First combined COVID-19 and influenza vaccine for people 50 years and older

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mCombriax helps to protect against both COVID-19 caused by SARS-CoV-2 and seasonal influenza

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EMA has recommended granting a marketing authorisation in the European Union (EU) for mCombriax, a messenger RNA vaccine for protecting people aged 50 years and older against COVID-19 and seasonal influenza (flu).

COVID-19 and influenza are infectious illnesses that mainly affect the respiratory system, causing symptoms such as cough and nasal congestion, as well as systemic symptoms like fever and chills.

Most cases of COVID-19 and influenza are mild or moderate, but severe cases do occur, particularly in older people and people with weakened immune systems. Co-infection with the influenza virus and SARS-CoV-2(the virus that causes COVID-19) can result in more severe disease than would occur with either SARS-CoV-2 or influenza virus infection alone.

According to data released by the World Health Organization,

as of 1 February 2026, there had been 281,728,062 cases of COVID-19 reported in Europe. Seasonal influenza also presents a significant burden, with up to 50 million symptomatic cases occurring every year in the European Economic Area (EEA).

mCombriax works like other vaccines by preparing the body to defend itself against infection. It contains messenger RNA with instructions for making proteins found on SARS-CoV-2 and the following seasonal influenza viruses: influenza type A-H1N1, influenza type A-H3N2 and influenza type B of the Victoria lineage.

As the first combined COVID-19/influenza vaccine, mCombriax provides people with the option of having a single shot to protect against both illnesses.

The strain of SARS-CoV-2 targeted by the vaccine was based on EMA's recommendation for 2023/2024, while the targeted influenza strains were based on the WHO's 2023/2024 recommendations. As with existing for COVID-19 and influenza, the composition of mCombriax is expected to be updated regularly to match the viral strains circulating in the community.

In recommending the vaccine's authorisation, EMA's human medicines committee (CHMP) considered data showing that mCombriax triggered the production of adequate amounts of antibodies against both viruses.

Data from a main study involving 8,000 people from 50 years of age showed that people who received mCombriax had levels of antibodies against influenza and SARS-CoV-2 that were statistically non-inferior to those seen in people who received both Spikevax (an authorised COVID-19 mRNA vaccine) and either Fluzone HD or Fluarix (authorised influenza vaccines).

In addition, a study of a similar mRNA vaccine containing only the influenza component in mCombriax showed that it can prevent influenza illness and trigger an adequate immune response.

The most common side effects with mCombriax (which can affect more than 1 in 10 people) are injection site pain, tiredness, muscle pain, joint pain, headache, chills, swollen lymph nodes, nausea and vomiting and fever. The median time

to onset for these adverse reactions was 2 days, while the median duration was 3 days.

The opinion adopted by the CHMP is an intermediary step on mCombriax's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role or use of this medicine in the context of the national health system of that country.

mCombriax will be one more option for national authorities to consider for vaccination campaigns against COVID-19 and influenza. National authorities decide which vaccines to roll out and make recommendations about who should receive them, taking into account the situation in their countries.

Notes:

- The applicant for mCombriax is Moderna Biotech Spain S.L.
- Data on seasonal influenza cases in the EEA are available from the European Centre for Disease Prevention and Control (ECDC): Factsheet about seasonal influenza. Accessed 23 February 2026.
- Data on cases of COVID-19 in Europe are available on WHO's COVID-19 dashboard: World Health Organization. WHO COVID-19 dashboard. Accessed 26 February 2026.

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