20 July 2023
EMA/CHMP/189667/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ervebo

recombinant vesicular stomatitis virus - Zaire Ebolavirus vaccine (live)

On 20 July 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 Ervebo. 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 vaccination of infants aged 1 year and older. For information, the full indication for Ervebo will therefore be as follows:[2]

> Ervebo is indicated for active immunisation of individuals ~~18 years~~ **1 year** of age or older to protect against Ebola Virus Disease (EVD) caused by Zaire Ebola virus

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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