

PART III: CONSUMER INFORMATION

**PrINVOKANA®
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).

If you have type 2 diabetes and an increased cardiovascular risk (health problems due to your heart and blood vessels), INVOKANA® can be used along with diet and exercise to lower your risk of dying from events related to your heart or blood vessels, and to lower your risk from having non-fatal heart attacks and non-fatal strokes.

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 (hypersensitive) to canagliflozin or any of the nonmedicinal ingredients listed below.
- have type 1 diabetes (a disease in which your body does not produce any insulin).
- have diabetic ketoacidosis (DKA, a complication of diabetes) or a history of DKA.
- have severe kidney problems or 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® and 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, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat.
- 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, however, amputations involving the leg, below and above the knee have also occurred. 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 type 1 diabetes (your body does not produce any insulin). INVOKANA® should not be used in patients with type 1 diabetes.
- 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; drink a lot of alcohol;
 - have/have had problems with your pancreas, including pancreatitis or surgery on your pancreas;
 - are hospitalized for major surgery, serious infection or serious medical illnesses;
 - 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
- are taking a diuretic medicine also known as water pills (used to remove excess water from the body), such as furosemide; or taking medicines to lower your blood pressure such as angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB); or have or have had low blood pressure (hypotension). Taking INVOKANA® with any of these medicines may increase the risk of becoming dehydrated and/or low blood pressure (hypotension).
- are older than 65 years of age.
- have kidney problems.
- 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 known 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® is not recommended for use in pregnant women.
- 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.

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. However, if you have a kidney problem your doctor will limit your dose to 100 mg.

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.

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 a double dose (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.

Very common side effects (may affect more than 1 in 10 people):

- Low blood sugar (hypoglycemia) when used with sulfonylurea (such as glimepiride, gliclazide, and glyburide) or insulin. The symptoms of low blood sugar include blurred vision, tingling lips, trembling, sweating, pale looking, a change in mood or feeling anxious or confused. You should ask your doctor or pharmacist what to do if you have any of the symptoms above.
- Vaginal yeast infection. The symptoms include vaginal odor, white or yellowish vaginal discharge, and/or itching.

Common side effects (may affect up to 1 in 10 people):

- Rash or redness of the penis or foreskin (yeast infection or balanitis).
- Urinary tract infection (burning sensation when urinating, cloudy urine, strong odor).
- Changes in urination such as urinating more often or in larger amounts, an urgent need to urinate, and a need to urinate at night.
- Constipation.
- Nausea.
- Feeling thirsty.

Uncommon side effects (may affect up to 1 in 100 people):

- Dehydration (not having enough water in your body). The symptoms include passing out

(fainting) or feeling dizzy or light-headed due to a drop in blood pressure when you stand up, have low blood pressure, very dry or sticky mouth, feeling very thirsty, weak or tired, passing little or no urine and/or fast heartbeat. Dehydration happens more often in older people (over 65 years of age) or people with kidney problems, and people taking water pills. Talk to your doctor about what you can do to prevent dehydration.

- Rash.
- Hives (raised red patches on the skin).

Diabetic Ketoacidosis (DKA) is a serious medical condition with normal or high blood glucose levels. 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.

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.

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

SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Frequency / Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Common	Vaginal yeast infection: vaginal odor, white or yellowish vaginal discharge and/or itching		✓	
	Hypoglycemia (low blood sugar), especially if you are also taking a sulfonylurea: shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood		✓	

SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Frequency / Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	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		✓	
	Urinary tract infection: burning sensation when passing urine, pain in the pelvis, or mid-back pain, or increased need to urinate		✓	
	Constipation	✓		
	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. Ulcers take a long time or may not heal.		✓	

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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. It can lead to Skin Ulcers and Lower Leg or Toe Amputation.		✓	
	Dehydration: 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		✓	
	Low blood pressure: dizziness, fainting or lightheadedness; may occur when you go from lying to sitting to standing up.		✓	
	Rash or hives			✓

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Frequency / Symptom / Effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<p>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.</p>		✓	
<p>Severe hypoglycemia (low blood sugar), especially when used with insulin or a sulfonylurea: disorientation, loss of consciousness, seizure</p>			✓
<p>Diabetic Ketoacidosis (DKA): 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</p>			✓

Rare

SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Frequency / Symptom / Effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<p>Severe allergic reaction: swelling of the face, lips, mouth, tongue or throat that may lead to difficulty breathing or swallowing</p>			✓
<p>Acute kidney infection: painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul smelling urine, blood in your urine</p>			✓
<p>Severe infection that spreads from urinary tract throughout body (sepsis): fever or low body temperature, rapid breathing, chills, rapid heartbeat, pain with urination, difficulty urinating, frequent urination</p>			✓
<p>Inflammation of the pancreas (pancreatitis): severe stomach pain that lasts and gets worse when you lie down, nausea, vomiting</p>		✓	

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

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