Package leaflet: Information for the patient

Invokana® 300 mg film-coated tablets

(canagliflozin)

Your medicine is known by the above name, but will be referred to as "Invokana" throughout this leaflet. Please note that the leaflet also contains information about other strengths (Invokana® 100 mg film-coated tablets).

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor, pharmacist or nurse.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. **What Invokana is and what it is used for**
2. **What you need to know before you take Invokana**
3. **How to take Invokana**
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1. What Invokana is and what it is used for

Invokana contains the active substance canagliflozin which belongs to a group of medicines called "blood-glucose lowering drugs."

Invokana is used:

- to treat adults and children aged 10 years and older with type 2 diabetes.

This medicine works by increasing the amount of sugar removed from your body in your urine. This reduces the amount of sugar in your blood and can help prevent heart disease in patients with type 2 diabetes mellitus (T2DM). It also helps to slow down deterioration of kidney function in patients with T2DM by a mechanism beyond blood glucose lowering.

Invokana can be used by itself or along with other medicines you may be using to treat your type 2 diabetes (such as metformin, insulin, a DPP-4 inhibitor [such as sitagliptin, saxagliptin, or linagliptin], a sulphonylurea [such as glimepiride or glipizide], or pioglitazone) that lower blood sugar levels. You may already be taking one or more of these to treat your type 2 diabetes.

It is also important to keep following advice about diet and exercise given by your doctor or nurse.

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.

2. What you need to know before you take Invokana

Do not take Invokana

- if you are allergic to canagliflozin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Invokana, and during treatment:
- about what you can do to prevent dehydration (see section 4 for signs of dehydration).
- if you have type 1 diabetes because Invokana should not be used to treat this condition.
- if you experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat, talk to a doctor or go to the nearest hospital immediately. These symptoms could be a sign of "diabetic ketoacidosis" – a rare but serious, sometimes life-threatening problem you can get with diabetes because of increased levels of "ketone bodies" in your urine or blood, seen in tests. The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.
- if you are going to have major surgery or a procedure that requires prolonged fasting, ask your doctor if you need to stop taking Invokana and when to start it again.
- 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.
- if you have severe kidney problems or are on dialysis.
- if you have severe liver problems.
- if you have ever had serious heart disease or if you have had a stroke.
- if you are on medicines to lower your blood pressure (anti-hypertensives) or have ever had low blood pressure (hypotension). More information is given below in "Other medicines and Invokana".
- if you have had a lower limb amputation.
- 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 signs of a genital yeast infection such as irritation, itching, unusual discharge or odour.
- 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, pharmacist, or nurse before taking this medicine.

Kidney function

Your kidneys will 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.

Children and adolescents

Invokana can be used in children aged 10 years and older. No data are available in children below 10 years of age. Invokana is not recommended for children under 10 years.

Other medicines and Invokana

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

In particular, tell your doctor if you are taking any of the following medicines:
- other antidiabetics - either insulin or a sulphonylurea (such as glimepiride or glipizide) – your doctor may want to reduce your dose in order to avoid your blood sugar level from getting too low (hypoglycaemia)
- medicines used to lower your blood pressure (anti-hypertensives), including diuretics (medicines used to remove levels of excess water in the body, also known as water tablets) since this medicine can also lower your blood pressure by removing levels of excess water in the body. Possible signs of losing too much fluid from your body are listed in section 4.
- St. John's wort (an herbal medicine to treat depression)
- carbamazepine, phenytoin, or phenobarbital (medicines used to control seizures)
- lithium (a medicine used to treat bipolar disorder)
- efavirenz or ritonavir (a medicine used to treat HIV infection)
- rifampicin (an antibiotic used to treat tuberculosis)
- cholestyramine (medicine used to reduce cholesterol levels in the blood). See section 3, "Taking this medicine".
- digoxin or digitoxin (medicines used for certain heart problems). The level 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).

Pregnancy and breast-feeding

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 or continuing to take this medicine. Invokana should not be used during pregnancy. Talk to your doctor about the best way to discontinue Invokana and control your blood sugar as soon as you know that you are pregnant.

You should not take this medicine if you are breast-feeding. Talk to your doctor about whether to stop taking this medicine or to stop breast-feeding.

Driving and using machines

Invokana has no or negligible influence on the ability to drive, cycle, and use tools or machines. However, dizziness or lightheadedness has been reported, which may affect your ability to drive, cycle, or use tools or machines.

Taking Invokana with other medicines for diabetes called sulphonylureas (such as glimepiride or glipizide) or insulin can increase the risk of having low blood sugar (hypoglycaemia). Signs include blurred vision, tingling lips, trembling, sweating, pale looking, a change in mood, or feeling anxious or confused. This may affect your ability to drive, cycle, and use any tools or machines. 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, talk to 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'.

3. How to take Invokana

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

How much to take

- The starting dose of Invokana is one 100 mg tablet each day. Your doctor will decide whether to increase your dose to 300 mg.
- Your doctor may limit your dose to 100 mg if you have a kidney problem.
- Your doctor will prescribe the strength that is right for you.

Taking this medicine

- Swallow the tablet whole with water.
- You can take your tablet with or without food. It is best to take your tablet before the first meal of the day.
- Try to take it at the same time each day. This will help you remember to take it.
- If your doctor has prescribed canagliflozin along with any bile acid sequestrant such as cholestyramine (medicines for lowering cholesterol) you should take canagliflozin at least 1 hour before or 4 hours to 6 hours after the bile acid sequestrant.

Your doctor may prescribe Invokana together with another glucose-lowering medicine. Remember to take all medicines as directed by your doctor to achieve the best results for your health.

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.

If you take more Invokana than you should

If you take more of this medicine than you should, talk to a doctor or go to the nearest hospital immediately.

If you forget to take Invokana

- If you forget to take a dose, 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 stop taking Invokana

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

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

4. Possible side effects

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

Stop taking Invokana and talk to a doctor or go to the nearest hospital immediately if you have any of the following serious side effects:

Severe allergic reaction (rare, may affect up to 1 in 1,000 people)

Possible signs of severe allergic reaction may include:
- swelling of the face, lips, mouth, tongue, or throat that may lead to difficulty breathing or swallowing.

Diabetic ketoacidosis (rare, may affect up to 1 in 1,000 people)

These are the signs of diabetic ketoacidosis (see also section 2):
- increased levels of “ketone bodies” in your urine or blood
- rapid weight loss
- feeling sick or being sick
- stomach pain
- excessive thirst
- fast and deep breathing
- confusion
- unusual sleepiness or tiredness
- a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat.

This may occur regardless of blood glucose level. Diabetic ketoacidosis may occur more frequently as the kidney function gets worse. The doctor may decide to temporarily or permanently stop the treatment with Invokana.

Dehydration (uncommon, may affect up to 1 in 100 people)

- loss of too much fluid from your body (dehydration). This happens more often in elderly people (aged 75 and over), people with kidney problems, and people taking water tablets (diuretics).
  Possible signs of dehydration are:
  - feeling light-headed or dizzy
  - passing out (fainting) or feeling dizzy or faint when you stand up
  - very dry or sticky mouth, feeling very thirsty
  - feeling very weak or tired
  - passing little or no urine
  - fast heartbeat.

Tell your doctor as soon as possible if you have any of the following side effects:

Hypoglycaemia (very common, may affect more than 1 in 10 people)

- low blood sugar levels (hypoglycaemia) - when taking this medicine with insulin or a sulphonylurea (such as glimepiride or glipizide).
  Possible signs of low blood sugar are:
  - blurred vision
  - tingling lips
  - trembling, sweating, pale looking
  - a change in mood or feeling anxious or confused.

Your doctor will tell you how to treat low blood sugar levels and what to do if you have any of the signs above.

Urinary tract infections (common, may affect up to 1 in 10 people)

- These are signs of a severe infection of the urinary tract, e.g.:
  - fever and/or chills
  - burning sensation when passing water (urinating)
  - pain in your back or side.

Although uncommon, if you see blood in your urine, tell your doctor immediately.

Other side effects:

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

- vaginal yeast infection.

Common (may affect up to 1 in 10 people)

- rash or redness of the penis or foreskin (yeast infection)
- changes in urination (including urinating more frequently or in larger amounts, urgent need to urinate, need to urinate at night)
- constipation
- feeling thirsty
- nausea
- blood tests may show changes in blood fat (cholesterol) levels and increases in amount of red blood cells in your blood (haematocrit).

Uncommon (may affect up to 1 in 100 people)

- rash or red skin – this may be itchy and include raised bumps, oozing fluid or blisters
- hives
- blood tests may show changes related to kidney function (increased creatinine or urea) or increased potassium
- blood tests may show increases in your blood phosphate level
- bone fracture
- kidney failure (mainly as a consequence of loss of too much fluid from your body).
- lower limb amputations (mainly of the toe) especially if you are at high risk of heart disease.
- phimosis – difficulty pulling back the foreskin around the tip of the penis.
- skin reactions after exposure to sunlight.

Not known (frequency cannot be estimated from the available data)

- necrotising fasciitis of the perineum or Fournier’s gangrene, a serious soft tissue infection of the genitals or the area between the genitals and the anus.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Invokana

- **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 blister and carton after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not use Invokana if the packaging is damaged or shows signs of tampering.
- 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 your medicine becomes discoloured or shows signs of any deterioration, consult your doctor or pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Invokana contains

- The active substance is canagliflozin.
  - Each tablet contains canagliflozin hemihydrate, equivalent to 300 mg canagliflozin.
- The other ingredients are:
  - tablet core: lactose (see section 2 ‘Invokana contains lactose’), microcrystalline cellulose (E460[i]), hydroxypropyl cellulose (E463), croscarmellose sodium (E468) and magnesium stearate (E572).
  - film-coating: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol/PEG 3350 (E1521) and talc (E553b).

What Invokana looks like and contents of the pack

- Invokana film-coated tablets (tablets) are white, capsule-shaped, 17 mm long, with “CFZ” on one side and “300” on the other side.

Invokana is available in PVC/aluminium perforated unit dose blisters. The pack size are cartons of 30 x 1 tablets.

PL: 15814/2026 **POM**

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Procured from within the EU and repackaged by the Product Licence holder:
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Leaflet revision and issue date (Ref.): 14.08.2026.

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