



ASSOCIATED DRUG COMPANY LIMITED
TRI Q L-ESPORATURI, ZONE 1, CENTRAL BUSINESS DISTRICT,
BIRKIRKARA CBD 1040, MALTA
TEL: 2277 8000 FAX: 2277 8120

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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 Malta Medicines Authority, would like to inform you of the following:

Summary

- **Effective 25Oct2021, 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 \geq 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 5 mg T1DM indication removal, the additional risk minimisation measures will no longer be available.

Call for reporting

Healthcare professionals should continue to report adverse reactions associated with the use of dapagliflozin in accordance with the national spontaneous reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt.

Company contact point

If you require any further information, please contact AstraZeneca Medical Information and Patient Safety at:

Company	Phone
Associated Drug Company Limited Triq l-Esportaturi, Zone 1, Central Business District, Birkirkara CBD 1040 Malta	+356 22778000

Best Regards,



Alexia Farrugia
Regulatory Affairs & Safety Manager
Tel: 22778000
Email: alexia.farrugia@astrazeneca.com