

INVOKANA[®] (canagliflozin) you and your medicine

*For patients who have been prescribed INVOKANA[®]
for the treatment of type 2 diabetes*



WHY AM I BEING PRESCRIBED ANOTHER MEDICINE?



Each person with diabetes is different. As time goes by your doctor or nurse will need to personalise and develop a medicine routine that lowers your blood glucose.

This may mean adding and/or taking away medicines. You and your HCP have agreed that INVOKANA® is a medicine you should start taking.

INVOKANA® (also called canagliflozin) is a type of medicine called an SGLT2 inhibitor, which works by removing sugar (glucose) from the body in the urine. This reduces the amount of sugar in the blood.

WHAT IS INVOKANA®?

INVOKANA® (also called canagliflozin) is a medicine used to treat type 2 diabetes.

HOW DOES INVOKANA® WORK?

INVOKANA® is a type of medicine called a sodium glucose transporter 2 (also known as SGLT2) inhibitor that with a healthy eating plan and increased activity can help control your blood sugar (sometimes referred to as glucose).

It works in your kidneys to remove the extra sugar from your body by letting it pass into the urine.

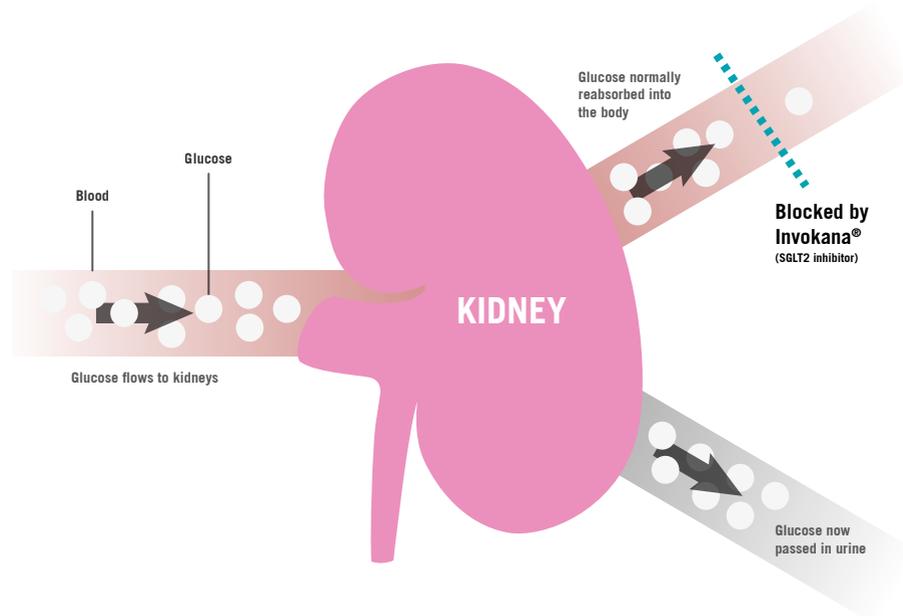
It is important to keep following advice about healthy eating and increased activity plan given by your nurse or doctor and continue any other medicines given to you. If you are following a diabetic weight control diet, continue to follow it while you are taking this medicine.



HOW DO MY KIDNEYS WORK?

Your kidneys act as a filtering and cleaning system for your body. Waste products are taken from the bloodstream and leave your body when you urinate.

Your kidneys filter sugar, water, salt and other small substances and then reabsorbs some back into the bloodstream, and eliminates some into the urine. This therefore maintains healthy levels of these substances in the blood.



HOW SHOULD I TAKE INVOKANA®?

Usually people will be started on the 100mg tablet, sometimes the dose may be increased to 300mg. This will be discussed with you.

This medicine is taken once a day:

- Swallow the tablet whole
- You can take your tablet with or without food
- Try to take it at the same time each day. This will help you remember to take it. The recommended time to take your tablet is before the first meal of the day

INVOKANA® can be prescribed by itself but it is more likely that it will be used along with one or more other medicines you may be taking to treat your type 2 diabetes, including injectable medicines.

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. As you get better you can discuss with your nurse, doctor or pharmacist.

Make sure you take your medicine as prescribed by your nurse, doctor or pharmacist. If you are unsure then you should check with them.

WHAT IF I FORGET TO TAKE MY TABLET?

If you miss your daily tablet it should be taken as soon as you can.

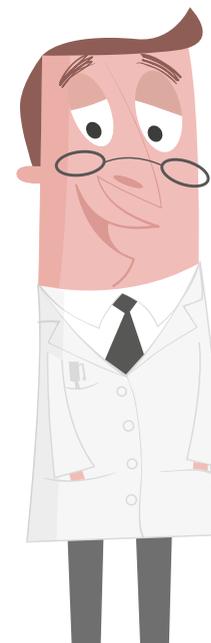
Do not take 2 tablets in the same day.

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 remind to take their medication.

WHAT POTENTIAL SIDE EFFECTS SHOULD I BE AWARE OF?

Like all medicines, INVOKANA® may cause side effects although not everybody gets them. Most side effects are mild to moderate but some people could experience a more serious side effect, and some of the side effects may need treatment. Most of the side effects you could get with INVOKANA® are the result of losing sugar/glucose in the urine.

Tell your nurse, doctor or pharmacist if you notice any of the following side effects as you may need medical treatment:



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

Diabetic Ketoacidosis

Rare (may affect up to 1 in 1,000 people)

What you need to know?

Talk to your doctor, pharmacist or nurse before taking this medicine and during treatment if you experience:

- 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.

- Contact a doctor or the nearest hospital straight away. These symptoms could be a sign of “diabetic ketoacidosis” – a 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.

This may occur regardless of blood glucose level. Your doctor may decide to temporarily or permanently stop your treatment with Invokana.

Hypoglycaemia

Very common (may affect more than 1 in 10 people) when Invokana is added with insulin or sulphonylurea.

Hypoglycaemia or “hypos” happen when you don’t have enough glucose in your blood to allow your body to function properly.

Possible signs of hypoglycaemia are:

- Feeling hungry
- Trembling
- Sweating
- Anxiety and irritability
- Paleness
- Fast pulse and palpitations
- Tingling of lips
- Blurred vision

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

Vulvovaginal Candidiasis

More commonly known as vaginal thrush.

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

The symptoms include itching, soreness, irritation, a stinging sensation when you urinate, pain or discomfort in that area or vaginal discharge, which is usually odourless. Treatment for vaginal thrush is available at your local pharmacy or from your doctor.

To reduce your risk of developing vaginal thrush, NHS choices recommends that you:

- Wash your vaginal area with water and avoid using perfumed soaps, shower gels, vaginal deodorants or douches
- Avoid using latex condoms, spermicidal creams or lubricants if they irritate your genital area
- Avoid wearing tight-fitting underwear or tights
- Wear cotton underwear and loose-fitting trousers and skirts

Balanitis or balanoposthitis

Common (may affect up to 1 in 10 men)

Usually caused in this case by a yeast infection, balanitis or balanoposthitis is inflammation of the penis or foreskin affecting men and boys. It is more common in men who have not been circumcised. Symptoms of balanitis include swelling, redness and soreness of the end of the penis. There might also be a thick discharge under the foreskin.

To reduce your risk of developing Balanitis, NHS choices recommends that you:

- Keep your penis clean by washing it with warm water twice a day
- Avoid using soap and other irritants. You could use aqueous cream as a substitute
- Wash your hands thoroughly after going to the toilet

Treatment for balanitis is available at your local pharmacy or from your doctor.

For more information please visit NHS choices website:

<http://www.nhs.uk/Conditions/Balanitis/Pages/Introduction.aspx>

Other common side effects include:

- Urinary tract infections
- 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)

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed.

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:

- Thirst
- Sleepiness
- Headache
- Constipation
- Little or no urination
- Dry mouth
- Dry skin
- Lightheadedness or dizziness

Other uncommon side effects include:

- Hives
- Rash or red skin – this may be itchy and include raised bumps, oozing fluid or blisters
- Blood tests may show changes related to kidney function (creatinine or urea) or potassium

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed.

WHAT ELSE SHOULD I KNOW ABOUT INVOKANA?

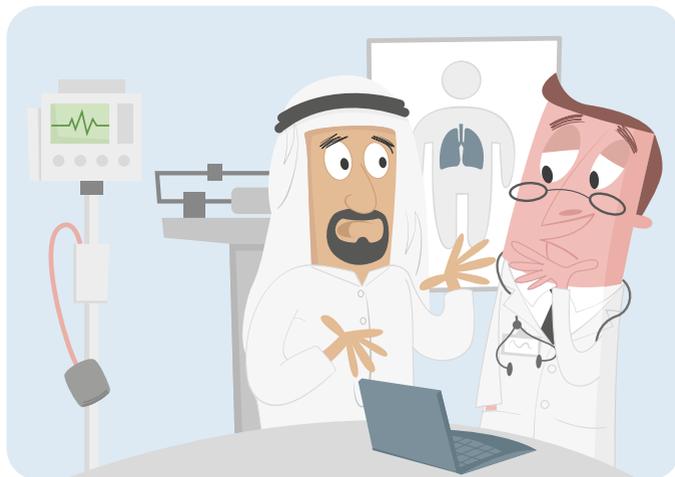
Weight loss

Although INVOKANA® is not a weight loss management drug, the way it works may result in you losing some weight (2-4 kg or 4-9 lbs) when you start taking this medicine. Talk to your nurse, doctor or pharmacist about this if you need any more information.

Blood Pressure

INVOKANA® is not a blood pressure management medicine, but due to the way it works it can also lower blood pressure. It is possible that you may get symptoms as a result of this blood pressure drop including feeling dizzy or faint after standing quickly.

Please see your doctor if you have any of these symptoms.



GLOSSARY

Type 2 diabetes: is a progressive condition (it advances over time), in which your body does not make enough insulin and/or use it effectively.

Insulin: Insulin is a natural hormone, created by the pancreas (an organ near your stomach). Insulin's job is to allow glucose (sugar) from the blood into your body's cells to use as energy. There are also 'insulins' in an injection that are used to treat diabetes when your body does not make enough.

Blood sugar: Your blood sugar (also known as blood glucose) is the amount of sugar in your blood. Your doctor or nurse can measure this with a blood test.

Hypoglycaemia: Hypoglycaemia means an abnormally low level of sugar (glucose) in the blood. When your glucose level is too low, your body does not have enough energy to carry out its activities. This is described as a 'hypo'.

Vaginal thrush: Thrush is a yeast infection, usually caused by a yeast-like fungus called *Candida albicans*. Problems arise when the natural balance in the vagina is upset and *Candida* multiplies.

Dehydration: when your body loses more fluid than you take in. When the normal water content of your body is reduced, it upsets the balance of minerals (salts and sugar) in your body, which affects the way that it functions.

Notes

Notes

Any suspected adverse events should be reported to the national spontaneous reporting system according to the national regulations.

SFDA (National pharmacovigilance and drug safety Center)

Email to: npc.drug@sfda.sa

Fax: 2057662-11-966+

Online: <http://ade.sfda.gov.sa/>

Toll free number: 8002490000

Or you can contact company scientific office at:

Email: GCC-PV2@its.jnj.com

Fax: 2153190-11-966+



