

INVOKANA[®] FILM-COATED TABLETS

Canagliflozin (100mg & 300mg)

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What INVOKANA[®] is used for

INVOKANA[®] contains the active substance canagliflozin. This belongs to a group of medicines called “oral antihyperglycemics.” INVOKANA[®] may also be known as a diabetes medicine.

INVOKANA[®] is used to lower blood sugar levels in adults with type 2 diabetes.

INVOKANA[®] can be used alone or together with other medicines that your doctor may prescribe to lower blood sugar.

It is also important to keep following your doctor's advice about diet and exercise.

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.

INVOKANA[®] is used for type 2 diabetes due to diabetic condition. This is when your kidneys are damaged as a result of your diabetes. INVOKANA[®] can be used to slow down the progression rate of your kidney disease and may also reduce death rate relating to cardiovascular disease.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When

this happens, sugar (glucose) builds up in the blood. This can lead to serious medical conditions such as heart disease, kidney disease, blindness, and amputation.

How INVOKANA[®] works

INVOKANA[®] works by increasing the amount of sugar removed from the body in the urine, which reduces the amount of sugar in the blood.

Before you use INVOKANA[®]

- When you must not use it

Do not take INVOKANA[®]

- if you are allergic to canagliflozin or any of the other ingredients of this medicine (see “Product description”).
- if you have type 1 diabetes (your body does not produce any insulin). INVOKANA[®] should not be used to treat this condition
- if you have diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea, or vomiting). INVOKANA[®] should not be used to treat this condition

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking INVOKANA[®].

During pregnancy, talk to your doctor about using other medicines to control your blood sugar, especially during the second and third trimesters.

Breast feeding

If you are breastfeeding, talk to your doctor about whether to stop taking this medicine or to stop breastfeeding.

Children and adolescents

INVOKANA[®] is not recommended for children and adolescents under 18 years

- Before you start use it

Check with your doctor or pharmacist before taking INVOKANA[®] if you:

- are older than 75 years of age
- have kidney problems
- have severe liver problems
- have ever had serious heart disease or if you have had a stroke

- have had a lower limb amputation
- are going to have major surgery or a procedure that requires prolonged fasting

It is important to check your feet regularly and adhere to any other advice regarding foot care and adequate hydration given by your healthcare professional. You should notify your doctor immediately if you notice any wounds or discolouration, or if you experience any tenderness or pain in your feet. Some studies indicate that taking canagliflozin may have contributed to the risk of lower limb amputation (mainly toe and midfoot amputations).

Talk to your doctor immediately if you develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier's gangrene which destroys the tissue under the skin. Fournier's gangrene has to be treated immediately.

If you have a serious infection of the kidney or the urinary tract with fever, your doctor may ask you to stop taking INVOKANA[®] until you have recovered.

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

Kidney function

Your kidneys will always be tested by a blood test before you start taking and while you are on this medicine.

Urine glucose

Because of how this medicine works, your urine will test positive for sugar (glucose) while you are on this medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or might take any other

medicines. In particular, tell your doctor if you are taking any of the following medicines:

- antihyperglycemic medicine known as ‘sulfonylurea’ (such as glimepiride, glipizide, glyburide) or insulin. Your doctor may want to reduce your dose in order to avoid your blood sugar level from getting too low (hypoglycemia)
- diuretic medicine also known as a water pill (used to remove excess water from the body)
- other medicines to lower your blood sugar
- St. John’s wort (a herbal medicine to treat depression)
- carbamazepine, phenytoin, or phenobarbital (used to control seizures)
- lithium (a medicine used to treat bipolar disorder)
- efavirenz or ritonavir (used to treat HIV infection)
- rifampicin (an antibiotic used to treat tuberculosis)
- cholestyramine (medicine used to reduce cholesterol levels in the blood)
- digoxin or digitoxin, a medicine used for certain heart problems. The levels of digoxin or digitoxin in your blood may need to be checked if taken with INVOKANA®
- dabigatran (blood thinner medicine that lowers the risk of blood clot formation)

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

How to use INVOKANA®

Always take INVOKANA® as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How much to use

- the starting dose of INVOKANA® is one 100 mg tablet each day. Your doctor will prescribe the strength that is right for you.
- your doctor may limit your dose to 100 mg if you have a kidney problem.

- When to use it

- It is best to take your tablet before the first meal of the day. Swallow the tablet whole with a half glass of water.

- Try to take it at the same time each day. This will help you remember to take it.
- Your doctor may prescribe INVOKANA® together with another antihyperglycemic medicine. Take all medicines as directed by your doctor.

- How long to use it

Continue taking INVOKANA® for as long as your doctor recommends.

Your blood sugar levels may rise if you stop taking this medicine. Do not stop taking INVOKANA® without talking to your doctor first.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

- If you forget to use it

- 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.
- Do not take a double dose (two doses on the same day) to make up for a forgotten dose.

- If you use too much (overdose)

If you take more of this medicine than you should, talk to a doctor straight away.

While you are using it

- Things you must do

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Diet and exercise

To control your diabetes, you still need to follow the advice about diet and exercise from your doctor, pharmacist or nurse. In particular, if you are following a diabetic weight control diet, continue to follow it while you are taking this medicine.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give INVOKANA® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Dizziness or light headedness has been reported, which may affect your ability to drive or use machines.

Taking INVOKANA® in combination with other medicines for diabetes called sulfonylureas or insulin can increase the risk of having low blood sugar (hypoglycemia). Signs include blurred vision, tingling lips, trembling, sweating, pale looking, a change in mood, or feeling anxious or confused. Tell your doctor as soon as possible if you get any of the signs of low blood sugar

INVOKANA® contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

INVOKANA® contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.

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

- Low blood sugar when used with sulfonylurea (such as glimepiride, glipizide, glyburide) or insulin (blurred vision, tingling lips, trembling, sweating, pale looking, or a change in mood and/or feeling anxious or confused).
- Vaginal yeast infection (vaginal odor, white or yellowish discharge, and/or vaginal itching).

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

- Rash or redness of the penis or foreskin (yeast infection)
- Urinary tract infection (fever and/or chills, burning sensation when urinating, pain in your back or side).
- Changes in urination (including urinating more frequently or in larger amounts, urgent need to urinate, need to urinate at night)
- Constipation
- Nausea
- Feeling thirsty
- Blood tests may show changes in blood fat (cholesterol) levels and increases in amount of red blood cells in your blood (haematocrit).

Seek immediate medical attention when symptoms such as nausea, vomiting, decreased appetite, abdominal pain, excessive thirst, difficulty in breathing, confusion, unusual fatigue or sleepiness, frequent urination and fruity-smelling breath occur.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website nptra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of INVOKANA®

- Storage

Do not store above 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

- Disposal

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.

Product Description

- What it looks like

- INVOKANA® 100 mg film-coated tablets (tablets) are yellow, capsule shaped, 11 mm long, with “CFZ” on one side and “100” on the other side.
- INVOKANA® 300 mg film-coated tablets (tablets) are white, capsule shaped, 17 mm with “CFZ” on one side and “300” on the other side.

- Ingredients

- Active ingredient
Canagliflozin. Each tablet contains 100mg or 300mg canagliflozin.
- Inactive ingredients
 - Tablet core: croscarmellose sodium (E468), hydroxypropyl cellulose (E463), lactose anhydrous, magnesium stearate (E572), and microcrystalline cellulose (E460[i]).
 - Film-coating: macrogol/PEG 3350 (E1521), polyvinyl alcohol (E1203), talc (E553b), and titanium dioxide (E171). The 100mg tablet also contains iron oxide yellow (E172).

- MAL numbers:

INVOKANA® 100mg film-coated tablets: MAL16045042AZ

INVOKANA® 300mg film-coated tablets: MAL16045038AZ

Manufacturer

Janssen Cilag SpA
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Product registration holder

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