



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 February 2021

COVID-19 vaccine safety update

COVID-19 VACCINE MODERNA

Moderna Biotech Spain, S.L.

This update presents the assessment of an investigation of reports of suspected severe allergic reaction coming from a single vaccination site in the United States.

The assessment of these reports has not identified new aspects regarding the nature of this known side effect.

The benefits of COVID-19 Vaccine Moderna in preventing COVID-19 continue to outweigh any risks, and there are no recommended changes regarding the use of the vaccine.

Safety updates provide the outcomes of the assessment of emerging data since marketing authorisation for COVID-19 vaccines. The assessments are carried out by EMA's safety committee ([Pharmacovigilance Risk Assessment Committee](#) [PRAC]). In addition, PRAC assesses promptly all other emerging data. The safety updates are published regularly at [Post-authorisation: Safety updates](#).

All published safety updates for COVID-19 Vaccine Moderna are available at [COVID-19 Vaccine Moderna: safety updates](#).

1. Updates on safety of COVID-19 Vaccine Moderna

On 28 January 2021, PRAC discussed a review submitted by the marketing authorisation holder of reports of suspected severe allergic reaction after administration of COVID-19 Vaccine Moderna at a single vaccination site in the United States (US). The following was concluded by PRAC:

Severe allergic reaction (anaphylaxis)

Anaphylaxis is a known side effect of COVID-19 Vaccine Moderna.

Several anaphylaxis cases were reported as a cluster during vaccination in January 2021 at a site in San Diego, California, US with vaccine from the production lot 041L20A. PRAC discussed the marketing authorisation holder's review of these cases.

It was noted that following investigations the responsible US authorities did not identify a quality defect and allowed vaccination with the lot in question to resume¹. In addition, a US analysis of anaphylaxis after administration of first doses of COVID-19 Vaccine Moderna estimated the frequency to be 2.5 cases per million doses administered, based on anaphylaxis cases reported between 21 December 2020 and 10 January 2021².

Information on the product quality of the lot 041L20A was provided by the marketing authorisation holder and assessed by the EU regulatory network as consistent with the previous vaccine lots and within the quality specifications.

Based on the current information, no new safety concern regarding anaphylaxis was identified for COVID-19 Vaccine Moderna.

PRAC requested the marketing authorisation holder to continue reviewing all anaphylaxis cases for further assessment by the committee as part of the assessment of the company's upcoming first Summary Monthly Safety Report.

Information on managing the risk of anaphylaxis is already available in the [product information](#). The product information also includes instructions for healthcare professionals to record the name and batch number of the administered vaccine to ensure traceability.

¹ California Department of Public Health. California State Epidemiologist Issues Update on Moderna COVID-19 Vaccine. 20 January 2021. Accessible at: <https://www.cdph.ca.gov/Programs/OPA/Pages/NR21-025.aspx>

² Centres for Disease Control and Prevention (CDC) COVID-19 Response Team, Food and Drug Administration: Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine: United States, December 21, 2020 - January 10, 2021. MMWR. 2021; 70 (4): 125-129 (epub 22 Jan 2021).

2. Other information for COVID-19 Vaccine Moderna

COVID-19 Vaccine Moderna is a vaccine that has been authorised in the European Union (EU) for use in people aged 18 years and older to prevent development of COVID-19 when infected with the coronavirus SARS-CoV-2. COVID-19 is a potentially severe disease that may result in death.

COVID-19 Vaccine Moderna contains a molecule called mRNA, which the body uses to temporarily produce the SARS-CoV-2 spike protein. The mRNA is broken down shortly after vaccination. The spike protein does not cause COVID-19.

Before COVID-19 Vaccine Moderna was granted a marketing authorisation in the EU on 6 January 2021, the efficacy and safety of the vaccine were assessed through pre-clinical studies and large clinical trials. More than 14,000 participants have been given the vaccine in clinical trials.

Like all medicines, this vaccine can cause side effects, although not everybody will experience them. The most common side effects known for COVID-19 Vaccine Moderna are usually mild or moderate and get better within a few days after vaccination.

More information on how COVID-19 Vaccine Moderna works and its use is available in the [medicine overview](#). This includes information on use in pregnant and breastfeeding women and immunocompromised individuals.

Information in all EU/EEA languages is available in the [product information](#), which includes the summary of product characteristics and the package leaflet.

3. How safety is monitored

As for all COVID-19 vaccines, all relevant new information emerging on COVID-19 Vaccine Moderna is collected and promptly reviewed. This is in line with the [pharmacovigilance plan for COVID-19 vaccines](#) of the EU regulatory network.

Collecting suspected side effects

The EU regulatory network continuously monitors reports of suspected side effects observed in vaccinated individuals. These reports are collected and recorded in EudraVigilance, a system operated by EMA for managing and analysing information on suspected adverse reactions to medicines.

Vaccinated individuals and healthcare professionals should report suspected side effects via the national reporting systems. For more information, see [Reporting side effects](#). Information on how to report side effects in your Member State is available in the [package leaflet](#) and the list of [national competent authorities](#).

You may visit [EudraVigilance – European database of suspected drug reaction reports](#) and search for “COVID-19 MRNA VACCINE MODERNA (CX-024414)” to see all suspected side effects reported for COVID-19 Vaccine Moderna. Please note that these reports describe suspected side effects in individuals, i.e. these events may not necessarily have been caused or otherwise be related to the vaccine.

Planned and ongoing studies

The company that markets COVID-19 Vaccine Moderna will continue to provide results from the main clinical trial, which is ongoing for up to two years, and will conduct additional studies to monitor the safety and effectiveness of the vaccine as it is used in vaccination campaigns and other clinical practice. For the list of planned or ongoing safety studies for COVID-19 Vaccine Moderna, see the [risk management plan](#).

A [paediatric investigation plan](#) (PIP) for COVID-19 Vaccine Moderna is in place. This describes how the company will collect data on the vaccine’s efficacy and safety for its potential use in children.

In addition, EMA is coordinating [observational studies](#) in EU Member States looking at real-world data from clinical practice to monitor the safety and effectiveness of COVID-19 vaccines, including in pregnant women.

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