

04 February 2019

## **Risk of Fournier's gangrene (necrotising fasciitis of the perineum) with Sodium-Glucose-Co-Transporter 2 inhibitors (SGLT2i)**

### **Direct Healthcare Professional Communication**

Dear Healthcare Professionals,

In agreement with the Saudi Food and Drug Authority (SFDA), Johnson & Johnson Middle East FZ Branch would like to inform you of the following regarding products containing SGLT2 inhibitors, including Invokana (canagliflozin).

### **Summary**

- Post-marketing cases of Fournier's gangrene (necrotising fasciitis of the perineum) have been associated with the use of SGLT2 inhibitors.
- Fournier's gangrene is a rare but serious and potentially life-threatening infection
- Uro-genital infection or perineal abscess may precede necrotizing fasciitis
- Advise patients to seek urgent medical attention if they experience severe pain, tenderness, erythema, or swelling in the genital or perineal area accompanied by fever or malaise
- If Fournier's gangrene is suspected, stop the SGLT2 inhibitor and promptly start treatment (including antibiotics and surgical debridement).

### **Background on the Safety Concern**

Cases of Fournier's gangrene have been reported across the class of SGLT2 inhibitors. Although diabetes mellitus is a risk factor for the development of Fournier's gangrene, some of the post-marketing reports are considered possibly related to the use of SGLT2 inhibitors.

Fournier's gangrene is known to occur almost exclusively in men. However, in association with SGLT2 inhibitors it was also reported in women.

The product information will be revised to list Fournier's Gangrene as adverse reaction in section 4.8 and will also include respective warning statements in section 4.4 of the SmPC as outlined in the summary above.

**The information in this letter has been approved by Saudi Food & Drug Authority (SFDA).**

**Call for Reporting**

Healthcare professionals are encouraged to report adverse events in patients taking Invokana in accordance with the national spontaneous reporting system.

**SFDA (National Pharmacovigilance and Drug Safety Department)**

**Email:** [npc.drug@sFDA.gov.sa](mailto:npc.drug@sFDA.gov.sa)

**Telephone:** 8002490000

**Fax:** +966 11 2057662


**Online:** <http://ade.sFDA.gov.sa>

If you have any further questions or require additional information, please contact out Local Safety Department at:

**Email:** [GCC-PV2@its.jnj.com](mailto:GCC-PV2@its.jnj.com)

**Fax:** +966 11 2153190

Yours faithfully,

  
4. Feb. 2019

**Hesham Atef**

**Medical Affairs Director - GCC**