

SGLT-2 inhibitors and rare side effect also known as Fournier's gangrene in Type 2 Diabetes, Chronic Kidney Disease and Heart Failure

Why have I been given this leaflet?

You have been given this leaflet because you are taking, or are 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®)
- canagliflozin (Invokana®)
- dapagliflozin (Forxiga®)
- 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) this 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 keep this leaflet for future information

This leaflet is for your information only but if you have any concerns please speak to the pharmacist either at the pharmacy or at the surgery. These side effects are very rare but it is important people are aware of them.