

Alerts and Recalls

Generic Name (Trade Name) Company

Uses/Notes

August 30, 2018

Sodium–glucose cotransporter-2 inhibitors

[FDA is warning](#) that cases of a rare but serious infection of the genitals and area around the genitals have been reported with sodium–glucose cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier’s gangrene. FDA said it is requiring a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient [Medication Guide](#).

SGLT2 inhibitors are FDA-approved for use with diet and exercise to lower blood glucose levels in adults with type 2 diabetes. First approved in 2013, medicines in the SGLT2 inhibitor class include canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin. In addition, empagliflozin is approved to lower the risk of death from heart attack and stroke in adults with type 2 diabetes and heart disease. Untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease.

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 100.4 F or a general feeling of being unwell. These symptoms can worsen quickly, so it is important to seek treatment right away.

Health professionals should assess patients for Fournier’s gangrene if they present with the symptoms described above. If suspected, start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary. Discontinue the SGLT2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

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

(Multiple trade names—Multiple companies) 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 patients with diabetes.

FDA warns about rare occurrences of a serious infection of the genital area with SGLT2 inhibitors

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<http://www.aphanet.org/alerts-and-recalls/fda-warns-about-rare-occurrences-serious-infection-genital-area-sgl2-inhibitors>

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