



SGLT-2 inhibitors have a potential rare side effect also known as Fournier's gangrene. The medication is used in the treatment of Type 2 Diabetes, Chronic Kidney Disease and Heart Failure

This leaflet was adapted from an information sheet from Brook Medical Centre

Who is this leaflet for?

This leaflet is for those taking, or about to take an SGLT-2 inhibitor drug to improve the treatment of your diabetes, chronic kidney disease or heart failure. The name of these drugs end with 'gliflozin'. Examples include:

- empagliflozin (Jardiance®)
- dapagliflozin (Forxiga®)
- canagliflozin (Invokana®)
- ertugliflozin (Steglatro®).

Research has found that there are some very rare but important side effects which appear to be more common in patients taking these drugs. You should be aware of these potential side effects as if they are not identified early, they can be extremely dangerous and life threatening.

What is this side effect?

Extremely rare but life-threatening bacterial infection of the tissue under the skin that surrounds muscles, nerves, fat, and blood vessels around the genital area. This is a rare serious infection, called necrotizing fasciitis of the perineum (Necrosis meaning: body tissue is dead or is dying because of a lack of blood flow or a bacterial infection. In this case includes the testicles, penis, and the perineum which is the area between the scrotum and anus for a man; or the area between the anus and vulva for a woman) is also referred to as Fournier's gangrene. If treatment is delayed it can be fatal. If you have any of these symptoms, please contact a medical professional, such as a doctor or nurse immediately, even if your blood sugars are near normal. If your GP practice is closed, please call the NHS 111 service, by dialling 111, for more advice. Tell them that you are worried about one of the conditions above. Stop this medication until you have further medical advice.

How common are these side effects?

Fournier's gangrene can occur in people who do not have diabetes, but is more common in people with diabetes. It is estimated to occur in approximately 1 in 100,000 patients treated with an SGLT-2 inhibitor. Most cases of Fournier's gangrene occur in men, but in patients treated with SGLT2 inhibitors it can also occur in women.

What should I look out for?

The following symptoms might indicate Fournier's gangrene: Tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum, and have a fever above 100.4 F (38C) or a general feeling of being unwell. These symptoms can worsen quickly, so it is important to seek treatment right away.

What if I am having major surgery?

Please stop this medication 24 hours before your surgery. Restart only after you are fully mobile and eating and drinking normally.

If I feel unwell, what will my doctor or nurse do?

You will have a finger prick blood test to test for the amount of glucose and ketones (a breakdown product of fat) in your blood. If the levels of ketones are high, you will likely require hospital treatment. If Fournier's gangrene is suspected you will require prompt hospital treatment with broad-spectrum antibiotics and surgical debridement if necessary.

PLEASE REVIEW PAGE TWO FOR FURTHER IMPORTANT INFORMATION

Type 2 Diabetes Sick Day Rules

If you become unwell ensure you:

- Stay hydrated
- Maintain food intake
- Never stop insulin, you may have to adjust the dose
- Increase the frequency of blood glucose testing if you have this option

If you are unable to eat and drink as normal:

- Stop SGLT2 inhibitor medication until you feel better (Gliflozin medications)
- Stop taking the diabetes medication below until you feel well again and are eating and drinking normally:
 - Metformin
 - Sulfonylureas e.g. gliclazide, glipizide
 - GLP-1 analogues (weekly injections or Rybelsus tablets)
- Stop taking the other medications below until you feel well again and are eating and drinking normally:
 - Diuretics (water pills) e.g. furosemide, bumetanide, bendroflumethiazide, indapamide
 - ACE inhibitors – names ending in “pril” e.g. ramipril, lisinopril
 - ARBs – names ending in “sartan” e.g. candesartan, losartan, irbesartan
 - NSAIDs – anti-inflammatory pain killers e.g. ibuprofen, naproxen diclofenac
- Drink regularly to avoid dehydration
- Seek medical advice if you have any ongoing infection or illness more than 24 hours
- If you are able to check your sugar levels seek medical attention if you levels are persistently over 18 mmol/L
- If you are able to check blood ketone levels then a level of >0.6 mmol/L would mean you should seek urgent medical advice or telephone 111

Diabetic Ketoacidosis (DKA)

DKA is a potentially life-threatening condition which can affect people who have diabetes. It is caused by a lack of insulin in the body. Without enough insulin, the body is unable to use glucose in the blood for fuel and starts to break down fat instead. These results in the production of acids called ketones.

High levels of acid (ketones) are harmful and can be fatal. DKA is a medical emergency and requires urgent treatment in hospital with careful monitoring, and insulin and fluids through an intravenous (IV) drip.

It is important to learn how to recognise symptoms of DKA and to seek medical help promptly.

Seek immediate medical attention if you experience:

- Nausea and vomiting
- Abdominal pain
- Unexpected drowsiness or extreme tiredness
- Over breathing and possible smell or taste of pear drops (acetone) on breath
- DKA is possible even if glucose levels are normal. Do not rely on urine ketone checks (levels are reduced by SGLT-2 inhibitors) but have blood ketones measured at your surgery or local hospital