

15 April 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), AstraZeneca-Saudi Arabia, would like to inform you of the following regarding products containing SGLT2 inhibitor, including Forxiga (dapagliflozin) and Xigduo XR (Dapagliflozin/Metformin).

### **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.

**Call for reporting**

Healthcare professional are encouraged to report suspected adverse drug reactions associated with the use of Forxiga (Dapagliflozin) or Xigduo XR (Dapagliflozin/Metformin) to:

**AstraZeneca-Saudi Arabia  
Pharmacovigilance Department**  
Phone Number: +966112249235  
Email: [EventsKSA.Adverse@astrazeneca.com](mailto:EventsKSA.Adverse@astrazeneca.com)

**Saudi Food and Drug Authority  
National Pharmacovigilance and Drug Safety Center**  
Land Line: 19999  
Website: [https://:ade.sfda.gov.sa](https://ade.sfda.gov.sa)  
Email: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)  
Fax: +96612057662

**Note.** For extra copies, please call +966112249235 or send an email to [EventsKSA.Adverse@astrazeneca.com](mailto:EventsKSA.Adverse@astrazeneca.com)

Your Faithfully,  
Dr Maher Al Matar, PhD



Qualified Person Responsible for Pharmacovigilance