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Spikevax[1] (*elasomeran*)

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 6 years and older.

Spikevax contains elasomeran, 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. Adults and adolescents from the age of 12 are given 100 micrograms per dose; children aged 6 to 11 years are given 50 micrograms per dose.

An additional dose may be given to people aged 6 years and older with a severely weakened immune system, at least 28 days after their second dose.

A booster dose of 50 micrograms may be given at least 3 months after the second dose to people aged 18 years and older. A booster dose of Spikevax can also be given to adults at least 3 months after primary vaccination with another mRNA vaccine or an adenoviral vector vaccine. At national level, public health bodies may issue official recommendations, taking into account emerging effectiveness data and the limited safety data.

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.

[1] Previously known as COVID-19 Vaccine Moderna

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.

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.

An additional study involving children aged 6 to 11 showed that Spikevax produced a comparable antibody response in this age group to that seen in young adults (aged 18 to 25 years), as measured by the level of antibodies against SARS-CoV-2. These results indicate that the efficacy of Spikevax in children 6 to 11 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.

Further data showed a rise in antibody levels when a booster dose was given after the second dose of Spikevax or after primary vaccination with another mRNA vaccine or an adenoviral vector vaccine in adults with a normal immune system.

Can children be vaccinated with Spikevax?

Spikevax is not currently authorised for children below 6 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?

Spikevax can be used during pregnancy. A large amount of data from pregnant women vaccinated with Spikevax during the second or third trimester of their pregnancy has been analysed and showed no signs of pregnancy complications. Although data in women in the first trimester of pregnancy are more limited, no increased risk of miscarriage was seen.

Spikevax can be used during breast-feeding. Data from women who were breast-feeding after vaccination have not shown a risk of adverse effects in breast-fed babies.

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 are usually mild or moderate and get better within a few days after vaccination. These include redness, 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.

Hives and rash at the injection site, sometimes occurring more than a week after injection, rash and diarrhoea may affect less than 1 in 10 people. Itching at the injection site, dizziness and abdominal pain 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.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) may occur in up to 1 in 10,000 people.

A very small number of cases of erythema multiforme (red patches on the skin with a dark red centre and paler red rings) have occurred. 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 6 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, as well as from the trial in children aged 6 to 11. These trials and additional studies, including independent studies of COVID-19 vaccines coordinated by EU authorities, will provide more information on the vaccine's long-term safety and its benefits.

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 for Spikevax are implemented 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 regular 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.

More information about the COVID-19 vaccines, such as expected duration of protection against infection or severe disease, mixing different vaccines and vaccination after recovery from COVID-19 disease, is available on the COVID-19 vaccines key facts page.

Further information on Spikevax can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna

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