11 December 2025
EMA/CHMP/381880/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

mNexspike

COVID-19 mRNA vaccine

On 11 December 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product mNexspike, intended for the prevention of COVID-19 in people from 12 years of age.

The applicant for this medicinal product is Moderna Biotech, Spain, S.L.

mNexspike will be available as a dispersion for injection in pre-filled syringe. mNexspike is an RNA-based COVID-19 vaccine (ATC code: J07BN01). It contains an mRNA that encodes for parts of the SARS-CoV-2 spike protein: the membrane-bound, linked N-terminal domain and the receptor-binding domain. Vaccination with mNexspike induces the production of neutralising antibodies targeting the spike protein, which helps protect people against COVID-19.

The benefits of mNexspike in the prevention of COVID-19 were shown in a large clinical trial in which participants received either a dose of mNexspike or Spikevax (authorised COVID-19 vaccine). Compared with Spikevax, mNexspike led to a comparable proportion of people who developed symptomatic COVID-19 which indicates that the vaccine efficacy of mNexspike is not worse than Spikevax. The most common side effects are injection site pain, fatigue, headache, myalgia, arthralgia, chills, axillary swelling or tenderness and nausea/vomiting.

The full indication is:

> *mNEXSPIKE is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years 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 summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after 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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