

MHRA Drug Safety Update

November 2021



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

AstraZeneca, in agreement with the European Medicines Agency and the MHRA, have informed health care professionals that effective from the 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.

Summary

- The removal of the T1DM indication is not due to any safety concern for dapagliflozin in any indication, including T1DM.
- 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.

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.

Please note that the 10mg strength of dapagliflozin had NOT been previously approved for treatment of T1D, so the change in licensing only relates to the 5mg strength.