

## **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 [National Competent 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  $\geq 27$  kg/m<sup>2</sup>, 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, 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 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 <include the

details. (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

**Company contact point**

If you require any further information, please contact AstraZeneca Medical Information and Patient Safety at [enter local contact details].

Best Regards,

<<Name of Signatory>>

<b>DHPC COMMUNICATION PLAN</b>	
<b>Medicinal product(s)/active substance(s)</b>	FORXIGA (dapagliflozin) 5mg
<b>Marketing authorisation holder(s)</b>	AstraZeneca
<b>Purpose of the communication</b>	<p><b>FORXIGA (dapagliflozin) - Removal of Type 1 Diabetes Mellitus (T1DM) Indication.</b></p> <p>The purpose of this communication is to notify prescribers that the FORXIGA (dapagliflozin) indication for T1DM as an adjunct to insulin in patients with BMI <math>\geq</math> 27 kg/m<sup>2</sup>, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy has been removed and to advise that other FORXIGA 5mg and 10mg indications are not affected by this communication.</p>
<b>DHPC recipients</b>	<p>Healthcare professionals involved in the prescription and renewal, supervision and monitoring of T1DM patients. This includes Diabetologists/Endocrinologists, Specialists in internal medicine, General practitioners, as well as Diabetes professional societies and National Diabetes associations.</p> <p>The target group should be further defined at national level, in agreement with the respective national competent authority.</p>
<b>Member States where the DHPC will be distributed</b>	In European Economic Area (EEA) member states where dapagliflozin in T1DM has been launched.
<b>Timetable</b>	<b>Date</b>
<b>DHPC and communication plan (in English) agreed by PRAC</b>	02/09/2021
<b>DHPC and communication plan (in English) agreed by CHMP/CMDh</b>	16/09/2021
<b>Submission of translated DHPCs to the national competent authorities for review</b>	30/09/2021
<b>Agreement of translations by national competent authorities</b>	15/10/2021
<b>Dissemination of DHPC</b>	Within one week of Commission Decision: expected in Mid-November 2021 (specific date TBC).