



EUROPEAN MEDICINES AGENCY
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Nuvaxovid (*COVID-19 vaccine (recombinant, adjuvanted)*)

An overview of Nuvaxovid 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 18 years and older.

Nuvaxovid contains a version of a protein found on the surface of SARS-CoV-2 (the spike protein), which has been produced in the laboratory.

How is Nuvaxovid used?

Nuvaxovid is given as two injections, usually into the muscle of the upper arm, 3 weeks apart.

Arrangements for the supply of the vaccine will be the responsibility of national authorities. For more information about using Nuvaxovid, 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 that has been produced in the laboratory. It also contains an 'adjuvant', a substance to help strengthen the immune responses 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, prevent its entry into the body's cells and destroy infected cells.

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 18 years of age. The studies involved over 45,000 people in total. In the first study, around two thirds of participants received the vaccine and the others were given placebo (a dummy

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injection); in the other study, participants were equally split between Nuvaxovid and placebo. People did not know if they had been given Nuvaxovid or placebo.

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

The second study conducted in the United Kingdom also showed a similar reduction in the number of symptomatic COVID-19 cases in people who received Nuvaxovid (10 cases out of 7,020 people) compared with people given placebo (96 out of 7,019 people); in this study, the vaccine efficacy was 89.7%.

Taken together, the results of the two studies show a vaccine efficacy for Nuvaxovid of around 90%. The original strain of SARS-CoV-2 and some variants of concern such as Alpha and Beta 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.

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

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

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

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

The impact of vaccination with Nuvaxovid 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 Nuvaxovid last?

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

Can children be vaccinated with Nuvaxovid?

Nuvaxovid is not currently recommended for people below 18 years of age. EMA has agreed with the company on a plan to trial the vaccine in 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.

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 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 should not receive the vaccine.

Cases of anaphylaxis (severe allergic reaction) have been seen in people receiving COVID-19 vaccines. Therefore, as for all vaccines, Nuvaxovid 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 should 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?

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

Redness and swelling at the injection site, fever, chills and pain in the limbs occurred in less than 1 in 10 people. Enlarged lymph nodes, high blood pressure, rash, reddening of the skin, itching at the injection site and itchy rash were uncommon side effects (affecting less than 1 in 100 people).

Why is Nuvaxovid authorised in the EU?

Nuvaxovid offers a high level of protection against COVID-19 which is a critical need in the current pandemic. The main trials showed that the vaccine has around 90% efficacy. Most side effects are mild to moderate in severity and are gone within a few days.

The Agency therefore decided that Nuvaxovid's benefits are greater than its risks and that it can be recommended for authorisation in the EU.

EMA has recommended a conditional marketing authorisation for Nuvaxovid. 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 Nuvaxovid?

As Nuvaxovid received a conditional marketing authorisation, the company that markets Nuvaxovid will carry out studies to provide additional assurance on the pharmaceutical quality of the vaccine.

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.

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 have been included in the summary of product characteristics and the package leaflet.

A risk management plan (RMP) for Nuvaxovid 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 Nuvaxovid 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 monthly safety reports.

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

Other information about Nuvaxovid

Nuvaxovid received a marketing authorisation valid throughout the EU on 20 December 2021.

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

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