18 September 2025
EMADOC-1700519818-2450542
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Bimervax

COVID-19 vaccine (recombinant, adjuvanted)

On 18 September 2025 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 Bimervax. The marketing authorisation holder for this medicinal product is Hipra Human Health S.L.

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

> BIMERVAX is indicated as a booster for active immunisation to prevent COVID-19 in individuals ~~16~~ **12** years of age and older who have previously received a mRNA COVID-19 vaccine (see sections 4.2 and 5.1).
>
> The use of this vaccine should be in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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