



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/564427/2021
EMA/H/C/005791

Spikevax¹ (COVID-19 mRNA vaccine [nucleoside modified])

An overview of Spikevax and why it is authorised in the EU

What is Spikevax and what is it used for?

Spikevax is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 12 years and older.

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

How is Spikevax used?

Spikevax is given as two injections, usually into the muscle of the upper arm, 28 days apart. An additional dose may be given to people with a severely weakened immune system, at least 28 days after their second dose.

For more information about using Spikevax, see the package leaflet or consult a healthcare professional.

How does Spikevax work?

Spikevax 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.

¹ Previously known as COVID-19 Vaccine Moderna



What benefits of Spikevax have been shown in studies?

A very large clinical trial showed that Spikevax, given as a two-dose regimen, 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.

The effects of Spikevax were also investigated in a study involving over 3,000 children aged 12 to 17 years. The study showed that Spikevax produced a comparable antibody response in 12- to 17-year-olds to that seen in young adults (aged 18 to 25 years), as measured by the level of antibodies against SARS-CoV-2. In addition, none of 2,163 children receiving the vaccine developed COVID-19, compared with four of 1,073 children given a dummy injection. These results allowed to conclude that the efficacy of Spikevax in children 12 to 17 years old is similar to that in adults.

Another study showed that an additional dose of Spikevax increased the ability to produce antibodies against SARS-CoV-2 in organ transplant patients with severely weakened immune systems.

Can people who have already had COVID-19 be vaccinated with Spikevax?

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

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

Can Spikevax reduce transmission of the virus from one person to another?

The impact of vaccination with Spikevax 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.

How long does protection from Spikevax last?

It is not currently known how long protection given by Spikevax 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.

Can children be vaccinated with Spikevax?

Spikevax is not currently authorised for children below 12 years of age.

Can immunocompromised people be vaccinated with Spikevax?

There are limited data on immunocompromised people. 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.

Severely immunocompromised people may be given an additional dose of Spikevax, at least 28 days after their second dose.

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

Animal studies do not show any harmful effects in pregnancy, however data on the use of Spikevax 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.

Can people with allergies be vaccinated with Spikevax?

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, Spikevax 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 Spikevax should not receive the second dose.

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

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

What are the risks associated with Spikevax?

The most common side effects with Spikevax in the trials were usually mild or moderate and got better within a few days after vaccination.

The most common side effects are pain and swelling at the injection site, tiredness, chills, fever, swollen or tender lymph nodes under the arm, headache, muscle and joint pain, nausea (feeling sick) and vomiting. They may affect more than 1 in 10 people.

Redness, hives and rash at the injection site, sometimes occurring more than a week after injection, and rash may affect less than 1 in 10 people. Itching at the injection site and dizziness may affect less than 1 in 100 people. Swelling of the face, which may affect people who had facial cosmetic injections in the past, weakness in muscles on one side of the face (acute peripheral facial paralysis or palsy) and hypoaesthesia (reduced sensation to touch, pain and temperature) may affect less than 1 in 1,000 people.

A very small number of cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) have occurred with Spikevax. Allergic reactions have also occurred in people receiving the vaccine, including a very small number of cases of severe

allergic reactions (anaphylaxis). As for all vaccines, Spikevax should be given under close supervision with appropriate medical treatment available.

Why is Spikevax authorised in the EU?

Spikevax 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 in adults; the efficacy of Spikevax in children 12 to 17 years old is similar to that in adults. Most side effects are mild to moderate in severity and are gone within a few days.

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

Spikevax has been given '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.

What information is still awaited for Spikevax?

Since Spikevax has been given conditional marketing authorisation, the company that markets Spikevax will provide final results from the two clinical trials, which will continue until the end of 2022. These trials 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, 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.

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

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

A [risk management plan \(RMP\)](#) for Spikevax 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.

Safety measures will be implemented for Spikevax 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 Spikevax will provide monthly safety reports.

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

Other information about Spikevax

COVID-19 Vaccine Moderna received a conditional marketing authorisation valid throughout the EU on 6 January 2021.

The name of the vaccine was changed to Spikevax on 22 June 2021.

Further information on Spikevax can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna

This overview was last updated in 10-2021.