

5 March, 2019

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

Dear Healthcare Professional

In collaboration with the Namibia Medicines Regulatory Council (NMRC),
Boehringer Ingelheim would like to inform you of the following:

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

SGLT2 inhibitors are indicated for the treatment of type 2 diabetes. The following SGLT2 inhibitor is currently authorised in Namibia: Jardiance (empagliflozin).

Our Reference: DHCPL SGLT
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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/Package Insert will be revised to list Fournier's Gangrene as an adverse reaction and will include respective warning statements as outlined in the summary above.

Healthcare professionals should report all suspected adverse events associated with the use of Jardiance (empagliflozin) to:

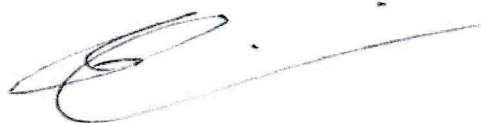
The Therapeutics Information and Pharmacovigilance Centre
Email: info.TIPC@mhss.gov.na
Fax: 088 660 6781
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Yours sincerely,

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NS2 Jardiance® 10 mg: Each film-coated tablet contains empagliflozin 10 mg. Namibia Reg. No. 15/21.2/0158

NS2 Jardiance® 25 mg: Each film-coated tablet contains empagliflozin 25 mg. Namibia Reg. No. 15/21.2/0159