

## **COVID-19 Vaccine Moderna**

### **COVID-19 mRNA vaccine (nucleoside modified)**

#### **1. What is COVID-19 Vaccine Moderna and what is it used for?**

COVID-19 Vaccine Moderna is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older.

COVID-19 Vaccine Moderna contains a molecule called messenger RNA (mRNA) with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID-19. COVID-19 Vaccine Moderna does not contain the virus itself and cannot cause COVID-19.

Detailed information about this vaccine is available in the [product information](#), which includes the package leaflet.

#### **2. How is COVID-19 Vaccine Moderna used?**

COVID-19 Vaccine Moderna is given as two injections, usually into the muscle of the upper arm, 28 days apart.

Arrangements for the supply of the vaccine will be the responsibility of national authorities. For more information about using COVID-19 Vaccine Moderna, see the package leaflet or consult a healthcare professional.

#### **3. How does COVID-19 Vaccine Moderna work?**

COVID-19 Vaccine Moderna works by preparing the body to defend itself against COVID-19. It contains a molecule called mRNA which has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.

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

If, later on, the person comes into contact with SARS-CoV-2 virus, their immune system will recognise it and be ready to defend the body against it.

The mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination.

#### **4. What benefits of COVID-19 Vaccine Moderna have been shown in studies?**

A very large clinical trial showed that COVID-19 Vaccine Moderna was effective at preventing COVID-19 in people from 18 years of age.

The trial involved around 30,000 people in total. Half received the vaccine and half were given dummy injections. People did not know whether they received the vaccine or the dummy injections.

Efficacy was calculated in around 28,000 people from 18 to 94 years of age who had no sign of previous infection.

The trial showed a 94.1% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (11 out of 14,134 vaccinated people got COVID-19 with symptoms) compared with people who received dummy injections (185 out of 14,073 people who received dummy injections got COVID-19 with symptoms). This means that the vaccine demonstrated a 94.1% efficacy in the trial.

The trial also showed 90.9% efficacy in participants at risk of severe COVID-19, including those with chronic lung disease, heart disease, obesity, liver disease, diabetes or HIV infection.

#### **5. Can people who have already had COVID-19 be vaccinated with COVID-19 Vaccine Moderna?**

There were no additional side effects in the 343 people who received COVID-19 Vaccine Moderna in the trial and had previously had COVID-19.

There were not enough data from the trial to conclude on how well COVID-19 Vaccine Moderna works for people who have already had COVID-19.

**6. Can COVID-19 Vaccine Moderna reduce transmission of the virus from one person to another?**

The impact of vaccination with COVID-19 Vaccine Moderna on the spread of the SARS-CoV-2 virus in the community is not yet known. It is not yet known how much vaccinated people may still be able to carry and spread the virus.

**7. How long does protection from COVID-19 Vaccine Moderna last?**

It is not currently known how long protection given by COVID-19 Vaccine Moderna lasts. The people vaccinated in the clinical trial will continue to be followed for 2 years to gather more information on the duration of protection.

**8. Can children be vaccinated with COVID-19 Vaccine Moderna?**

COVID-19 Vaccine Moderna is not currently recommended for use in children. EMA has agreed with the company on a plan to conduct trials involving children at a later stage.

**9. Can immunocompromised people be vaccinated with COVID-19 Vaccine Moderna?**

There are limited 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.

**10. Can pregnant or breast-feeding women be vaccinated with COVID-19 Vaccine Moderna?**

Animal studies do not show any harmful effects in pregnancy, however data on the use of COVID-19 Vaccine Moderna during pregnancy are very limited. Although there are no studies on breast-feeding, no risk from breast-feeding is expected.

The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks.

**11. Can people with allergies be vaccinated with COVID-19 Vaccine Moderna?**

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

Allergic reactions (hypersensitivity) have been seen in people receiving the vaccine. A very small number of cases of anaphylaxis (severe allergic reaction) have occurred. Therefore, as for all vaccines, COVID-19 Vaccine Moderna should be given under close medical supervision, with the appropriate medical treatment available in case of allergic reactions. People who have a severe allergic reaction when they are given the first dose of COVID-19 Vaccine Moderna should not receive the second dose

***12. How well does COVID-19 Vaccine Moderna work for people of different ethnicities and genders?***

The clinical trial included people of different ethnicities and genders. The high efficacy was maintained across genders and racial and ethnic groups.

***13. What are the risks associated with COVID-19 Vaccine Moderna?***

The most common side effects with COVID-19 Vaccine Moderna in the trial were usually mild or moderate and got better within a few days after vaccination. They included pain and swelling at the injection site, tiredness, chills, fever, swollen or tender lymph nodes under the arm, headache, muscle and joint pain, nausea and vomiting. They affected more than 1 in 10 people.

Redness, hives and rash at the injection site and rash occurred in less than 1 in 10 people. Itching at the injection site occurred in less than 1 in 100 people. Swelling of the face, which may affect people who had facial cosmetic injections in the past, and weakness in muscles on one side of face (acute peripheral facial paralysis or palsy) occurred rarely, in less than 1 in 1000 people.

Allergic reactions have occurred in people receiving the vaccine, including a very small number of cases of severe allergic reactions (anaphylaxis). As for all vaccines, COVID-19 Vaccine Moderna should be given under close supervision with appropriate medical treatment available.

#### **14. Why has EMA recommended the authorisation of COVID-19 Vaccine Moderna?**

COVID-19 Vaccine Moderna offers a high level of protection against COVID-19 which is a critical need in the current pandemic. The main trial showed that the vaccine has a 94.1% efficacy. Most side effects are mild to moderate in severity and are gone within a few days.

The European Medicines Agency therefore decided that COVID-19 Vaccine Moderna's benefits are greater than its risks and it can be recommended for authorisation in the EU. COVID-19 Vaccine Moderna has been recommended for 'conditional marketing authorisation'. This means that there is more evidence to come about the vaccine (see below), which the company is required to provide. The Agency will review any new information that becomes available and this overview will be updated as necessary.

#### **15. What information is still awaited for COVID-19 Vaccine Moderna?**

Since COVID-19 Vaccine Moderna has been recommended for conditional marketing authorisation, the company that markets COVID-19 Vaccine Moderna will continue to provide results from the clinical trial, which is ongoing, for 2 years. This trial and additional studies will provide information on how long protection lasts, how well the vaccine prevents severe COVID-19, how well it protects immunocompromised people, children and pregnant women, and whether it prevents asymptomatic cases.

In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will also give more information on the vaccine's long-term safety and benefit in the general population.

The company will also carry out studies to provide additional assurance on the pharmaceutical quality of the vaccine as the manufacturing continues to be scaled up.

#### **16. What measures are being taken to ensure the safe and effective use of COVID-19 Vaccine Moderna?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of COVID-19 Vaccine Moderna have been included in the summary of product characteristics and the package leaflet.

A risk management plan for COVID-19 Vaccine Moderna is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks. A summary of the RMP is available.

Safety measures will be implemented for COVID-19 Vaccine Moderna in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets COVID-19 Vaccine Moderna will provide monthly safety reports.

As for all medicines, data on the use of COVID-19 Vaccine Moderna are continuously monitored. Suspected side effects reported with COVID-19 Vaccine Moderna are carefully evaluated and any necessary action taken to protect patients.

#### ***17. Other information about COVID-19 Vaccine Moderna***

COVID-19 Vaccine Moderna was recommended by EMA's human medicines committee (CHMP) on 6 January 2021 for a conditional marketing authorisation valid throughout the EU. The European Commission will issue a decision shortly.

Detailed recommendations for the use of this product are described in the product information, which will be available in all official European Union languages after a decision on the marketing authorisation has been issued by the European Commission.

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