

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

P^rINVOKANA[®] canagliflozin tablets

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**.

Serious Warnings and Precautions

Diabetic Ketoacidosis (DKA)

- DKA may happen during or after stopping treatment with INVOKANA. It is a serious and life-threatening condition, which may need urgent hospital care. Some cases of DKA have led to death. DKA is a complication of diabetes, where your body produces high levels of blood acids called ketones. It can happen in patients with type 2 diabetes mellitus (T2DM), with normal or high blood sugar (glucose) levels who are treated with INVOKANA or with other sodium-glucose co-transporter-2 (SGLT2) inhibitors.
- **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.
- Do NOT use INVOKANA if you have:
 - type 1 diabetes.
 - DKA or a history of DKA.

Lower Limb Amputation

- INVOKANA may increase your risk of lower limb amputations. Amputations have happened mainly on 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.
- Tell your healthcare professional if you have ever had an amputation, blood vessel disease, nerve disease, or a foot ulcer (sore) caused by diabetes.
- **Seek medical attention right away** if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot. Your healthcare professional may decide to stop your INVOKANA if you have any of these signs or symptoms. Talk to your healthcare professional about proper foot care and keeping hydrated.

What is INVOKANA 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;
- with metformin;
- with a sulfonylurea;
- with metformin and a sulfonylurea;
- with metformin and a pioglitazone;
- with metformin and sitagliptin; or
- 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.

How does INVOKANA work?

INVOKANA belongs to a group of medicines called sodium-glucose co-transporter 2 (SGLT2) inhibitors. It lowers blood sugar by causing the kidneys to get rid of more sugar in the urine.

What are the ingredients in INVOKANA?

Medicinal ingredients: Canagliflozin

Non-medicinal ingredients: 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.

INVOKANA comes in the following dosage forms:

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.

Do not use INVOKANA if you:

- are allergic to canagliflozin or any other ingredients in INVOKANA.
- have type 1 diabetes (your body does not produce any insulin).
- have or have had diabetic ketoacidosis (DKA). This is a complication of diabetes.
- are on dialysis.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take INVOKANA. Talk about any health conditions or problems you may have, including if you:

- **have any of the following conditions:**
 - liver problems.
 - heart problems.
 - intolerance to some milk sugars. INVOKANA tablets contain lactose.
 - pregnant or are planning to have a baby. INVOKANA should not be used during pregnancy. It is not known if INVOKANA can harm your unborn baby.
 - breast-feeding. INVOKANA should not be used during breast-feeding.
 - current or history of low blood pressure (hypotension).
 - often get urinary tract infections.

- are taking any of the medications listed in the drug interactions section below (see **The following may interact with INVOKANA**).

- **have risk factors for 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 or 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.
 - need to have a procedure that requires long periods of fasting.
 - have an acute illness.
 - have sudden reductions in insulin dose.
 - have diabetic kidney disease.
 - have a history of diabetic ketoacidosis (DKA).

- **have risk factors for 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.

Other warnings you should know about:

Children and adolescents (under 18 years of age)

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

Adults aged 65 years of age and older

You could have more side effects with INVOKANA.

Check-ups and testing

You will have regular visits with your healthcare professional before and during treatment with INVOKANA to monitor your health. They may check:

- your blood sugar levels. INVOKANA will cause your urine to test positive for sugar.
- that your kidneys are working properly.
- blood fat levels.
- the amount of red blood cells in your blood.
- the potassium levels in your blood.
- ketone levels in your blood or urine. Ketones are a type of chemical that your liver produces when it breaks down fats for energy.
- the levels of lithium in your blood.

Broken bones (fracture)

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

Surgery and illnesses

Tell your healthcare professional if you:

- have a serious medical illness.
- are going to have a surgery.
- are hospitalized for a serious infection or a serious medical illness.
- had major surgery.

Stopping treatment:

- Your healthcare professional may temporarily stop your INVOKANA treatment:
 - before and after certain types of surgery or procedures associated with long periods of fasting. Your healthcare professional may stop your treatment for at least three days before you undergo these procedures or surgeries, or
 - when you are hospitalized for a serious infection or illness.

If INVOKANA is stopped, your healthcare professional will:

- continue to monitor for signs or symptoms of DKA.
- tell you when to start taking INVOKANA again.

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.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with INVOKANA:

- digoxin, a medicine used to treat heart problems.
- furosemide or other diuretics (water pills), used to treat high blood pressure and other heart problems.
- Angiotensin-Converting Enzyme (ACE) inhibitors or Angiotensin Receptor Blockers (ARB) used to treat high blood pressure.
- insulin or a sulfonylurea (such as glimepiride, gliclazide, or glyburide), used to help control blood sugar.

- carbamazepine, phenytoin or phenobarbital, used to treat seizures.
- barbiturates, used as sedatives and sleep-aids.
- efavirenz or ritonavir, used to treat HIV infection.
- rifampin, an antibiotic used to treat bacterial infections such as Tuberculosis.
- lithium, used to treat bipolar disorder.
- St. John's wort, an herbal product used to treat depression.

How to take INVOKANA:

- Take exactly as your healthcare professional tells you. Check with your healthcare professional if you are not sure.
- **Take once per day** with or without food. It is best to take INVOKANA before the first meal of the day and at the same time each day.
- Swallow the tablet(s) whole with water.
- Continue taking INVOKANA for as long as your healthcare professional tells you to.
- Your healthcare professional may temporarily stop your treatment for a minimum of three days if you are undergoing:
 - a major surgery.
 - procedures that are associated with long periods of fasting.

Your healthcare professional may prescribe INVOKANA alone or together with another medicine.

Usual dose:

Adults: One 100 mg tablet per day.

Your healthcare professional may increase your dose to 300 mg once a day, if necessary.

Overdose:

If you think you, or a person you are caring for, have taken too much INVOKANA, contact a healthcare professional, 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.

What are possible side effects from using INVOKANA?

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.

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

- Feeling thirsty.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	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 or insulin: shaking, sweating, pale skin, rapid heartbeat, change in vision, hunger, headache and change in mood, feeling anxious or confused		✓	
COMMON			
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		✓	
Urinary tract infection: burning sensation when passing urine, pain in the pelvis, or mid-back pain, or increased need to urinate		✓	
Constipation	✓		
Bone fracture (broken bones)		✓	
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.		✓	
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.		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
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		✓	
Hypotension (low blood pressure): dizziness, fainting or light-headedness; may occur when you go from lying to sitting to standing up.		✓	
Rash or hives			✓
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.		✓	
RARE			
Severe hypoglycemia (low blood sugar), especially when used with insulin or a sulfonylurea: disorientation, loss of consciousness, seizure			✓
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			✓
Anaphylactic reaction (Severe allergic reaction):swelling of the face, lips, mouth, tongue or throat that may lead to difficulty breathing or swallowing			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Acute kidney infection: painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul-smelling urine, blood in your urine			✓
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			✓
Pancreatitis (inflammation of the pancreas): severe stomach pain that lasts and gets worse when you lie down, nausea, vomiting		✓	
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			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.

Storage:

- 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 wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If you want more information about INVOKANA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.janssen.com/canada or by calling 1-800-567-3331 and 1-800-387-8781

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