27 January 2022
EMA/CHMP/36445/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Jardiance

empagliflozin

On 27 January 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 Jardiance. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH.

The CHMP adopted an extension to the existing indication as follows:[2]

> Type 2 diabetes mellitus
>
> Jardiance is indicated for the treatment of adults with 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 diabetes
>
> For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1.
>
> Heart failure
>
> Jardiance is indicated in adults for the treatment of symptomatic chronic heart failure ~~with reduced ejection fraction~~.

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] Removed text as strikethrough

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