

Invokana[®]

(canagliflozin)



You and Your Medicine

for patients who have been prescribed
Invokana for the treatment of
insufficiently controlled type 2 diabetes



You have received this booklet because you have been prescribed Invokana for the treatment of insufficiently controlled type 2 diabetes.

This guide will help you understand your treatment and give you important information you should know.

Before starting to take your tablets, carefully read the patient information leaflet included in the box with your tablets.

If you have any questions about what you read in this booklet, or any other questions about diabetes or your medicines, please speak to your doctor, nurse or pharmacist (in this booklet, we refer to these people, and any other healthcare professionals involved in the management of your diabetes, as ‘your diabetes team’). If you like, you can write their details in the spaces below as a reminder.

Your doctor

Name

Contact details

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Your nurse

Name

Contact details

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Your pharmacist

Name

Contact details

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Diabetes



What is type 2 diabetes?

Insulin is a hormone your body produces. It helps to control blood sugar (glucose) levels by allowing cells in your body to absorb glucose from the blood and use it for energy.¹ If you have type 2 diabetes, your body doesn't respond properly to the insulin you produce. Your body also makes less insulin.¹ When this happens, glucose builds up in the blood. This can lead to serious medical conditions such as heart disease, kidney disease, blindness and amputation.²

Although type 2 diabetes is a life-long condition, medicines and lifestyle changes can help to keep your blood glucose under control and reduce the risk of these serious complications.

Type 1 diabetes is a different condition, where the pancreas doesn't produce any insulin. It is caused by the body's immune system attacking the cells of the pancreas.³ Invokana can't be used to treat type 1 diabetes.

Diabetes complications^{2,4-9}

Heart disease

In people with diabetes, the excess glucose can lead to blood vessel disease called cardiovascular disease. Damaged blood vessels can become blocked and cause serious heart complications, such as a heart attack, and could also lead to a stroke. High blood pressure and high blood cholesterol (fat) can also damage the blood vessels and increase the risk of cardiovascular disease. Keeping your blood glucose, blood pressure and blood fats under control can help reduce your risk of heart disease.

Kidney disease

The main job of your kidneys is to filter your blood, keeping important things like protein in the body and filtering out waste products and extra fluid, which leave the body in the urine. Over time, high blood glucose levels (and/or high blood pressure) in people with diabetes can damage the tiny blood vessels and filters in the kidneys, causing them to leak. Protein and other substances are then lost in the urine.

Diabetic kidney disease doesn't normally cause symptoms in the early stages, and by the time symptoms occur the damage to the kidneys can be quite serious. Luckily, regular testing can pick up the early signs of kidney damage (for example protein in the urine) and early treatment can help to slow down further kidney damage.

Eye problems

Diabetes can cause a serious condition called diabetic retinopathy, which can lead to sight loss if it's not diagnosed or treated quickly. High blood glucose and blood pressure can damage the blood vessels in the eye. If this happens, not enough blood gets to the retina (the seeing part of the eye) and the vision is damaged.

There are different stages of diabetic nephropathy. If it is spotted at an early stage, there is more chance of being able to stop it getting worse. Regular eye tests are important for detecting damage at an early stage.

Nerve damage

Over time, high blood glucose levels can damage the small vessels that supply blood to the nerves. This causes the nerves to stop working properly or even disappear. Nerve damage is also called neuropathy, and different types of neuropathy affect different nerves:

- **Sensory neuropathy** affects the nerves that allow you to feel things. Symptoms can include tingling and not being able to feel pain.
- **Autonomic neuropathy** affects the nerves connected to organs and glands. Symptoms can include digestion problems and incontinence.
- **Motor neuropathy** affects the nerves involved in moving. Symptoms can include muscle weakness, loss of muscle tissue and twitching.

Foot problems

Diabetes can cause damage to nerves in the feet, which can mean you don't feel a foot problem like a cut or a blister. It can also cause reduced blood flow to the feet, which can slow down wound healing and affect your ability to fight infections.

If foot problems aren't treated in time, they can cause ulcers or infections, which in severe cases can lead to amputation. Diabetes is one of the main causes of amputation of the lower limbs (lower legs, feet and toes) throughout the world, so it's important to check your feet regularly (see Pages 22 – 23 for more information about foot care).



Invokana

What is Invokana?

Invokana (also called canagliflozin) is a medicine used in adults to treat insufficiently controlled type 2 diabetes.

It helps to lower blood glucose levels, and can help to prevent heart disease. It can also be used to treat diabetic kidney disease in people with type 2 diabetes.

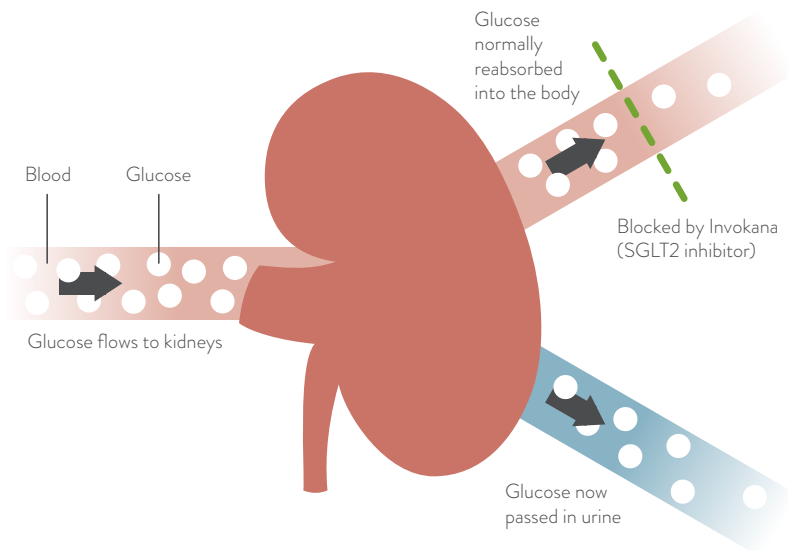
Invokana is one of a class of medicines called SGLT2 inhibitors (sodium-glucose co-transporter 2 inhibitors).

Invokana is a tablet you take once a day. Although it can be prescribed by itself, it is more likely to be used along with one or more other medicines to treat your type 2 diabetes.

How does Invokana work?

Invokana works in the kidneys to change the way glucose is processed in the body. Your kidneys act as a filtering and cleaning system for your body, filtering glucose, water, salt and other small substances. Some of these substances are reabsorbed back into the bloodstream, and any waste products are taken out of the bloodstream and leave your body when you urinate. The aim of this is to maintain healthy levels of these substances in the blood, which can help prevent heart disease.

Invokana works by increasing the amount of glucose removed from your body in your urine. This reduces the amount of glucose in your blood.²



How should I take Invokana?

Always take this medicine exactly as your diabetes team has told you. Check with your diabetes team if you are not sure.

Dose

Treatment of type 2 diabetes without diabetic kidney disease

The starting dose for Invokana is one 100 mg tablet, once a day. Sometimes the dose may be increased, for example if you get on well with Invokana but need a little more help controlling your blood glucose. Your diabetes team can increase your dose to one 300 mg tablet per day, if you agree.

Treatment of diabetic kidney disease

If you have diabetic kidney disease, the dose is one 100 mg tablet, once a day. If you need more help controlling your blood glucose, the dose of Invokana can't be increased, but your diabetes team may prescribe you a different medicine to help reduce your blood glucose levels.

How to take your tablets

- Swallow the tablet whole.
- You can take your tablet with or without food. The recommended time to take your tablet is 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.

What if I forget to take my tablet?

If you miss your daily tablet it should be taken as soon as you can. Do not take two tablets in the same day.

You may find it helpful to consider some other options to help you to remember to take your tablet every day. For example, some people find it helpful to leave their medication next to their toothbrush so that when they brush their teeth in the morning they are reminded to take it.

What if I take more Invokana than I should?

If you take more of this medicine than you should, seek medical advice or go to your nearest hospital immediately.

How long will I need to take my tablets for?

Many people will need to keep taking their tablets or medication for type 2 diabetes throughout their lives in order to stay well, but everyone is different.

Make sure you take your medicine as prescribed by your diabetes team. If you are unsure then you should check with them.

Is it OK to take Invokana if I'm taking other medicines?

Tell your diabetes team if you are taking any other medicines, including those you have recently taken or might take in the future. Invokana can affect the way some other medicines work, and vice versa.

It is particularly important to tell your diabetes team if you are taking:

- **other medicines used to treat diabetes**, including insulin or a sulphonylurea (e.g. glimepiride or glipizide). Your diabetes team may reduce your dose to avoid your blood glucose level 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). Invokana may add to the blood pressure-lowering effects of these medicines;
- **St. John's wort** – a herbal medicine to treat depression;
- **carbamazepine, phenytoin, or phenobarbital** – medicines used to control seizures;
- **efavirenz or ritonavir** – medicines used to treat HIV infection;

- **rifampicin** – an antibiotic used to treat infections including tuberculosis;
- **cholestyramine** – a medicine used to reduce cholesterol levels in the blood. Invokana should be taken least 1 hour before this type of medicine, or 4 – 6 hours afterwards. Your diabetes team will discuss with you the best way to take your medicines;
- **digoxin or digitoxin** – medicines used for certain heart problems. The level of digoxin or digitoxin in your blood may need to be checked if you are taking either of these medicines as well as Invokana;
- **dabigatran** – a blood thinning medicine that lowers the risk of blood clot formation.



What potential side-effects should I be aware of?

Like all medicines, Invokana may cause side-effects, although not everybody gets them. Most of the side-effects you could get with Invokana are the result of losing glucose in the urine. While most side-effects are mild, some people could experience a more serious side-effect, and some of the side-effects may need treatment.

Tell your diabetes team if you notice any of the following side-effects, as you may need medical treatment.

Common side-effects

For more detailed information on all possible side-effects, including those seen less commonly, please see the patient information leaflet in the box with your tablets.

- **Hypoglycaemia** (see Page 13)
- **Urinary tract infections** these are often mild, but can sometimes be serious (see Page 17)
- **Genital infections** including vaginal thrush, and rash or redness of the penis or foreskin
- **Constipation**
- **Feeling thirsty**
- **Nausea**
- **Changes in urination** including urinating more frequently or in larger amounts, urgent need to urinate, need to urinate at night
- **Blood tests** may show changes in blood fat (cholesterol) levels and increased numbers of red blood cells in your blood (haematocrit)

Hypoglycaemia

This is very common (may affect more than 1 in 10 people) if you are taking Invokana as well as insulin or sulphonylurea (other diabetes medicines). Hypoglycaemia, ‘hypos’ or ‘lows’ happen when you don’t have enough glucose in your blood to allow your body to function properly. Possible signs of hypoglycaemia include:

- Blurred vision
- Sweating
- Anxiety
- Tingling of lips
- Looking pale
- Confusion
- Trembling
- Change in mood

Tell your diabetes team as soon as possible if you think you could have hypoglycaemia. Your diabetes team will tell you how to treat low blood glucose levels and what to do if you have any of these symptoms.

Reporting side-effects

Talk to your diabetes team if you get any side-effects, including any not listed in the package 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.

Other side-effects

Weight loss

The way Invokana works may result in you losing some weight when you start taking this medicine. This is not usually anything to be concerned about, but talk to your diabetes team if you have any questions. They will also be able to advise you about the amount of weight loss that would be normal for you.

Blood pressure

Because of the way Invokana works, it can also lower blood pressure. It is possible you may get symptoms as a result of lower blood pressure, including feeling dizzy or faint after standing quickly. Make sure you drink enough fluid through the day, as keeping hydrated can help to reduce these effects.

Please see your diabetes team if you have any of these symptoms.

Serious side-effects

Stop taking Invokana and talk to your diabetes team or go to the nearest hospital immediately if you have any of the following serious side-effects.

Severe allergic reaction

This is a rare side-effect that could affect up to 1 in 1,000 people. Signs you could be experiencing a severe allergic reaction include swelling of your face, lips, mouth, tongue or throat, which could lead to difficulty breathing or swallowing.

Dehydration

One of the side-effects of Invokana is urinating more often, or in larger amounts. Some people taking Invokana may lose too much fluid from their body and become dehydrated. Dehydration is uncommon, affecting up to 1 in 100 people. It is more likely to affect you if you are aged 75 or over, have kidney problems or are taking diuretic medicines (also called water tablets).

Possible signs of dehydration include:²

- Feeling light-headed or dizzy
- Feeling very thirsty
- Fainting, or feeling dizzy or faint when you stand up
- Feeling very weak or tired
- Having a very dry or sticky mouth
- Passing little or no urine
- Fast heart rate

Diabetic ketoacidosis (DKA)

DKA is a rare but serious, sometimes life-threatening, complication of diabetes, which may affect up to 1 in 1,000 people. It occurs when there is not enough insulin available in the body, so blood glucose can't be used for energy. Instead, fat is used as an alternative source of fuel. This causes a build-up of potentially harmful by-products called 'ketone bodies', which can be detected in blood and urine tests.

You may be more likely to develop DKA if you don't eat for a long time, drink excessive alcohol, are dehydrated, suddenly reduce your insulin dose or need more insulin because of surgery or serious illness.

Symptoms of diabetic ketoacidosis include:

- 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
- A different odour to your urine or sweat

You should contact your diabetes team or nearest hospital immediately if you have any of these symptoms, irrespective of your blood glucose levels. Your diabetes team may decide to temporarily or permanently stop your treatment with Invokana.

Fournier's gangrene

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

Amputation

Some studies indicate that taking Invokana may have contributed to the risk of lower limb amputation, mainly of the toes or the middle part of the foot. It is important to check your feet regularly and contact your diabetes team immediately if you notice any changes (see Pages 22 – 23 for more information about foot care).

Urinary tract infections

Although uncommon, some people taking Invokana have experienced serious urinary tract infections, including pyelonephritis (inflammation of the kidney) or urosepsis (a urinary infection that spreads to the blood).

Contact your diabetes team if you have symptoms of a severe urinary tract infection, including fever or chills, a burning sensation when you pee, pain in your back or side, or blood in your urine. If you have a serious infection, you may need to stop taking Invokana until you have recovered.

For more detailed information on any of these side-effects please see the patient information leaflet in the box with your tablets.



Self care

Keeping healthy^{5,10-13}

As you have been diagnosed with type 2 diabetes, it's especially important that you look after your physical and mental health and well-being. Staying fit and healthy and managing your blood glucose levels will make treating your diabetes easier and reduce your risk of developing future complications.

Keeping healthy can also help you to reduce your risk of developing diabetic kidney disease, or slow it down if you already have it.

Making changes to the way you live can be difficult, but even small steps towards a healthier lifestyle can really make a difference. Your diabetes team can give you information and advice, and support from people close to you can be very helpful.

- **Healthy eating** – eating a balanced diet can help you maintain a healthy weight and can help keep your blood glucose at the right level
- **Regular exercise** is crucial as it can help to keep your blood glucose and blood pressure at healthy levels
- **Stop smoking** to reduce the risk of developing heart or kidney disease
- **Limit your alcohol** – as alcohol can affect your blood glucose, avoid drinking more than the recommended daily amount and don't drink on an empty stomach
- **Keeping well** – ensure you attend any check-up appointments with your GP or diabetes nurse; you should also have the flu jab every winter
- **Check your feet regularly** – diabetes can affect the blood circulation and nerves in your feet and make it more difficult for you to notice problems; see Pages 22 – 23 for more information about foot care
- **Regular eye tests** – too much glucose in the blood can damage blood vessels in the eye, causing sight problems or blindness; regular eye tests can help spot symptoms early and monitor any damage
- **Regular kidney function tests** – you will have blood and urine tests every year as part of your diabetes review to see how well your kidneys are working; these can spot problems early so they can be treated
- **Follow the 'sick day rules'** – if you feel unwell (see Pages 20 – 21)

Sick day rules¹⁴⁻¹⁸

If you feel unwell, your blood glucose levels can be affected. Illness or infections can raise your blood glucose, or if you are sick or have diarrhoea, your blood glucose can drop. You can also become dehydrated, which can cause serious side-effects, especially when your blood sugar levels are high.

If you are feeling unwell

①



Contact your diabetes team for information and advice

②



Stay hydrated and eat little and often

③



Your diabetes team may tell you to stop taking some of your medicines until you feel better

If you can't keep food down:

- Eat carbohydrate-rich snacks to give you energy
- Sip sugary drinks – letting fizzy drinks go flat may help keep them down
- Suck on glucose tablets or sweets like jelly beans

You shouldn't make any changes to your medication without speaking to your diabetes team

④



Check your blood glucose more often
At least 4 times a day, including at night

Check for ketones (if possible)

If you have got the equipment, check for ketones if your blood glucose is 15 mmol/l or more (13 mmol/l if you use an insulin pump); contact your diabetes team if ketones are present

If you are unable to eat or drink, your diabetes team may advise you to stop taking Invokana

- Diabetic ketoacidosis (DKA) is a serious side-effect that could happen if you are feeling unwell and taking Invokana or other sodium-glucose co-transporter 2 (SGLT2) inhibitors (names ending in ‘flozin’ e.g. canagliflozin, dapagliflozin, empagliflozin, ertugliflozin). See Page 16 for more information about DKA
- Your diabetes team might test your ketones, or ask you to test yourself if you’ve got the equipment, even if your blood glucose isn’t higher than normal

Your diabetes team may ask you to stop taking these medicines temporarily:

- **Angiotensin-converting enzyme (ACE) inhibitors** (names ending in ‘pril’ e.g. ramipril, lisinopril)
- **Diuretics** (sometimes called water pills e.g. bendroflumethiazide)
- **Metformin**
- **Angiotensin-II receptor blockers (ARBs)** (names ending in ‘sartan’ e.g. losartan, valsartan, candesartan)
- **Non-steroidal anti-inflammatory drugs (NSAIDs)** (anti-inflammatory pain killers e.g. ibuprofen, diclofenac, naproxen)

Other medicines:

- **Glucagon-like peptide 1 (GLP-1) receptor agonists** (names ending in ‘tide’ e.g. exenatide, liraglutide, lixisenatide, dulaglutide)
 - if you have abdominal pain and you are feeling or being sick, your diabetes team may ask you to stop taking this medicine and seek urgent medical attention
- **Sulphonylureas** (names ending in ‘ide’ e.g. gliclazide, glimepiride)
 - your diabetes team might increase the dose, or even start insulin injections while you’re ill; if you can’t eat normally, you may need meal replacements

Seek medical help **immediately** if you are vomiting, drowsy, unable to keep fluids down or have persistent diarrhoea

Foot care^{2,8,9}

The best way to prevent foot problems, including amputation, and other severe diabetes complications is to manage your blood glucose.

Checking your feet regularly can help identify and treat any problems quickly and reduce the chance of amputation. Everyone with diabetes should have foot check-ups as part of their regular care routine. You can also help reduce the chance of problems with your feet by following a simple foot care routine at home.

If you find it difficult to reach your feet, or you don't feel you can see your feet well enough to check them properly, ask a family member, friend or carer to check them for you.

Every day



Check your feet



Check your toenails

If they are too long,
cut them carefully



Wash your feet

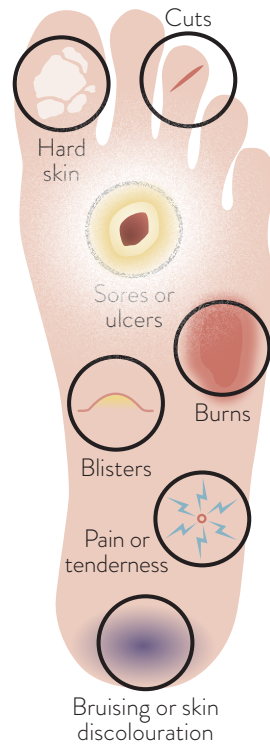
Use warm water and dry
them carefully, especially
between your toes

What should I look for?

Notify your diabetes team
immediately if you notice any
changes to your feet

Other advice

- Wear clean, well-fitting shoes and socks
- Be careful not to tie your shoelaces too tightly
- Don't walk around with bare feet, even indoors
- Follow any other advice given by your diabetes team about foot care and keeping hydrated



What can I do to help reduce my risk of side-effects?

Preventing genital infections

One of the common side-effects of Invokana for both men and women is genital infections, for example vaginal yeast infection. There are some things you can do to help prevent these infections from occurring:

- Wash the area with warm water and avoid using perfumed soaps, shower gels, or douches
- Avoid using latex condoms, spermicidal creams or lubricants if they irritate your genital area
- Avoid wearing tight-fitting underwear
- Wear cotton underwear and loose-fitting trousers and skirts
- Wash your hands thoroughly after going to the toilet

If you do get an infection, treatment is available at your local pharmacy or from your doctor.

Preventing dehydration

It is important to stay hydrated. You can prevent dehydration by drinking plenty of fluids through the day; you should aim to drink about six to eight glasses of fluid every day.¹⁹

Resources



Useful websites

There are a number of reliable information sources available online that provide advice on diet, exercise and healthy living for people with diabetes.

The websites below are a good place to start:

www.diabetes.org.uk

www.nhs.uk

www.diabetes.co.uk

www.mydiabetesmyway.scot.nhs.uk

My diabetes medicines

List your diabetes medicines and the doses you take here.

Speak to your diabetes team if you need any help.

| My medicines | Dosage | Notes |
|-----------------------------|--------|-------|
| Invokana (canagliflozin) | | |
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Questions for my next diabetes appointment

You may find it helpful to think of some questions to ask your diabetes team when you next discuss your diabetes.

Below are some examples of questions you could ask, but think about any concerns you have about your diabetes that you would like to talk about.

Blood glucose

- How often should I check my blood glucose?
- What should my blood glucose level be?
- What should I do if my blood glucose is too low or too high?

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Self-management

- What foods can I eat?
- How much weight do I need to lose?
- How much exercise do I need to do?
- What type of exercise should I do?

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Complications

- If I become ill should I stop taking my medication?
- Should I start seeing specialists to prevent any complications e.g. eye doctor, foot specialist?
- What can I do to help prevent heart disease?

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Other questions

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Weight

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Date

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eGFR (blood test of kidney function)

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Date

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ACR (urine test of kidney function)

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Further information

For further information contact Napp Medical Information on 01223 424444 or speak to your diabetes team

Key advice



Because Invokana increases the frequency of urination, it's important you drink plenty of fluids to stay hydrated (6 – 8 glasses of water a day)



You also need to maintain good genital hygiene to reduce the risk of urinary tract infections and other infections



A good foot care routine helps to identify problems quickly – regularly check your feet and toenails