23 April 2026
EMADOC-1700519818-3080442
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Comirnaty

COVID-19 mRNA vaccine

On 23 April 2026, 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 a change to the existing indication for all Comirnaty 10 micrograms formulations, as follows:[2]

> Comirnaty JN.1 dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals ~~5 years~~ **6 months** of age and older.
>
> Comirnaty KP.2 dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals ~~5 years~~ **6 months** of age and older.
>
> Comirnaty LP.8.1 dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals ~~5 years~~ **6 months** of age and older.

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] Summary 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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