14 December 2023
EMA/CHMP/534898/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zinplava

bezlotoxumab

On 14 December 2023, 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 Zinplava. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension to the existing indication to include treatment of paediatric patients from 1 to 18 years of age.

For information, the full indication for Zinplava will therefore be as follows:[2]

> *ZINPLAVA is indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in adult* ***and paediatric patients 1 year of age and older*** *at high risk for recurrence of CDI (see sections 4.2, 4.4 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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