EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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COVID-19 vaccine safety update

COVID-19 VACCINE MODERNA

Moderna Biotech Spain, S.L.

Diarrhoea and delayed injection site reactions will be added as side effects to the product information.

Case reports of inflammation of the heart muscle and membrane will be further assessed.

COVID-19 Vaccine Moderna is effective in preventing COVID-19.

This safety update follows the last update of 29 March 2021.

Safety updates provide information about the assessments of emerging worldwide safety data since marketing authorisation for COVID-19 vaccines. Safety assessments are carried out primarily by EMA's 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.

Since its marketing authorisation in the European Union (EU) on 6 January 2021 until 6 May 2021, more than 11.5 million doses of COVID-19 Vaccine Moderna have been administered in the EU/EEA[1].

1. Updates on safety of COVID-19 Vaccine Moderna

At its meeting held 3 to 6 May 2021, based on new safety data including the latest Monthly Summary Safety Report (MSSR)[2] from the marketing authorisation holder, PRAC assessed the following:

Diarrhoea

PRAC identified diarrhoea after vaccination as a new side effect of COVID-19 Vaccine Moderna, based on cases reported in clinical trials and from vaccination campaigns. The frequency of this side effect is being assessed further. The product information will be updated accordingly.

Delayed injection site reactions

Based on cases reported in clinical trials and from vaccination campaigns, PRAC concluded that information on delayed injection site reactions should be added to the product information of COVID-19 Vaccine Moderna[3]. The characteristics of these side effects, including the frequency, are being assessed further for inclusion in the product information.

Immune thrombocytopenia (ITP)

PRAC assessed cases of immune thrombocytopenia (ITP, an auto-immune condition of low blood platelet levels that can lead to bruising and bleeding) reported with COVID-19 Vaccine Moderna. PRAC has requested further data from the marketing authorisation holder to continue the assessment.

[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] Monthly Summary Safety Reports, also known as pandemic summary safety reports, will be compiled by the marketing authorisation holders to support timely and continuous benefit-risk evaluations for COVID-19 vaccines used during the pandemic. These reports complement the submission of Periodic Safety Update Reports (PSURs).
[3] See also Blumenthal KG, Freeman EE, Saff RR, et al. Delayed large local reactions to mRNA-1273 vaccine against SARS-CoV-2. N Engl J Med. 2021; 384: 1273-1277.

Myocarditis and pericarditis

EMA is aware of cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) reported following vaccination with COVID-19 Vaccine Moderna. There is no indication at the moment that these cases are due to the vaccine. However, PRAC has requested the marketing authorisation holder to provide further detailed data, including an analysis of the cases according to age and gender, in the context of the next MSSR and will consider if other regulatory action is needed[4].

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.

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

[4] See Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-6 May 2021

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.

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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