

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عُمان
وزارة الصحة
المديرية العامة للصيرورة
والرقابة الدوائية
مسقط

To:

Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Health Institutions)
Director General of Health Services in all Governorates
Director of Rational Use of Medicine (MOH)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
Director of Pharmacy & Medical Stores in all Governorate (for distribution pls.)
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. ⁵⁸..... dated ^{6/9/2018}.....
regarding SGLT2 (sodium-glucose cotransporter-2) inhibitors for
diabetes.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Supdt. of Central Drug Information
- Head of Cordin. & FU



Circular No. 58 / 2018

26-12-1439 H

6-09-2018

SGLT2(sodium-glucose cotransporter-2) Inhibitors for Diabetes: Drug Safety Communication - Regarding Rare Occurrences of a Serious Infection of the Genital Area

Please be informed that the US Food & 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. FDA requires a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide.

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. 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 they 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.

There are different brands of SGLTs inhibitors registered in Oman with active ingredients for e.g. Canagliflozin, Dapagliflozin and Empagliflozin.

The healthcare professionals are kindly requested to report any adverse events or side effects associated with the use of the above product or any other medicinal product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.


Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

