10 November 2022
EMA/873797/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Comirnaty

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On 10 November 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 Comirnaty. The marketing authorisation holder for this medicinal product is BioNTech Manufacturing GmbH.

The CHMP adopted an extension to an existing indication to include use of Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose as a booster in children aged 5 to 11 years. For information, the full indication for Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose will be as follows:

> Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children 5 to 11 years of age who have previously received at least a primary vaccination course against COVID-19 (see sections 4.2 and 5.1).
>
> The use of this vaccine should be in accordance with official recommendations.

For information, the indications for other compositions of the vaccine are provided in the Summary of Product Characteristics for Comirnaty.

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

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