24 June 2021
EMA/CHMP/347888/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Forxiga

dapagliflozin

On 24 June 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Forxiga. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a new indication as follows:

Forxiga is indicated in adults for the treatment of chronic kidney disease.

For information, the full indications for Forxiga will be as follows:

Type 2 diabetes mellitus

Forxiga is indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance.
- in addition to other medicinal products for the treatment of type 2 diabetes.

For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1.

Type 1 diabetes mellitus

Forxiga is indicated in adults for the treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI ≥ 27 kg/m^2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy.

Heart failure

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Forxiga is indicated in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.

Chronic kidney disease

Forxiga is indicated in adults for the treatment of chronic kidney disease.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.