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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 12 years and older.

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

How is Nuvaxovid used?

Primary vaccination

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

Booster vaccination

A booster dose of Nuvaxovid may be given to people aged 18 years and older around 6 months after primary vaccination with Nuvaxovid. A booster dose of Nuvaxovid may also be given after primary vaccination with an mRNA vaccine or adenoviral vector vaccine; in this case a booster dose of Nuvaxovid should be given according to the dosing intervals recommended for booster doses of specific mRNA and adenoviral vector vaccines.

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

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 of the original SARS-CoV-2 virus strain and has been produced in the laboratory. It also contains an 'adjuvant', a substance to help strengthen the immune response to the vaccine.

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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?

Primary vaccination

Results from two main clinical trials found that Nuvaxovid was effective at preventing COVID-19 in people from 12 years of age. 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, 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 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 was carried out in the United Kingdom and 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.

Booster vaccination

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. 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.

Can children be vaccinated with Nuvaxovid?

Nuvaxovid is not currently authorised for use in children below 12 years of age. EMA has agreed with the company on a plan to trial the vaccine in 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.

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. Fever was seen more frequently in adolescents (occurring in more than 1 in 10 people) compared with adults. Enlarged lymph nodes, high blood pressure, rash, reddening of the skin, itching at the injection site, itching at areas other than the injection site and itchy rash were 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. As for all vaccines, Nuvaxovid should be given under close supervision with appropriate medical treatment available.

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. Clinical trials showed that the vaccine has around 90% efficacy in adults. The immune response to the vaccine is similar in adolescents compared with adults. Most side effects are mild to moderate in severity and are gone within a few days.

The European Medicines Agency therefore decided that Nuvaxovid's benefits are greater than its risks and that it can be authorised for use 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 provide more information on the vaccine's long-term safety and its benefits.

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 for Nuvaxovid 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 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 conditional marketing authorisation valid throughout the EU on 20 December 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 Nuvaxovid can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/nuvaxovid

This overview was last updated in 11-2022.