

SGLT-2 inhibitors and associated rare side effects

Why have I been given this leaflet?

You have been given this leaflet for information only as 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 you should be aware of while taking this type of medication.

This leaflet is for information only and there is no need to contact the practice. However, it is important that you are aware of these potential rare side effects, because if they are not identified early, they can be extremely dangerous.

What are these side effects?

- The first is called **diabetic ketoacidosis**, a condition in which there is too much acid in the blood. This can very rarely happen in some people with type 2 diabetes and these drugs can increase this risk **even when the blood glucose concentration is normal**.
- The second is called **Fournier's gangrene**. This is a very rare and severe spreading skin infection in the genital or groin area which leads to abscesses and skin destruction. If treatment is delayed it can be fatal.

How common are these side effects?

- **Diabetic ketoacidosis** is estimated to occur in between **1 in 1,000** and **1 in 10,000** patients treated with an SGLT-2 inhibitor.
- **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. This appears to be approximately 12 times more common than in patients treated with other diabetes drugs. Most cases of Fournier's gangrene occur in men, but in patients treated with SGLT-2 inhibitors it can also occur in women.

What should I look out for?

The following symptoms might indicate **diabetic ketoacidosis**: nausea, vomiting, fast breathing, abdominal pains, unusual drowsiness or fever.

The following symptoms might indicate **Fournier's gangrene**: severe pain, tenderness, redness, or swelling in the genital or groin area accompanied by fever or a general feeling of being unwell.

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.

Is there anything more likely to cause diabetic ketoacidosis?

- Any conditions leading to restricted food intake or severe dehydration.
- You need to be especially careful if you develop an infection (like a chest or urine infection) or undergo surgery.
- If you are planning to have a minor operation, or any other procedure which involves fasting overnight, we suggest you stop your SGLT-2 tablets on the day of the procedure.
- Alcohol misuse.

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 intravenous antibiotics and possibly surgery.

Please keep this leaflet for future information.

If you have any general medication questions

If you have any general medication questions, please get in touch with the practice in the usual way. If required we can arrange an appointment with one of our Practice Pharmacists or a GP.