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SGLT-2 inhibitors and rare side effects in type 2 diabetes

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. 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 associated with diabetes 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.

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 1000 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 SGLT2 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 malaise.

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 abuse.

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.