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

Safety Announcement



[8-29-2018] The U.S. Food and Drug Administration (FDA) is warning that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. We are requiring a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide (</drugs/drug-safety-and-availability/medication-guides>).

SGLT2 inhibitors are FDA-approved 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. First approved in 2013, medicines in the SGLT2 inhibitor class include canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin (see FDA-Approved SGLT2 Inhibitors). 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 you 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 care 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 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. Overall published literature about the occurrence of Fournier’s gangrene for men and women is very limited. Publications report that Fournier’s gangrene occurs in 1.6 out of 100,000 males annually in the U.S., and most frequently occurs in males 50-79 years (3.3 out of 100,000).¹⁻³ In our case series, however, we observed events in both women and men.

In the five years from March 2013 to May 2018, we identified 12 cases of Fournier’s gangrene in patients taking an SGLT2 inhibitor. This number includes only reports submitted to FDA* and found in the medical literature,⁴⁻⁶ so there may be additional cases about which we are unaware. In 2017, an estimated 1.7 million patients received a dispensed prescription for an SGLT2 inhibitor from U.S. outpatient retail pharmacies.⁷ Although most cases of Fournier’s gangrene have previously been reported in men, our 12 cases included 7 men and 5 women. Fournier’s gangrene developed within several months of the patients starting an SGLT2 inhibitor and the drug was stopped in most cases. All 12 patients were hospitalized and required surgery. Some patients required multiple disfiguring surgeries, some developed complications, and one patient died. In comparison, only six cases of Fournier’s gangrene (all in men) were identified in review of other antidiabetic drug classes over a period of more than 30 years.

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving SGLT2 inhibitors or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

*The cases were reported to the FDA Adverse Event Reporting System (FAERS) ([/fda-adverse-event-reporting-system-faers](https://www.fda.gov/oc/ohrt/faers)).

FDA-Approved SGLT2 Inhibitors

Brand Name	Active Ingredient(s)
Invokana	canagliflozin
Invokamet	canagliflozin and metformin
Invokamet XR	canagliflozin and metformin extended-release
Farxiga	dapagliflozin
Xigduo XR	dapagliflozin and metformin extended-release
Qtern	dapagliflozin and saxagliptin
Jardiance	empagliflozin
Glyxambi	empagliflozin and linagliptin
Synjardy	empagliflozin and metformin
Synjardy XR	empagliflozin and metformin extended-release
Steglatro	ertugliflozin
Segluromet	ertugliflozin and metformin
Steglujan	ertugliflozin and sitagliptin

- Facts about SGLT2 Inhibitors** ▼
- Additional Information for Patients** ▼
- Additional Information for Health Care Professionals** ▼
- Data Summary** ▼
- References** ▼

[en Español \(/drugs/drug-safety-and-availability/la-fda-advierte-acerca-de-casos-poco-frecuentes-de-una-infeccion-grave-del-area-genital-con-los\)](#)

[Drug Safety Communication \(/media/115602/download\) \(PDF - 74KB\)](#)

Related Information

- [Sodium-glucose Cotransporter-2 \(SGLT2\) Inhibitors \(/drugs/postmarket-drug-safety-information-patients-and-providers/sodium-glucose-cotransporter-2-sgl2-inhibitors\)](#)
- [Necrotizing Fasciitis \(https://www.cdc.gov/Features/NecrotizingFasciitis/\)](https://www.cdc.gov/Features/NecrotizingFasciitis/)
- [The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective \(/drugs/information-consumers-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective\)](#)
- [Think It Through: Managing the Benefits and Risks of Medicines \(/drugs/information-consumers-drugs/think-it-through-managing-benefits-and-risks-medicines\)](#)