Saudi Food & Drug Authority (SFDA)

SAFETY COMMUNICATION

04/09/2018

The Risk of Rare but Serious Infection in the Genital Area with Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors

The Saudi Food and Drug Authority (SFDA) would like to notify healthcare professionals (HCPs) about the possible occurrence of a rare but serious infection in the genitals and area around the genitals while using sodium-glucose cotransporter-2 (SGLT2) inhibitors. This extremely rare but life-threatening bacterial infection is called necrotizing fasciitis of the perineum, and is also known as Fournier's gangrene.

SGLT2 inhibitors is a class of oral antidiabetic medications that is approved for the management of type 2 diabetes in adjunct to diet and exercise. The current SFDA-approved drugs in this class include canagliflozin, dapagliflozin, and empagliflozin (listed below). This concern emerged from a number of internationally reported cases of necrotizing fasciitis of the perineum, which occurred within months after starting the treatment with SGLT2 inhibitors.

The SFDA urges healthcare providers to perform a full assessment for Fournier's gangrene when patients present with symptoms that include edema, redness, or tenderness of the genitals, the area around it or around the rectum, which is often accompanied by fever and general lethargy. If this condition is suspected, the patient must be treated with broad-spectrum antibiotics immediately, and surgical debridement should be performed if needed. The SFDA also recommends physicians and pharmacist to counsel patients who use SGLT2 inhibitors to immediately seek medical attention if the aforementioned symptoms occur.

The SFDA will continue to closely monitor the safety of SGLT2 inhibitors and will update healthcare providers upon the emergence of any new safety information.

SFDA-Approved SGLT2 Inhibitors:

Trade Name	Generic Name
Jardiance	empagliflozin
Invokana	canagliflozin
Forxiga	dapagliflozin
Synjardy	empagliflozin and metformin
Xigduo XR	dapagliflozin, and metformin

Report Adverse Drug Events (ADEs) to the SFDA

The SFDA urges healthcare professionals to report ADEs resulted from involving SGLT2 inhibitors or other medicines to the SFDA using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Reporting hotline: 19999
Fax: 01 2057662
Email: npc.drug@sfda.gov.sa
Webpage: http://ade.sfda.gov.sa