



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/73915/2026
EMA/H/C/006472

mCombriax (*influenza and COVID-19, mRNA vaccine*)

A plain-language overview of mCombriax and why it is authorised in the EU

What is mCombriax and what is it used for?

mCombriax is a vaccine for protecting people aged 50 years and older against seasonal influenza (flu) and COVID-19.

mCombriax contains as its active substance messenger RNA (mRNA) with instructions for producing proteins from the influenza virus and SARS-CoV-2, the virus that causes COVID-19.

mCombriax does not contain the viruses themselves and cannot cause flu or COVID-19.

How is mCombriax used?

mCombriax is given as a single injection into the muscle of the upper arm. In people previously vaccinated against COVID-19, mCombriax should be given at least 3 months after the last COVID-19 vaccine.

The vaccine should be used according to official recommendations issued at national level by public health bodies.

mCombriax can only be obtained with a prescription. For more information about using mCombriax, see the package leaflet or contact your doctor or pharmacist.

How does mCombriax work?

mCombriax works by preparing the body to defend itself against influenza and COVID-19. It contains a molecule called mRNA which has instructions for making proteins from the influenza virus and SARS-CoV-2.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce these proteins. The person's immune system will then recognise the proteins as foreign and produce antibodies and activate T cells (white blood cells) to attack them.

If, later on, the person comes into contact with the viruses, the immune system will recognise them and be ready to defend the body against them.

After vaccination, the mRNA from the vaccine is broken down and removed from the body.

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



What benefits of mCombriaX have been shown in studies?

Data from a main study involving over 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 similar to those seen in people who received either Fluzone HD or Fluarix (authorised influenza vaccines) and Spikevax (an authorised COVID-19 mRNA vaccine) at the same time.

In addition, a study of a similar mRNA vaccine containing only the influenza component in mCombriaX showed that the influenza component (at a different dose) can trigger an adequate immune response to prevent influenza illness.

Can children be vaccinated with mCombriaX?

mCombriaX is only authorised for adults aged 50 years and older.

Can immunocompromised people be vaccinated with mCombriaX?

There are no data on immunocompromised people (people with weakened immune systems). Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19 and influenza.

Can pregnant or breast-feeding women be vaccinated with mCombriaX?

There is a lack of data on the use of mCombriaX in pregnancy. Animal studies do not show harmful effects in pregnancy. As a precaution, it is preferable not to use mCombriaX during pregnancy.

No effects on breastfed babies are expected. mCombriaX can be used during breast-feeding.

Can people with allergies be vaccinated with mCombriaX?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet must not receive the vaccine. As for all vaccines, mCombriaX should be given under close medical supervision, with the appropriate medical treatment available.

People who have had a severe allergic reaction after being given mCombriaX should not receive the vaccine again.

How well does mCombriaX work for people of different ethnicities and genders?

The main mCombriaX trial included people of different ethnicities and genders. Studies showed no differences in how the vaccine works in people of different genders and ethnicities.

What are the side effects and restrictions with mCombriaX?

For the full list of side effects and restrictions with mCombriaX, see the package leaflet.

The most common side effects with mCombriaX (which may affect more than 1 in 10 people) include injection site pain, tiredness, muscle pain, joint pain, headache, chills, swollen or tender lymph nodes

under the arm, nausea (feeling sick), vomiting and fever. They typically start 2 days after vaccination and last for around 3 days.

Why is mCombriax authorised in the EU?

The main study showed that people from 50 years of age who receive mCombriax have levels of antibodies against influenza and SARS-CoV-2 comparable to those seen in people who received an authorised COVID-19 and influenza vaccine at the same time. Data from another study showed that the influenza component of mCombriax (at a different dose) can prevent influenza.

Although side effects were more common with mCombriax than with the comparator combinations, they were generally mild and short-lived.

The European Medicines Agency therefore decided that mCombriax's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of mCombriax?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of mCombriax have been included in the summary of product characteristics and the package leaflet.

A risk management plan (RMP) for mCombriax is in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks.

As for all medicines, data on the use of mCombriax are continuously monitored. Suspected side effects reported with mCombriax are carefully evaluated and any necessary action taken to protect patients.

Other information about mCombriax

mCombriax received a marketing authorisation valid throughout the EU on 20 April 2026.

Further information on mCombriax, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/mcombriax.

For information about the availability of this medicine in your country, contact your national competent authority.