23 June 2022
EMA/604944/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Nuvaxovid

SARS-CoV-2, spike protein, recombinant, expressed in Sf9 cells derived from Spodoptera frugiperda

On 23 June 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 Nuvaxovid. The marketing authorisation holder for this medicinal product is Novavax CZ, a.s.

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

> Nuvaxovid is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals ~~18~~ **12** years of age and older.

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

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