



EUROPEAN MEDICINES AGENCY  
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## Spikevax<sup>1</sup> (*COVID-19 mRNA Vaccine (nucleoside modified)*)

An overview of Spikevax, including its adapted vaccines, 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 from the age of 6 months.

Spikevax contains elasomeran, a molecule called messenger RNA (mRNA) with instructions for producing a protein from the original strain of SARS-CoV-2, the virus that causes COVID-19.

Spikevax is also available as two adapted vaccines:

- Spikevax bivalent Original/Omicron BA.1 contains elasomeran and an additional mRNA molecule, imelasomeran, with instructions for producing a protein from the Omicron BA.1 subvariant of SARS-CoV-2;
- Spikevax bivalent Original/Omicron BA.4-5 contains elasomeran and an additional mRNA molecule, davesomeran, with instructions for producing a protein from the Omicron BA.4 and BA.5 subvariants of SARS-CoV-2.

The adapted vaccines are authorised for use in people who have previously received at least a primary vaccination course against COVID-19.

Spikevax and its adapted vaccines do not contain the virus itself and cannot cause COVID-19.

### How is Spikevax used?

#### Primary vaccination

Spikevax is given as two injections, usually into the muscle of the upper arm, or the thigh in infants and young children, 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, and children aged 6 months to 5 years are given 25 micrograms per dose.

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<sup>1</sup> Previously known as COVID-19 Vaccine Moderna



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

### **Booster vaccination**

A booster dose of Spikevax may be given to adults and children from the age of 6 years, at least 3 months after primary vaccination with Spikevax, or another mRNA vaccine or an adenoviral vector vaccine. Adults and adolescents from the age of 12 years are given 50 micrograms per dose and children aged 6 to 11 years are given 25 micrograms per dose.

A booster dose of Spikevax bivalent Original/Omicron BA.1 may be given to adults and children from the age of 6 years, at least 3 months after primary vaccination or a booster dose with a COVID-19 vaccine. Adults and adolescents from the age of 12 years are given 50 micrograms per dose and children aged 6 to 11 years are given 25 micrograms per dose.

A booster dose of Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms) may be given to adults and adolescents from the age of 12 years, at least 3 months after primary vaccination or a booster dose with a COVID-19 vaccine.

The vaccines should be used according to official recommendations, issued at national level, by public health bodies.

For more information about using Spikevax and its adapted vaccines, 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 and can differ between variants of the virus. An adapted vaccine works in the same way as the original vaccine and is expected to broaden protection against the virus as it also contains mRNA matching other variants of the virus.

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, their immune system will recognise it and be ready to defend the body against it.

After vaccination the mRNA from the vaccine is broken down and removed from the body.

### **What benefits of Spikevax have been shown in studies?**

#### **Primary vaccination**

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.

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.

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 immune 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 the 2,163 children who received 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 three groups of children aged 6 months to under 2 years, 2 to 5 years and 6 to 11 years showed that Spikevax produced a comparable immune response in these age groups 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 months to 11 years old is similar to that in adults.

## **Booster vaccination**

### Spikevax

Data showed a rise in antibody levels when a booster dose of Spikevax was given in adults with a normal immune system after the second dose of Spikevax or after primary vaccination with another mRNA vaccine or an adenoviral vector vaccine. The company also presented supporting evidence from studies, including data regarding the use of a booster dose of Spikevax in young adults aged between 18 and 25 years, together with post-authorisation data and real-world evidence from the use of a booster dose in young people.

Further data showed that a booster dose of Spikevax in children aged 6 to 11 years and in adolescents aged 12 to 17 produced a comparable immune response to that seen in young adults (aged 18 to 25 years).

### Spikevax bivalent Original/Omicron BA.1

A study involving more than 800 adults aged 18 years and above found that a booster dose of Spikevax bivalent Original/Omicron BA.1 induced a stronger immune response against the SARS-CoV-2 strain and the Omicron subvariant BA.1, compared with a booster dose of Spikevax. The study compared the level of antibodies in people who were given a second booster dose of either Spikevax or Spikevax bivalent Original/Omicron BA.1, after previous vaccination with a primary series and booster dose of Spikevax. It was also concluded that Spikevax bivalent Original/Omicron BA.1 could be used as a first booster after primary vaccination and that the immune response induced by a booster dose of Spikevax bivalent Original/Omicron BA.1 in children aged 6 to 11 and adolescents aged 12-17 years would be at least equal to that in adults, given that previous data with Spikevax have shown a comparable effect.

### Spikevax bivalent Original/Omicron BA.4-5

The composition of Spikevax bivalent Original/Omicron BA.4-5 is identical to that of Spikevax bivalent Original/Omicron BA.1, with the exception of an mRNA molecule encoding for different, but closely related, Omicron subvariants. Therefore, based on the clinical study showing that Spikevax bivalent Original/Omicron BA.1 induced a strong immune response against both the original SARS-CoV-2 strain

and the Omicron subvariant BA.1, Spikevax bivalent Original/Omicron BA.4-5 is expected to generate an immune response against both the original SARS-CoV-2 strain and the BA.4 and BA.5 subvariants. Spikevax bivalent Original/Omicron BA.4-5 is expected to be more effective at triggering an immune response against the BA.4 and BA.5 subvariants compared with Spikevax. This is further supported by non-clinical laboratory data, which showed that the adapted vaccine is able to trigger an adequate immune response.

### **Can children be vaccinated with Spikevax?**

Spikevax is authorised as a primary vaccination course for children from 6 months of age.

The adapted vaccine Spikevax bivalent Original/Omicron BA.1 is authorised for booster vaccination in children from 6 years of age.

The adapted vaccine Spikevax bivalent Original/Omicron BA.4-5 is authorised for booster vaccination in children from 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 as part of their primary vaccination.

### **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 increase in 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.

No data are currently available regarding the use of Spikevax bivalent Original/Omicron BA.1 in pregnant or breast-feeding women. However, based on the similarity with the original vaccine, including a comparable safety profile, Spikevax bivalent Original/Omicron BA.1 can be used during pregnancy and breast-feeding. In addition, based on the data available for Spikevax and Spikevax bivalent Original/Omicron BA.1, Spikevax bivalent Original/Omicron BA.4-5 can also be used during pregnancy and breast-feeding.

### **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 and its adapted vaccines 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 a dose of Spikevax or its adapted vaccines should not receive subsequent doses.

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

The main clinical trials for Spikevax 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. In infants under 3 years of age, irritability, crying, sleepiness and loss of appetite were also very common side effects (affecting more than 1 in 10 infants).

Hives and rash at the injection site, sometimes occurring more than a week after injection, rash affecting areas other than the injection site 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), paraesthesia (unusual feeling in the skin, such as tingling or a crawling feeling) 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).

Available data show that Spikevax bivalent Original/Omicron BA.1 has comparable side effects to Spikevax. Based on the safety data for Spikevax and for Spikevax bivalent Original/Omicron BA.1, the safety profile for Spikevax bivalent Original/Omicron BA.4-5 is expected to be comparable to those of these vaccines.

As for all vaccines, Spikevax and its adapted vaccines 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 months 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.

Spikevax bivalent Original/Omicron BA.1 was found to induce high levels of antibodies against the original strain of SARS-CoV-2 and the Omicron BA.1 subvariant. It had a comparable safety profile to the original vaccine. Spikevax bivalent Original/Omicron BA.4-5 is expected to trigger an immune response against both the original strain and the subvariants BA.4 and BA.5 of SARS-CoV-2, and its

safety profile is expected to be comparable to that of Spikevax and Spikevax bivalent Original/Omicron BA.1.

The European Medicines Agency therefore decided that the benefits of Spikevax, including its adapted vaccines, are greater than its risks, and it can be authorised for use in the EU.

Spikevax was originally given 'conditional authorisation' because there was more evidence to come about the vaccine. The company has provided comprehensive information, including data regarding its safety, efficacy, and how well Spikevax prevents severe disease. In addition, the company has completed all requested studies on the pharmaceutical quality of the vaccine. As a result, the conditional authorisation has been switched to a standard one.

## **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 and its adapted vaccines have been included in the summary of product characteristics and the package leaflet.

A [risk management plan \(RMP\)](#) 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 and its adapted vaccines 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 and its adapted vaccines are continuously monitored. Suspected side effects 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. This was switched to a standard marketing authorisation on 3 October 2022.

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

More information about the COVID-19 vaccines, such as the use of adapted vaccines and boosters, is available on the [COVID-19 vaccines key facts page](#).

Further information on Spikevax and its adapted vaccines, can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna](https://ema.europa.eu/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna)

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