

INVOKANA[®]

canagliflozin hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Invokana. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about using Invokana, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this information handy. You can refer to it later if you have any questions.

Please also refer to Consumer Medicine Information documents of other medicines your doctor may have prescribed for use in combination with Invokana. Ask your doctor or pharmacist if you have any questions.

What Invokana is used for

Invokana belongs to a group of medicines called “oral antihyperglycemics.” It may also be known as a diabetes medicine.

Invokana is used to lower blood glucose in patients with type 2 diabetes mellitus, (“non-insulin-dependent diabetes” or “maturity onset diabetes”) when diet and exercise are not enough to control your blood glucose.

Lowering and controlling blood sugar may help prevent or delay complications of diabetes, which include kidney disease, blindness and amputation.

Invokana has not been tested in children and use in children is not recommended.

Your doctor may prescribe Invokana to be used alone, or in combination with other medicines for treating your diabetes. It is important to keep following your doctor’s advice about diet and exercise while you are taking Invokana.

Ask your doctor if you have any questions about why it has been prescribed for you.

How it works

Invokana contains the active ingredient canagliflozin, which works by inhibiting the activity of a protein in your kidneys that reabsorbs glucose (sugar) from the urine. By inhibiting this protein, Invokana increases glucose excretion in your urine. In this way it lowers elevated blood glucose levels to help control your diabetes.

Before you take it

When you must not use it

Do not use Invokana if you know you are allergic to any of its ingredients listed at the end of this leaflet.

Signs of allergy may include skin rash, itching, shortness of breath, and/or swollen face.

Do not use it after the expiry date printed on the pack.

Do not use it if the packaging is torn or shows signs of being tampered with.

Invokana: is not intended to treat:

- type 1 diabetes (when your body does not produce any insulin) or diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea, or vomiting).

Invokana should not be used if you have poorly functioning kidneys since Invokana requires good functioning kidneys to work well.

Before you start to use it

Invokana should be used with caution in some patients.

Tell your doctor or pharmacist if you have, or have had, any medical conditions, especially the following:

- severe problems with your liver
Signs depend on the disorder but might include yellowing of the skin (jaundice), fluid accumulation in the stomach, abdominal pain in the upper right side or vomiting of blood. Your doctor may evaluate how severe your liver disease is before deciding if you can take Invokana.
- kidney problems
- heart disease or at high risk of heart disease
- are taking a medicine for high blood pressure or taking a water pill (diuretic) to remove excess water from the body
- are taking other medicines to lower your blood sugar, the dose of these medicines may need to be reduced to prevent your blood sugar getting too low
- frequently get genital or urinary tract infections (infections of the

bladder, kidney, or tubes that carry urine)

- an illness that will make you dehydrated such as diarrhoea or a severe infection
- are pregnant or plan to become pregnant. It is not known if Invokana will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if Invokana passes into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking Invokana.

If any of the above apply to you or you are not sure, talk to your doctor or pharmacist before taking Invokana.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

INVOKANA might interact with other medicines.

Be sure to tell your doctor if you are taking:

- other medicines that can lower your blood sugar.
- Digoxin or digitoxin, medicines used to treat heart problems. Your doctor will need to monitor the levels of digoxin or digitoxin in your blood.
- rifampicin (an antibiotic used to treat tuberculosis).
- carbamazepine, phenytoin or phenobarbital (used to control seizures).
- ritonavir, efavirenz (used to treat HIV infection).
- St John's Wort

If you take cyclosporin, a medicine used to prevent rejection of an organ transplant, with Invokana, you may experience mild flushing.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Invokana.

How to take it

Your doctor will decide the dose of Invokana suitable for you. Take Invokana exactly as directed by your doctor.

The recommended Invokana dose is 100 mg or 300 mg once a day. It is best to take Invokana before the first meal of the day. Swallow the tablet whole.

If you are taking other medicinal products, please refer to Consumer Medicine Information documents of other medicines your doctor may have prescribed for use in combination with Invokana. Ask your doctor or pharmacist if you have any questions.

Follow your doctor's instructions carefully and do not change or stop the required dosage without consulting your doctor first.

If you forget to take it

- If you miss a dose, take it soon as you remember. However, if it is nearly time for the next dose, skip the missed dose and take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

If you have problems remembering when to take your medicine, ask your pharmacist for some hints.

Overdose

If you think you or anybody else has taken too much Invokana, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

You may need urgent medical attention.

While you are using it

Things you must do

Follow your doctor's instructions carefully.

Tell your doctor if you are pregnant or are planning to become pregnant before taking Invokana.

Tell all of your doctors, dentists, and pharmacists who are treating you that you are taking Invokana before taking any new medicines that they may prescribe for you.

Ask your doctor or pharmacist before taking any other medicines.

These include herbal treatments and those bought in a pharmacy or supermarket.

In certain patients your doctor may need to order blood tests to monitor your blood potassium levels.

The function of your kidneys will be tested from time to time. If your kidneys don't function normally Invokana does not work as well and you may be more likely to experience side effects from taking it.

Things you must not do

Do not miss or stop the treatment without consulting your doctor first.

Your blood sugar levels may increase when you stop taking Invokana. Don't take any more or less Invokana than what has been prescribed for you. Your doctor will be happy to discuss any questions you may have about your treatment.

Do not take Invokana to treat any other complaints unless your doctor tells you to.

Do not give Invokana to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery.

You may feel dizzy while taking Invokana. If you experience this or similar effects, you should avoid driving and using machines.

Make sure you know how you react to Invokana before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

Taking Invokana in combination with other medicines to treat high blood sugar can cause blood sugar levels to fall too low (hypoglycemia), which may affect your ability to drive and use machines.

Invokana can cause some people to have dehydration (the loss of body water and salt). Dehydration 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 pill)
- are on a low sodium (salt) diet
- have kidney problems
- are 65 years of age or older

Maintaining good foot care is recommended; particularly if you have heart disease or at high risk of heart disease,

Tell your doctor or healthcare professional if you get pins and needles, numbness or cold toes or feet and have regular checks with your doctor.

Side Effects

All medicines may have some unwanted side effects although not everyone will get them. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have about the risks of Invokana treatment.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Invokana.

Tell your doctor if you notice any of the following and they worry you:

- feeling dizzy or lightheaded
- changes in urination (including urinating more frequently or in larger amounts, urgent need to urinate, need to urinate at night).
- signs of a yeast infection in the vagina or penis (rash or redness)
- urinary tract infection (burning sensation when urinating, cloudy urine, and/or passing frequent small amount of urine, strong odour)
- feeling thirsty
- constipation
- nausea
- rash
- hives
- signs of low blood sugar such as shaking, sweating, rapid

heartbeat, change in vision, hunger, headache and confusion

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- severe dehydration (loss of needed fluids from the body) which may make you feel very weak, confused and be unable to stand up
- fever (this may indicate you have a severe infection)
- allergic reaction which may be serious.

Including rash, hives, and swelling of the face lips, tongue and throat that may cause difficulty in breathing or swallowing. If you have an allergic reaction, stop taking Invokana and call your doctor right away.

These may be serious side effects of Invokana. You may need urgent medical attention.

Serious side effects are uncommon.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Do not hesitate to report any other side effects to your doctor or pharmacist.

After using it

Storage

Keep the tablets in its original container in a dry place where the temperature stays below 25°C.

Do not store it or any medicines in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use it beyond the expiry date (month and year) printed on the pack.

Medicines cannot be stored indefinitely, even if stored properly.

AUST R 200180.

This leaflet was prepared in September 2016.

Product Description

What it looks like

You can identify Invokana tablets by their colour and shape. This is important because each type of tablets, contains a different amount of the active canagliflozin.

- 100 mg tablet: Yellow, capsule-shaped, film-coated, with “CFZ” on one side and “100” on the other side.
- 300 mg tablet: White, capsule-shaped, film-coated, with “CFZ” on one side and “300” on the other side.

Both strengths are available in blister packs of 30 tablets.

Ingredients

The active ingredient in Invokana is canagliflozin.

Both 100 mg and 300 mg strengths contain the inactive ingredients microcrystalline cellulose, lactose anhydrous, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, polyvinyl alcohol, titanium dioxide, macrogol 3350, talc-purified. In addition, the 100 mg strength contains iron oxide yellow.

Sponsor

Janssen-Cilag Pty Ltd
1-5 Khartoum Road, Macquarie Park
NSW 2113
Telephone: 1800 226 334

NZ Office: Auckland New Zealand
Telephone: 0800 800 806

Registration Numbers

100 mg film-coated tablets:
AUST R 200184.

300 mg film-coated tablets: