19 October 2022
EMA/838787/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Comirnaty

tozinameran

On 19 October 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 3 micrograms/dose in children from 6 months of age. The full indication for Comirnaty 3 micrograms/dose will be as follows:

> Comirnaty 3 micrograms/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.
>
> 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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