22 April 2022
EMA/CHMP/224384/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Bydureon

exenatide

On 22 April 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 Bydureon. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a change to the existing indication.

For information, the full indication is as follows:[2]

> Bydureon is indicated in adults**, adolescents and children aged 10 years and above** ~~18 years and older~~ with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose lowering medicinal products including basal insulin, when the therapy in use, together with diet and exercise, does not provide adequate glycaemic control.
>
> 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.

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, removed text as strikethrough

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