15 December 2022
EMA/CHMP/938370/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Forxiga

dapagliflozin

On 15 December 2022, 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 an extension to an existing indication as follows:[2]

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

For information, the full indications for Forxiga will be:

> Type 2 diabetes mellitus
>
> Forxiga is indicated in adults and children aged 10 years and above 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.
>
> Heart failure
>
> Forxiga is indicated in adults for the treatment of symptomatic chronic heart failure.
>
> Chronic kidney disease
>
> Forxiga is indicated in adults for the treatment of chronic kidney disease.

[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] Removed text as strikethrough

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.