26 February 2026
EMADOC-1829012207-43023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

mCombriax

influenza and COVID 19, mRNA vaccine

On 26 February 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product mCombriax, intended for the prevention of influenza disease and COVID-19 caused by SARS-CoV-2 in adults aged 50 years and older.

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

mCombriax will be available as a dispersion for injection in pre-filled syringes. mCombriax is a messenger RNA (mRNA)-based influenza and COVID-19 vaccine (ATC code: not yet assigned). It contains mRNA molecules that encode the full-length, membrane-bound haemagglutinin glycoproteins of seasonal influenza virus types A (H1N1 and H3N2) and B (Victoria lineage), as well as parts of the SARS-CoV-2 spike protein, namely the membrane-bound, linked N-terminal domain and the receptor-binding domain. Vaccination with mCombriax elicits immune responses to the targeted proteins of each virus, which helps protect people against seasonal influenza and COVID-19 disease.

The benefit of mCombriax is its ability to induce a non-inferior immune response in adults from 50 years of age compared with simultaneous administration of an authorised seasonal influenza vaccine (Fluzone HD or Fluarix) and an authorised COVID-19 vaccine (Spikevax). The most common side effects are injection site pain, fatigue, myalgia, headache, arthralgia, chills, lymphadenopathy, nausea/vomiting and pyrexia.

The full indication is:

> mCOMBRIAX is indicated for active immunisation for the prevention of influenza disease and COVID-19 caused by SARS-CoV-2 in individuals 50 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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