



Direct Healthcare Professional Communication

Oct. 2025

SGLT2 inhibitors: Reminder to prevent the risks of diabetic ketoacidosis and Fournier's gangrene (perineal necrotizing fasciitis)

Dear Healthcare Professional,

MAH, in agreement with the General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority, would like to inform you of the following:

Summary:

Fournier's gangrene:

- Post- marketing cases of Fournier's gangrene (necrotizing fasciitis of the perineum) have occurred with the use of SGLT2 inhibitors.
- Fournier's gangrene is a rare but serious and potentially life-threatening infection.
- Urogenital infection or perineal abscess may precede necrotizing fasciitis.
- Advise patients to seek emergency care if they experience severe pain, tenderness, erythema, or swelling of the genitals or perineum, accompanied by fever or general malaise
- If Fournier's gangrene is suspected, the SGLT2 inhibitor should be discontinued and treatment should be initiated immediately (antibiotics and surgical debridement).

Diabetic Ketoacidosis

- Patients presenting with non-specific symptoms like nausea, vomiting, or confusion must be immediately evaluated for **diabetic ketoacidosis (DKA)**, regardless of their blood glucose levels, and if DKA is suspected or diagnosed, treatment with the relevant medication **must be interrupted** and managed with **insulin** and supportive care

Background

Fournier's gangrene

SGLT-2 inhibitors are indicated for the treatment of type 2 diabetes mellitus. Cases of Fournier gangrene have been reported within the SGLT-2 inhibitor class. Although type 2 diabetes mellitus is a risk factor for the development of Fournier gangrene, some of the reported post-marketing cases are considered possibly related to SGLT-2 inhibitor.

Patients should be advised to seek medical advice if they develop symptoms such as pain, tenderness, erythema, or swelling in the genital or perineal area, accompanied by fever or malaise. It should be borne in mind that necrotizing fasciitis may be preceded by a urogenital infection or perineal abscess. If Fournier's



gangrene is suspected, SGLT-2 inhibitor class should be discontinued and prompt treatment (including antibiotics and surgical debridement) should be initiated.

Diabetic Ketoacidosis

The majority of cases of diabetic ketoacidosis reported in patients receiving SGLT2 inhibitor therapy required hospitalization. Many of these cases occurred within the first 2 months of treatment. In some cases, just before or at the same time as the onset of ketoacidosis, patients experienced dehydration, decreased food intake, weight loss, infection, surgery, vomiting, a decrease in their insulin dose, or inadequate control of their diabetes.

In some atypical cases, moderately elevated blood glucose levels or levels below 14 mmol/L (250 mg/dL) have been reported, while hypoglycemia was reported in one case. Cases of ketoacidosis have also been described shortly after discontinuation of SGLT2 inhibitors.

The mechanism by which diabetic ketoacidosis occurs when taking SGLT2 inhibitors is not established. Diabetic ketoacidosis usually develops when insulin levels are too low.

Diabetic ketoacidosis occurs more frequently in patients with type 1 diabetes and is usually accompanied by elevated blood glucose levels (>14 mmol/L). However, the cases mentioned above involved patients with type 2 diabetes, and in a number of cases, blood glucose levels were only slightly elevated, unlike typical cases of diabetic ketoacidosis.

Reference

<https://ansm.sante.fr/informations-de-securite/forxiga-r-10-mg-dapagliflozine-xigduo-r-dapagliflozine-metformine-recommandations-pour-prevenir-les-risques-dacidocetose-diabetique-et-de-gangrene-de-fournier-fasciite-necrosante-perineale>

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: : <https://vigiflow-eforms.who-umc.org/eg/med>

QR Code:

Hotline: 15301

