



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 March 2021

COVID-19 vaccine safety update

COVID-19 VACCINE MODERNA

Moderna Biotech Spain, S.L.

The latest safety data for this vaccine are in line with the known benefit-risk profile; the outcomes of the assessments are presented in this update.

The benefits of COVID-19 Vaccine Moderna in preventing COVID-19 continue to outweigh the risks, and there are no recommended changes regarding the use of this 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]). The safety updates are published regularly at [COVID-19 vaccines: authorised](#).

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

This safety update follows the last update of 4 March 2021.

Since its marketing authorisation in the European Union (EU) on 6 January 2021 until 25 March 2021, more than 3 million doses of COVID-19 Vaccine Moderna have been administered in the EU/EEA¹.

1. Updates on safety of COVID-19 Vaccine Moderna

On 25 March 2021, PRAC assessed all new safety data emerging worldwide, including the latest Summary Monthly Safety Report² from the marketing authorisation holder, and concluded that the benefit-risk balance of COVID-19 Vaccine Moderna remains positive.

Specifically, the following was concluded by PRAC in relation to:

Immune thrombocytopenia (ITP)

For all COVID-19 vaccines used in the EU, a specific PRAC assessment of immune thrombocytopenia (ITP, low blood platelet levels that can lead to bruising and bleeding) as a suspected side effect has been initiated. At this stage of the assessment, a causal association of ITP with any COVID-19 vaccine has not been established³.

2. Other information for COVID-19 Vaccine Moderna

COVID-19 Vaccine Moderna was authorised in the EU on 6 January 2021 for use in people aged 18 years and older to prevent 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.

¹ The [European Centre for Disease Prevention and Control \(ECDC\)](#) collects these data from EU Member States as well as from the additional countries of the European Economic Area (EEA) Norway, Iceland and Liechtenstein.

² Summary Monthly Safety Reports will be compiled by the marketing authorisation holders for COVID-19 vaccines to support timely and continuous benefit-risk evaluations. These reports complement the submission of [Periodic Safety Update Reports \(PSURs\)](#).

³ See [Meeting Highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 8-11 March 2021](#).

Before COVID-19 Vaccine Moderna was granted an EU marketing authorisation, 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, 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 (comprising the regulatory bodies of the EU Member States, EMA and the European Commission).

Collecting case reports of suspected side effects

The EU regulatory network continuously monitors reports of suspected side effects observed in vaccinated individuals. These case reports are collected and recorded in [EudraVigilance](#), a system operated by EMA for managing and analysing information on suspected side effects of medicines.

Vaccinated individuals and healthcare professionals should report suspected side effects via the national reporting systems, which also contribute to EudraVigilance. 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 in the EU/EEA. Please note that these reports describe suspected side effects in individuals, i.e. these events may not necessarily have been caused by, or be otherwise related to, the vaccine.

By 22 March 2021, 4 550 cases of suspected side effects reported for COVID-19 Vaccine Moderna from the EU/EEA had been included and

monitored in EudraVigilance, relating to around 2.6 million doses administered⁴.

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. It will also 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 and 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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⁴ See [EMA Public stakeholder meeting: approval, safety monitoring and impact of COVID-19 vaccines in the EU](#) on 26 March 2021.