - rash on the penis
  - bad smelling discharge from the penis
  - pain in the skin around the penis

Talk to your healthcare provider about what to do if you get symptoms of a yeast infection. They may suggest you use an over-the-counter antifungal medicine. Contact your healthcare provider right away if your symptoms do not improve after using an over-the-counter antifungal medicine.

What is INVOKANA?

- INVOKANA is a prescription medicine used:
  - along with diet and exercise to lower blood sugar (glucose) in adults and children aged 10 years and older with type 2 diabetes.
  - to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes who have known cardiovascular disease.
  - to reduce the risk of end stage kidney disease (ESKD), worsening of kidney function, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes and diabetic kidney disease (nephropathy) with a certain amount of protein in the urine.
- INVOKANA is not recommended to decrease blood sugar (glucose) in people with type 1 diabetes.
- INVOKANA is not recommended to decrease blood sugar (glucose) in people with type 2 diabetes with severe kidney problems.
- It is not known if INVOKANA is safe and effective in children under 10 years of age.

Do not take INVOKANA if you:

- are allergic to canagliflozin or any of the ingredients in INVOKANA. See the end of this Medication Guide for a list of ingredients in INVOKANA. Symptoms of allergic reaction to INVOKANA may include:
  - rash
  - raised red patches on your skin (hives)
  - swelling of the face, lips, mouth, tongue, and throat that may cause difficulty in breathing or swallowing

Before taking INVOKANA, tell your healthcare provider about all of your medical conditions, including if you:

- have type 1 diabetes or have had diabetic ketoacidosis.
- have a decrease in your insulin dose.
- have a serious infection.
- have a history of infection of the vagina or penis.
- have a history of amputation.
- have had blocked or narrowed blood vessels, usually in your leg.
- have damage to the nerves (neuropathy) in your leg.
- have had diabetic foot ulcers or sores.
- have kidney problems.
- have liver problems.
- have a history of urinary tract infections or problems with urination.
- are on a low sodium (salt) diet. Your healthcare provider may change your diet or your dose of INVOKANA.
- are going to have surgery or a procedure that requires not having food for a long time (prolonged fasting). Your healthcare provider may stop your INVOKANA before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking INVOKANA and when to start it again.
- are eating less or there is a change in your diet.
- are dehydrated.
- have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas.
- drink alcohol very often, or drink a lot of alcohol in the short-term (“binge” drinking).
- have ever had an allergic reaction to INVOKANA.
- are pregnant or plan to become pregnant. INVOKANA may harm your unborn baby. If you become pregnant while taking INVOKANA, tell your healthcare provider as soon as possible. Talk with your healthcare provider about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. INVOKANA may pass into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you are taking INVOKANA. Do not breastfeed while taking INVOKANA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

INVOKANA may affect the way other medicines work, and other medicines may affect how INVOKANA works. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take INVOKANA?

- Take INVOKANA by mouth 1 time each day exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much INVOKANA to take and when to take it. Your healthcare provider may change your dose if needed.
- It is best to take INVOKANA before the first meal of the day.
- Your healthcare provider may tell you to take INVOKANA along with other diabetes medicines. Low blood sugar can happen more often when INVOKANA is taken with certain other diabetes medicines. See "**What are the possible side effects of INVOKANA?**"
- Your healthcare provider may tell you to stop taking INVOKANA at least 3 days before any surgery or procedure that requires not having food or water for a long time (prolonged fasting).
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take two doses of INVOKANA at the same time. Talk to your healthcare provider if you have questions about a missed dose.
- If you take too much INVOKANA, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount of diabetes medicine you need may change. Tell your healthcare provider right away if you have any of these conditions and follow your healthcare provider's instructions.
- INVOKANA will cause your urine to test positive for glucose.
- Your healthcare provider may do certain blood tests before you start INVOKANA and during treatment as needed. Your healthcare provider may change your dose of INVOKANA based on the results of your blood tests.

What are the possible side effects of INVOKANA?

INVOKANA may cause serious side effects including:

See "**What is the most important information I should know about INVOKANA?**"

- **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.
  Signs and symptoms of low blood sugar may include:
  - headache
  - confusion
  - hunger
  - shaking or feeling jittery
  - drowsiness
  - dizziness
  - fast heartbeat
  - weakness
  - irritability
  - sweating
- **serious allergic reaction.** If you have any symptoms of a serious allergic reaction, stop taking INVOKANA and call your healthcare provider right away or go to the nearest hospital emergency room. See **"Do not take INVOKANA if you:"**. Your healthcare provider may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.
- **broken bones (fractures).** Bone fractures have been seen in patients taking INVOKANA. Talk to your healthcare provider 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 (See "**What is the most important information I should know about INVOKANA?**")
- changes in urination, including urgent need to urinate more often, in larger amounts, or at night

These are not all the possible side effects of INVOKANA.

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 Pharmaceuticals, Inc. at 1-800-526-7736.

How should I store INVOKANA?

- Store INVOKANA at room temperature between 68 °F to 77 °F (20 °C to 25 °C).
- **Keep INVOKANA and all medicines out of the reach of children.**

General information about the safe and effective use of INVOKANA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use INVOKANA for a condition for which it was not prescribed. Do not give INVOKANA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about INVOKANA that is written for health professionals.

What are the ingredients in INVOKANA?

Active ingredient: canagliflozin

Inactive ingredients: croscarmellose sodium (E468), hydroxypropyl cellulose (E463), lactose anhydrous, magnesium stearate (E572), and microcrystalline cellulose (E460[i]). In addition, the tablet coating contains iron oxide yellow (E172) (100 mg tablet only), macrogol/PEG3350 (E1521), polyvinyl alcohol (E1203) (partially hydrolyzed), talc (E553b), and

titanium dioxide (E171).

Active ingredient made in Belgium. Manufactured for: Janssen Pharmaceuticals, Inc., Titusville, NJ 08560, USA.
Licensed from Tanabe Pharma Corporation. For patent information: www.janssenpatents.com
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For more information about INVOKANA, call 1-800-526-7736 or visit our website at www.invokana.com.

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