Direct Healthcare Professional Communication

January 2022

Dapagliflozin 5mg should no longer be used for the treatment of Type 1 Diabetes Mellitus

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary

• Effective 25 October 2021 Forxiga (dapagliflozin) 5mg is no longer authorised for the treatment of patients with type 1 diabetes mellitus (T1DM) and should no longer be used in this population. This is based on Astra Zeneca's decision to remove the T1DM indication for dapagliflozin 5mg.

• Diabetic ketoacidosis (DKA) is a known side effect of dapagliflozin. In T1DM studies with dapagliflozin, DKA was reported with common frequency (occurring in at least 1 per 100 patients).

• Additional risk minimisation measures for healthcare professionals and patients, implemented to mitigate the risk of DKA with the use of dapagliflozin in T1DM will no longer be available.

• Discontinuation of dapagliflozin in patients with T1DM must be made by or in consultation with a physician specialised in diabetes care and be conducted as soon as clinically practical.

• After stopping dapagliflozin treatment, frequent blood glucose monitoring is recommended, and the insulin dose should be increased carefully to minimise the risk of hypoglycaemia.

Background information

Dapagliflozin 5mg should no longer be used for the treatment of patients with T1DM as an adjunct to insulin in patients with BMI ≥ 27 kg/m2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy.

Dapagliflozin remains authorised in adults for the treatment of type 2 diabetes mellitus, and for the treatment of symptomatic chronic heart failure with reduced ejection fraction.

The use of dapagliflozin 5mg for the treatment of T1DM required specific additional risk minimisation measures for DKA, such as a patient alert card and a Health Care professional Guide. As a result of the

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dapagliflozin 5 mg T1DM indication removal, the additional risk minimisation measures will no longer be available.

References:

EMA

https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-forxiga-dapagliflozin-5mg-should-no-longer-be-used_en.pdf

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202- 25354100, Extension: 1470 Fax: +202 – 23610497

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG

QR Code:

Hotline: 15301

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