



# Food and Drugs Authority

Head Office  
P. O. Box CT 2783,  
Cantonments, Accra-Ghana  
Tel: (+233-302)233200, 235100  
Fax: (+233-302)229794, 225502  
Email: fda@fdaghana.gov.gh

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Dear Healthcare Professional

## **RARE OCCURRENCES OF A SERIOUS INFECTION OF THE GENITAL AREA WITH SODIUM-GLUCOSE COTRANSPORTER-2(SGLT2) INHIBITORS FOR DIABETES**

The Food and Drugs Authority would like to notify you of a drug safety communication published by the US Food and Drugs Administration regarding warning about cases of a rare but serious infection of the genitals and area around the genitals reported with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors<sup>1</sup>.

SGLT2 inhibitors are approved by the Food and Drugs Authority for use with diet and exercise to lower blood sugar in adults with type 2 diabetes. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine.

The serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. Fournier's gangrene is an extremely rare but life-threatening bacterial infection of the tissue under the skin that surrounds muscles, nerves, fat, and blood vessels of the perineum. The bacteria usually get into the body through a cut or break in the skin, where they quickly spread and destroy the tissue they infect. Having diabetes is a risk factor for developing Fournier's gangrene; however, this condition is still rare among diabetic patients.

### **Advice to Patients:**

Patients should **seek medical attention immediately** if they experience any symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum, and have a fever above 38°C or a general feeling of being unwell.

### **Advice to Health care professionals:**

Healthcare professionals should assess patients who present with the symptoms above for Fournier's gangrene. Treatment should start immediately with broad-spectrum antibiotics and surgical debridement as necessary if Fournier's gangrene is suspected, SGLT2 inhibitors should be discontinued. The blood glucose levels should be closely monitored and appropriate alternative therapy given for glycemic control.

SGLT2 containing-medicines registered for use in Ghana are Forxiga (Dapagliflozin) tablets, Invokana (Canagliflozin) tablets and Vokanamet

<sup>1</sup> <https://www.fda.gov/Drugs/DrugSafety/ucm617360.htm>

The FDA will like to advice healthcare professionals to educate patients on the possible side effect of all medicines and also report these to the FDA by completing the Adverse Reaction Reporting Form or online using the link <http://adr.fdaghana.gov.gh>/or call 024 431 0297 or send an email to [drug.safety@fdaghana.gov.gh](mailto:drug.safety@fdaghana.gov.gh).

Yours faithfully,

Signed

SETH K. SEANEKE (MR)  
AG. DCE, DRUG REGISTRATION AND INSPECTORATE DIVISION  
FOR: CHIEF EXECUTIVE OFFICER