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# Nuvaxovid *(COVID-19 vaccine (recombinant, adjuvanted))*

An overview of Nuvaxovid, including its adapted vaccine, and why it is authorised in the EU

## What is Nuvaxovid and what is it used for?

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

The originally authorised Nuvaxovid contains a version of a protein found on the surface of SARS-CoV-2 (the virus that causes COVID-19), which has been produced in the laboratory.

Nuvaxovid is also available as an adapted vaccine, Nuvaxovid XBB.1.5, which contains a version of the protein from the Omicron XBB.1.5 subvariant of SARS-CoV-2.

## How is Nuvaxovid used?

The originally authorised Nuvaxovid is given as two injections, usually into the muscle of the upper arm, 3 weeks apart, as part of a primary vaccination. A booster dose may be given after primary vaccination with Nuvaxovid or another authorised COVID-19 vaccine.

Nuvaxovid XBB.1.5 is given as a single dose, irrespective of the person's COVID-19 vaccination history. For people who have previously been vaccinated with a COVID-19 vaccine, Nuvaxovid XBB.1.5 should be given at least 3 months after the most recent dose of 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 Nuvaxovid, including information about the adapted vaccine, see the package leaflet or consult a healthcare professional.

## How does Nuvaxovid work?

Nuvaxovid works by preparing the body to defend itself against COVID-19. It contains a version of the spike protein of SARS-CoV-2, which has been produced in the laboratory. This is a protein on the surface of SARS-CoV-2 which the virus needs to enter the body's cells and which can differ between

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variants of the virus. The vaccine also contains an 'adjuvant', a substance to help strengthen the immune response to the vaccine.

When a person is given the vaccine, their immune system will identify the protein in the vaccine as foreign and produce natural defences — antibodies and T cells — against it.

If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the spike protein on the virus and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, preventing its entry into the body's cells and destroying infected cells.

The adapted vaccine works in the same way as the originally authorised vaccine and is expected to maintain protection against the virus as they more closely match circulating variants of the virus.

## What benefits of Nuvaxovid have been shown in studies?

Results from two main clinical trials found that Nuvaxovid was effective at preventing COVID-19 in people from 12 years of age when given as primary vaccination. In these studies, over 47,000 people were given two doses of Nuvaxovid or placebo (a dummy injection).

In the first study, conducted in adolescents and adults, around two thirds of participants received the vaccine and the others were given placebo.

The study found a 90.4% reduction in the number of symptomatic COVID-19 cases from 7 days after the second dose in adults who received Nuvaxovid (14 cases out of 17,312 people) compared with adults given placebo (63 out of 8,140 people). This means that the vaccine had a 90.4% efficacy in this study.

The trial also showed that the immune response to Nuvaxovid, which was measured as the level of antibodies against SARS-CoV-2, was comparable between adolescents and young adults aged 18 to 25 years. Compared with placebo, the vaccine led to an 80% reduction in the number of symptomatic COVID-19 cases seen from 7 days after the second dose onward in adolescents; six out of 1,205 adolescents who received the vaccine and 14 out of 594 who received placebo developed COVID-19.

The second study included only adults. The study showed a similar reduction in the number of symptomatic COVID-19 cases in people who received Nuvaxovid (10 cases in 7,020 people) compared with people given placebo (96 in 7,019 people); in this study, the vaccine efficacy was 89.7%. Taken together, the results of the two studies show that Nuvaxovid was effective at preventing COVID-19 in both adults and adolescents. The original strain of SARS-CoV-2 and variants of concern such as Alpha, Beta and Delta were the most common viral strains circulating when the studies were ongoing. There is currently limited data on the efficacy of Nuvaxovid against other variants of concern, including Omicron.

Data from two studies showed a rise in antibody levels when a booster dose of Nuvaxovid was given in adults after primary vaccination with the vaccine. The vaccine is expected to produce a similar booster response in adolescents. Data from an additional study also showed a rise in antibody levels when a booster dose of Nuvaxovid was given in adults after primary vaccination with an mRNA vaccine or adenoviral vector vaccine.

For the adapted vaccine Nuvaxovid XBB.1.5, laboratory data showed that it is able to trigger an adequate immune response against Omicron XBB.1.5. In addition, data from a study in previously vaccinated adults showed that when Nuvaxovid was adapted to target another related strain, Omicron BA.5, it was able to trigger a strong immune response against this strain. Based on these data, Nuvaxovid XBB.1.5 is expected to trigger an adequate immune response against XBB.1.5.

## Can children be vaccinated with Nuvaxovid?

The originally authorised Nuvaxovid and Nuvaxovid XBB.1.5 are not currently authorised for use in children below 12 years of age. EMA has agreed with the company on a plan to study the vaccine in a clinical trial involving younger children at a later stage.

## Can immunocompromised people be vaccinated with Nuvaxovid?

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.

Severely immunocompromised people may be given additional doses of Nuvaxovid XBB.1.5.

## Can pregnant or breast-feeding women be vaccinated with Nuvaxovid?

Animal studies do not show any harmful effects in pregnancy, however data on the use of Nuvaxovid during pregnancy are limited. Although there are no studies on breast-feeding, no risk for breast-feeding is expected.

The decision on whether to use the originally authorised Nuvaxovid or the adapted 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 Nuvaxovid?

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

Cases of anaphylaxis (severe allergic reaction) have been seen in people receiving COVID-19 vaccines. Therefore, as for all vaccines, the originally authorised Nuvaxovid and Nuvaxovid XBB.1.5 should be given under close medical supervision, with the appropriate medical treatment available. People who have a severe allergic reaction when they are given the first dose of Nuvaxovid must not receive the second dose.

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

The main trial included people of different ethnicities and genders. Efficacy was maintained across genders and ethnic groups.

## What are the risks associated with Nuvaxovid?

For the full list of side effects and restrictions with Nuvaxovid, see the package leaflet.

The most common side effects with Nuvaxovid are usually mild or moderate and get better within a few days after vaccination. These include headache, nausea (feeling sick) or vomiting, muscle and joint pain, tenderness and pain at the injection site, tiredness and feeling unwell. These may affect more than 1 in 10 people.

Redness and swelling at the injection site, fever and pain in the limbs may affect less than 1 in 10 people. Fever may occur more frequently in adolescents after the second dose (in more than 1 in 10 people) compared with adults. Enlarged lymph nodes, high blood pressure (this was not reported in

adolescents), rash, reddening of the skin, itching at the injection site, itching at areas other than the injection site and itchy rash are uncommon side effects (affecting less than 1 in 100 people).

A very small number of cases of paraesthesia (unusual feeling in the skin, such as tingling or a crawling feeling), hypoaesthesia (reduced sensation to touch, pain and temperature), myocarditis (inflammation of the heart muscle), pericarditis (inflammation of the membrane around the heart) and anaphylaxis (severe allergic reactions) have occurred.

The safety of Nuvaxovid XBB.1.5 is comparable to that of the originally authorised vaccine.

## Why is Nuvaxovid authorised in the EU?

Data have shown that originally authorised Nuvaxovid and its adapted vaccine cause the production of antibodies against SARS-CoV-2 that can protect against COVID-19. The main trial showed that the originally authorised vaccine offers a high level of protection against COVID-19 in adults. The immune response to the vaccine is similar in adolescents and adults.

Most side effects are mild to moderate in severity and are gone within a few days.

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

Nuvaxovid was originally given 'conditional authorisation' because there was more evidence to come about the vaccine. The company has provided comprehensive information, including data 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 Nuvaxovid?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nuvaxovid and its adapted vaccine 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 Nuvaxovid and its adapted vaccine 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 Nuvaxovid will provide regular safety reports.

As for all medicines, data on the use of Nuvaxovid and its adapted vaccine are continuously monitored. Suspected side effects are carefully evaluated and any necessary action taken to protect patients.

## Other information about Nuvaxovid

Nuvaxovid received a conditional marketing authorisation valid throughout the EU on 20 December 2021. This was switched to a standard marketing authorisation on 4 July 2023.

More information about the COVID-19 vaccines is available on the COVID-19 vaccines key facts page.

Further information on Nuvaxovid can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/nuvaxovid

This overview was last updated in 11-2023.