PART III: CONSUMER INFORMATION

**INVOKANA®**
canagliflozin tablets

This leaflet is Part III of a three-part "Product Monograph" published when INVOKANA® was approved for sale in Canada and is designed specifically for Consumers. Read this carefully before you start taking INVOKANA® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about INVOKANA®.

ABOUT THIS MEDICATION

**What the medication is used for:**
INVOKANA® is used along with diet and exercise to improve blood sugar levels in adults with type 2 diabetes. INVOKANA® can be used:

- alone, in patients who cannot take metformin, or
- along with metformin, or
- along with a sulfonylurea, or
- along with metformin and a sulfonylurea, or
- along with metformin and a pioglitazone, or
- along with metformin and sitagliptin or
- along with insulin (with or without metformin).

INVOKANA® can also be used, along with diet and exercise, if you have type 2 diabetes and:

- an increased cardiovascular risk. This means that you have or may have health problems due to your heart and blood vessels. INVOKANA® can be used to lower your risk of dying from events related to your heart or blood vessels. It may also lower your risk of having heart attacks and strokes.

- diabetic kidney disease. This is when your kidneys are damaged as a result of your diabetes. INVOKANA® can be used to lower the risk that your kidney function will worsen to the point where your kidneys fail and you need dialysis. As well, INVOKANA® may also lower your risk of dying from events related to your heart and blood vessels.

**What it does:**
INVOKANA® works by increasing the amount of sugar removed from the body in the urine, which reduces the amount of sugar in the blood.

**What is type 2 diabetes?**
Type 2 diabetes is a condition in which your body does not make enough insulin, and/or does not use the insulin that your body produces as well as it should. When this happens, sugar (glucose) builds up in the blood. This can lead to serious problems.

**When it should not be used:**
Do not take INVOKANA® if you:
- are allergic to canagliflozin or any of the other ingredients in this medication.
- have type 1 diabetes. This is a disease where your body does not produce any insulin.
- have or have had diabetic ketoacidosis (DKA). This is a complication of diabetes.
- you are on dialysis.

**What the medicinal ingredient is:**
Canagliflozin

**What the nonmedicinal ingredients are:**
Croscarmellose sodium, hydroxypropyl cellulose, iron oxide yellow (100 mg tablet only), lactose anhydrous, Macrogol (polyethylene glycol), magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, talc, titanium dioxide.

**What dosage forms it comes in:**
100 mg tablets: Yellow, capsule-shaped tablets with “CFZ” on one side and “100” on the other side.

300 mg tablets: White, capsule-shaped tablets with "CFZ" on one side and “300” on the other side.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

**Diabetic Ketoacidosis (DKA)**
- DKA is a serious and life-threatening condition that requires urgent hospitalization. DKA has been reported in patients with type 2 diabetes mellitus (T2DM), with normal or high blood sugar levels, who are treated with INVOKANA® or with other sodium-glucose co-transporter 2 (SGLT2) inhibitors. Some cases of DKA have led to death.

- Seek medical attention right away and stop taking INVOKANA® immediately if you have any of the following symptoms (even if your blood sugar levels are normal): difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty, feeling unusually tired or sleepy, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat.

- If you have diabetic kidney disease, you may have a higher chance of DKA while you are taking INVOKANA®.

- INVOKANA® should not be used in patients with type 1 diabetes.

- INVOKANA® should not be used to treat DKA or if you have a history of DKA.
Lower Limb Amputation

- INVOKANA® may increase your risk of lower limb amputations. Amputations mainly involve removal of the toe or part of the foot but could also involve the leg, below and above the knee. Some people had more than one amputation, some on both sides of the body.

- Seek medical attention if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot. Your doctor may decide to stop your INVOKANA® if you have any of these signs or symptoms. Talk to your doctor about proper foot care and keeping hydrated.

BEFORE you use INVOKANA® talk to your doctor or pharmacist if you:

- have an increased chance of developing DKA, including if you:
  - are dehydrated or suffer from excessive vomiting, diarrhea, or sweating;
  - are on a very low carbohydrate diet;
  - have been fasting for a while;
  - are eating less, or there is a change in your diet;
  - drink a lot of alcohol;
  - have/have had problems with your pancreas, including pancreatitis or surgery on your pancreas;
  - are hospitalized for major surgery, or are about to have major surgery;
  - are hospitalized for serious infection or serious medical illnesses;
  - have an acute illness;
  - have sudden reductions in insulin dose;
  - have diabetic kidney disease;
  - have a history of diabetic ketoacidosis (DKA).

- have an increased chance of needing an amputation, including if you:
  - have a history of amputation
  - have heart disease or are at risk for heart disease
  - 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 a lower limb infection
  - are dehydrated

- have or have had low pressure (hypotension) or are taking medicines to:
  - remove excess water from your body. These are called diuretics or water pills. An example is furosemide.
  - lower your blood pressure. Examples are angiotensin-convert ing enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB).

Taking INVOKANA® with any of these medicines may increase your risk for dehydration and/or low blood pressure.

- are older than 65 years of age.
- are taking medicines to lower your blood sugar such as glyburide, gliclazide or glimepiride (sulfonylureas) or insulin. Taking INVOKANA® with any of these medicines can increase the risk of having low blood sugar (hypoglycemia). Take precautions to avoid the potential for low blood sugar while driving or using heavy machinery.
- are taking medicines used to treat pain and reduce inflammation and fever knowns as NSAIDs (nonsteroidal anti-inflammatory drugs). Taking INVOKANA® with these medicines can increase the risk for kidney problems.

- have liver problems.
- have heart problems.
- have intolerance to some milk sugars. INVOKANA® tablets contain lactose.
- are pregnant or are planning to have a baby. INVOKANA® should not be used during pregnancy.
- are breast-feeding. INVOKANA® should not be used during breast-feeding.
- often get urinary tract infections

INVOKANA® is not recommended for use in patients under 18 years of age.

INVOKANA® will cause your urine to test positive for sugar (glucose).

Taking INVOKANA® increases your risk of breaking a bone. Talk to your doctor about factors that may increase your risk of bone fracture.

While taking INVOKANA® your doctor may order a blood test to check your kidney function, blood fat levels (Low-Density Lipoprotein cholesterol or LDL-C) amount of red blood cells in your blood (haematocrit), and potassium blood levels.

INVOKANA® may cause necrotizing fasciitis of the perineum (area between and around the anus and genitals). This is a rare but serious and potentially life-threatening infection that can affect both men and women. It is also known as Fournier’s gangrene and requires urgent treatment. If you experience tenderness, redness or swelling of the genitals or the area from the genitals back to the rectum, especially if you also have a fever or you are feeling very weak, tired, or uncomfortable, seek medical attention immediately. These may be signs of Fournier’s gangrene.
If you are going to have a surgery and after your surgery, or if you are hospitalized for a serious infection, a serious medical illness, or a major surgery, your doctor may stop your INVOKANA®. Talk to your doctor about when to stop taking INVOKANA® and when to start it again. Your doctor will check for ketones in your blood or urine.

**Driving and using machines:** INVOKANA® may cause dizziness or light-headedness. DO NOT drive or use machines until you know how the medicine affects you.

**INTERACTIONS WITH THIS MEDICATION**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because this medicine may affect the way INVOKANA® works.

**Drugs that may interact with INVOKANA® include:**
- digoxin, a medicine used to treat heart problems.
- furosemide or other diuretics (water pills).
- an ACE inhibitor or an ARB (to lower your blood pressure).
- insulin or a sulfonylurea (such as glimepiride, gliclazide, or glyburide).
- carbamazepine, phenytoin or phenobarbital.
- efavirenz or ritonavir.
- rifampin.
- St. John’s wort.

**PROPER USE OF THIS MEDICATION**

**Usual starting dose:**
100 mg by mouth each day with or without food. Your doctor may increase your dose to 300 mg per day. However, if you have a kidney problem, your dose may stay at 100 mg per day.

It is best to take INVOKANA® before the first meal of the day and at the same time each day. Swallow the tablet whole with water.

Before starting INVOKANA®, your doctor will do tests to see how well your kidneys are working.

**Overdose:**
In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed dose:**
- If you forget to take a dose of INVOKANA®, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose and follow your usual schedule.
- Do not take two doses on the same day to make up for a forgotten dose.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

These are not all the possible side effects you may feel when taking INVOKANA®. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

- Changes in urination such as urinating more often or in larger amounts, an urgent need to urinate, and a need to urinate at night.
- Nausea.
- Feeling thirsty.

Diabetic Ketoacidosis (DKA) is a serious, life-threatening medical condition that may lead to death. DKA can occur with normal or high blood glucose levels. DKA has happened in people with diabetes who were sick or who had surgery, during treatment with INVOKANA®. DKA requires immediate treatment in a hospital. DKA can happen with INVOKANA® even if your blood sugar is at normal or near normal levels. **Stop taking INVOKANA® immediately and get medical help right away if you have any of the symptoms in the table below under DKA, even if your blood glucose levels are normal.**

Tell your doctor if you are hospitalized for major surgery, serious infection or serious medical illness.

Increased need for lower leg or toe amputation (removal) especially if you are at high risk of heart disease. Talk to your doctor if you experience symptoms including leg pain, poor circulation, bluish, cold skin, and poor hair and toe nail growth. Good foot care and drinking an adequate amount of fluid are recommended.

<table>
<thead>
<tr>
<th>SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency / Symptom / Effect</strong></td>
</tr>
<tr>
<td><strong>Talk with your doctor or pharmacist</strong></td>
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<td><strong>Stop taking drug and call your doctor or pharmacist</strong></td>
</tr>
<tr>
<td><strong>Only if severe</strong></td>
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<tr>
<td>In all cases</td>
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<tr>
<td><em>Very Common:</em></td>
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<tr>
<td>Vaginal yeast infection: vaginal odor, white or yellowish vaginal discharge and/or itching</td>
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### Hypoglycemia (low blood sugar), especially if you are also taking a sulfonylurea or insulin:
- shaking,
- sweating, pale skin,
- rapid heartbeat,
- change in vision, hunger, headache and change in mood,
- feeling anxious or confused

#### Common

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### Balanitis (yeast infection of the penis):
- red, swollen,
- itchy head of penis,
- thick, lumpy discharge under foreskin,
- unpleasant odour, difficulty retracting foreskin,
- pain passing urine or during sex

#### Common

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### Urinary tract infection:
- burning sensation when passing urine,
- pain in the pelvis, or mid-back pain,
- increased need to urinate

#### Common

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### Bone fracture (broken bones)

#### Uncommon

### Skin Ulcer (a break or sore on the skin with tissue breakdown) predominantly of the lower leg:
- It may start off red then get swollen and tender.
- Next, blisters can form with loss of skin layers.
- It can lead to an open round crater with a bad smell.

#### Uncommon

### Peripheral Ischemia (blocked or narrow blood vessels):
- Leg pain with walking that gets better with rest.
- Poor circulation, bluish, cold skin, and poor nail and hair growth.

#### Uncommon

### Dehydration (not having enough water in your body):
- feeling very thirsty, weak or tired,
- passing little or no urine and/or fast heartbeat;
- it can be from nausea, vomiting and/or diarrhea or not drinking enough liquids

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<td>Hypotension (low blood pressure): dizziness, fainting or lightheadedness; may occur when you go from lying to sitting to standing up.</td>
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<td>✓</td>
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<tr>
<td>Rash or hives</td>
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<tr>
<td>Kidney problems: nausea, vomiting, diarrhea; muscle cramps; swelling of the legs, ankles, feet, face and/or hands; shortness of breath due to extra fluid on the lungs; more frequent urination or in greater amounts than usual, with pale urine; or, less frequent urination, or in smaller amounts than usual, with dark coloured urine.</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Severe hypoglycemia (low blood sugar), especially when used with insulin or a sulfonylurea: disorientation, loss of consciousness, seizure</td>
<td></td>
<td>✓</td>
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<tr>
<td>Rare</td>
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<td>Diabetic Ketoacidosis (when your body produces high levels of blood acids called ketones): difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty and feeling unusual tiredness, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat</td>
<td></td>
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<td>Anaphylactic reaction (Severe allergic reaction): swelling of the face, lips, mouth, tongue or throat that may lead to difficulty breathing or swallowing</td>
<td></td>
<td>✓</td>
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<td>Acute kidney infection: painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul-smelling urine, blood in your urine</td>
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### SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

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<td>Urosepsis (severe infection that spreads from the urinary tract and throughout the body): fever or low body temperature, rapid breathing, chills, rapid heartbeat, pain with urination, difficulty urinating, frequent urination</td>
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<td>In all cases</td>
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<td>Pancreatitis (inflammation of the pancreas): severe stomach pain that lasts and gets worse when you lie down, nausea, vomiting</td>
<td>Rare</td>
<td>✓</td>
</tr>
<tr>
<td>Fournier’s gangrene (a serious infection affecting soft tissue around the groin): pain or tenderness, redness of the skin, or swelling in the genital or perineal area, with or without fever or feeling very weak, tired, or uncomfortable</td>
<td>Rare</td>
<td>✓</td>
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This is not a complete list of side effects. For any unexpected effects while taking INVOKANA®, contact your doctor or pharmacist.

### REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:
- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

**NOTE:** Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

### HOW TO STORE IT

- This medicine does not require any special storage conditions.
- Store at room temperature (15-30°C).
- Keep out of the reach and sight of children.
- Do not use INVOKANA® after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### MORE INFORMATION

**NOTE:** This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing

For questions, concerns, or the Product Monograph go to www.janssen.com/canada or call: 1-800-567-3331 and 1-800-387-8781

This leaflet was prepared by JANSSEN Inc.
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