31 January 2019
EMA/56302/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Forxiga

dapagliflozin

On 31 January 2019, 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:[2]

"Forxiga is indicated in adults for the treatment of insufficiently controlled

- type 2 diabetes mellitus as an adjunct to diet and exercise, to improve glycaemic control,
  - as monotherapy when metformin is considered inappropriate due to intolerance.
  - in addition to other medicinal products for the treatment of type 2 diabetes.
- **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**.

For clinical study results with respect to populations studied, effects on glycaemic control and combinations with other medicinal products see sections 4.4, 4.5 and 5.1."

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.

[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
[2] New text in bold

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