

Direct Healthcare Professional Communication on the association of Sodium-Glucose-Co-Transporter 2 inhibitors (SGLT2i) with Risk of Fournier's gangrene (necrotising fasciitis of the perineum)

16 Dec 2018

Dear Healthcare Professional,

In agreement with Saudi Food & Drug Authority (SFDA), Boehringer Ingelheim would like to inform you of Fournier's gangrene with Jardiance (empagliflozin), Synjardy (empagliflozin / 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).

Further information on the safety concern

SGLT2 inhibitors are indicated for the treatment of type 2 diabetes. Jardiance (empagliflozin), Synjardy (empagliflozin / metformin), 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 include respective warning statements in section 4.4 of the SPC as outlined in the summary above.

Further information on recommendations to healthcare professionals

- Assess patients if they present with symptoms described above and start treatment immediately with antibiotics, and if necessary, surgical debridement, in case Fournier's gangrene is suspected.
- Discontinue the SGLT-2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy.
- Counsel patients to promptly seek medical attention, if they experience any of the above mentioned symptoms. These symptoms can worsen quickly, and therefore it is important to seek treatment right away.

Call for reporting

Healthcare professionals are reminded to continue to report suspected adverse reactions associated with these products in accordance with the Saudi Vigilance spontaneous reporting system to:

The National Pharmacovigilance and Drug Safety Centre NPC

Email: npc.drug@sfd.gov.sa

Fax: +966112057662

Toll free phone: 8002490000

Website: <https://ade.sfda.gov.sa/>

In addition, suspected adverse reactions related Boehringer Ingelheim products may be reported to Boehringer Ingelheim

Pharmacovigilance department:

Email: PV_local_Saudi_Arabia@boehringer-ingelheim.com

Phone: +966-11-52044143

Company contact point

If you have further questions or require additional information, please contact medical information department email

information@boehringer-ingelheim.com

QPPV

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on behalf



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