Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
The Director General of Health Services in all Governorates
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies, MOH
Director General of Pvt. Health Est. (to kindly arrange distribution to all Pvt. Hospitals)
Director General of Primary Health Care, MOH
Director General of Specialised Medical Care, MOH
Director General of Quality Assurance Centre, MOH
Director General of Disease Surveillance and Control, MOH
Director of Rational Drug Use
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
All Private Pharmacies & Drug Stores

After Compliments,

Please find attached our Circular No. 72 dated 18/04/2022 regarding SGTL2 inhibitors and the risk of diabetic ketoacidosis (DKA).

- Copy to:
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Section Head (Drug Information)

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Circular No. 72 / 2022

16-09-1443 H
18-04-2022

SGTL2 inhibitors and the risk of DKA

The Directorate General of Pharmaceutical Affairs & Drug Control would like to share a new safety communication issued from the Therapeutic Goods Administration (TGA). The TGA has published the following safety updates about SGTL2 inhibitors and the risk of diabetic ketoacidosis (DKA):

Sodium glucose co-transporter 2 inhibitor products are approved for use in the management of type 2 diabetes mellitus - they are not approved for use in type 1 diabetes. Prescribers are reminded of the risk of diabetic ketoacidosis with the off-label use of these medicines.

Sodium glucose co-transporter 2 (SGLT2) inhibitors improve glycaemic control in patients with type 2 diabetes mellitus (T2DM) by reducing renal glucose reabsorption. Through inhibition of SGLT2 in these patients, excess glucose is excreted in the urine.

Due to continued local and international post-marketing reports of off-label use of SGLT2 inhibitors, these products are approved for use in the management of T2DM only. They are not approved for use in patients with type 1 diabetes mellitus (T1DM).

This applies to the SGLT2 inhibitors empagliflozin, dapagliflozin, ertugliflozin and canagliflozin.

The current Product Information (PI) for these medicines has not changed, and still includes lengthy warnings regarding the increased risk of DKA with SGLT2 inhibitor use in T1DM.

Based on data with sotagliflozin in T1DM, the United States Food and Drug Administration (FDA) estimated an 8-fold increase in the risk of ketoacidosis with an additional case of ketoacidosis being observed for every 26 patient-years of adjunctive therapy.

Adverse events reported to the TGA

In 2021, the TGA received 6 reports of off-label use with SGLT2 inhibitors in T1DM patients. Of these, 3 were associated with DKA, indicating that off-label prescribing of SGLT2 inhibitors in T1DM continues. The TGA considers that the seriousness of the risk of DKA requires an updated reminder for prescribers about the risks of off-label use of SGLT2 inhibitors in T1DM patients.

SGLT2 inhibitors should be used according to the PI, and T1DM is not an approved indication for these medicines.

Call to Report Suspected Adverse Drug Reactions

SGLT2 inhibitors: empagliflozin, dapagliflozin, ertugliflozin and canagliflozin, are registered in Oman under different trade names. The healthcare professionals are encouraged to report any suspected adverse drug reaction and or any drug related problem to the Department of Pharmacovigilance & Drug Information in DGPA&DC.

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
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