19 September 2024
EMA/CHMP/423614/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Synjardy

empagliflozin / metformin

On 19 September 2024, 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 Synjardy. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH.

The CHMP adopted a new indication to include treatment of children aged 10 years and older. For information, the full indication will be as follows:[2]

> Synjardy is indicated in adults and **children aged 10 years and above** for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise:
> - in patients insufficiently controlled on their maximally tolerated dose of metformin alone
> - in combination with other medicinal products for the treatment of diabetes, in patients insufficiently controlled with metformin and these medicinal products
> - in patients already being treated with the combination of empagliflozin and metformin as separate tablets.
>
> For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the population studied, 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 made 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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