Date 02/11/2021

Forxiga (dapagliflozin) 5mg should no longer be used for the treatment of Type 1 Diabetes Mellitus

Dear Healthcare Professional,

AstraZeneca, in agreement with the European Medicines Agency and the MHRA would like to inform you of the following:

Summary

- Effective 25th October 2021 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 AstraZeneca's decision to remove the T1DM indication for dapagliflozin 5mg
- The removal of the T1DM indication is not due to any safety concern for dapagliflozin in any indication, including T1DM
- Diabetic ketoacidosis (OKA) 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 OKA 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.

AstraZeneca has taken the decision to remove the T1DM indication for dapagliflozin. Other dapagliflozin 5mg and 10mg indications are not affected by this licensing change. Dapagliflozin remains authorised in adults for the treatment of type 2 diabetes mellitus, for the treatment of symptomatic chronic heart failure with reduced ejection fraction, and for the treatment of chronic kidney disease.

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

Call for reporting

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website **https://yellowcard.mhra.gov.uk/**
- the free Yellow Card app available from the **Apple App Store or Google Play Store**
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for

free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible, including information about batch numbers, medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

By reporting side effects, you can help provide more information on the safety of this medicine

Company contact point

If you require any further information, please contact AstraZeneca Medical Information at **Medical.InformationUK@astrazeneca.com** and Patient Safety at **AstraZenecaUKMCDrugSafety@astrazeneca.com.**

Best Regards,

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