



Information on COVID-19 Nuvaxovid (Novavax) vaccine

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About the vaccine

Nuvaxovid (Novavax) is a vaccine that can prevent people from becoming ill from COVID-19. Two doses are required initially (called the primary course). These 2 doses are usually given at least 3 weeks apart.

The Novavax COVID-19 vaccine does not contain any live virus, and it cannot give you COVID-19. It contains an important part of the SARS-CoV-2 virus called the spike protein. It also contains an adjuvant called Matrix-M, which helps create a stronger immune response. After getting the vaccine, your immune system learns to recognise and fight against the SARS-CoV-2 virus, which causes COVID-19.

Vaccination is voluntary and free. You can discuss any concerns or questions you have about COVID-19 vaccination with your immunisation provider or your GP before you receive the vaccine.

Benefits of the vaccine

Two large clinical trials showed that Novavax is effective in preventing COVID-19 in people aged 18 years and older. People who had two doses of Novavax were about 90% less likely to get symptomatic COVID-19 than people who did not get the vaccine. It was equally effective in people over the age of 65 years, as well as people with some stable pre-existing medical conditions.

Protection against COVID-19 starts from about 2–3 weeks after the first dose. While one dose may give some protection, it may only last for the short term. Two doses will give improved protection. No vaccine is 100% effective, so it is possible that you can still get sick from COVID-19 after vaccination.

SARS-CoV-2 could potentially still infect a vaccinated person. Even if they have no symptoms or only mild symptoms, they could still pass it on to others. However, the COVID-19 vaccines

currently used in Australia are effective in reducing the likelihood of a vaccinated person transmitting the virus to close contacts if the person is infected.

This is why after vaccination it is important to continue other preventive measures like:

- physical distancing
- hand washing
- wearing a face mask
- COVID-19 testing and quarantine/isolation as required by your state/territory.

If you have been vaccinated with Novavax, you should still get a COVID-19 test if you have symptoms that meet testing criteria according to your local health authority (e.g. fever, cough, sore throat).

Safety of the vaccine

Novavax has been safely given to thousands of people around the world. This is a relatively small number of people compared with other COVID-19 vaccines, so we don't yet know if there are any rare side effects associated with Novavax.

For updates on any rare side effects that are identified for Novavax, please refer to the weekly updates published by the Therapeutic Goods Administration (TGA), available at: www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

Who can receive this vaccine

People aged 18 years and older can receive the Novavax COVID-19 vaccine for their primary course.

Booster doses

A booster dose refers to an additional vaccine dose after the primary vaccine course. It is intended to strengthen and prolong protection against COVID-19.

Novavax is not currently registered for use as a booster vaccine.

If you are 16 years or older, you can receive a booster dose if it has been 3 months or more after your primary course. Booster doses are not currently recommended for younger people.

People aged 16 and over can have a booster dose of Pfizer.

People aged 18 and over can have a booster dose of Pfizer or Moderna. AstraZeneca is not preferred but can be used in some instances.

Novavax is not currently registered with the TGA for use as a booster dose.

For more information on boosters, see: <u>www.health.gov.au/resources/publications/atagi-</u> recommendations-on-the-use-of-a-booster-dose-of-covid-19-vaccine.

Who should not receive this vaccine

You should not receive this vaccine if you have had:

- anaphylaxis (a type of severe allergic reaction) to a previous dose of Novavax COVID-19 vaccine
- anaphylaxis after exposure to any component of the vaccine, including polysorbate 80
- any other serious adverse event that, following review by an experienced immunisation provider or medical specialist, was attributed to a previous dose of the Novavax COVID-19 vaccine and without another cause identified.

Precautions for vaccination

People with certain conditions may need additional precautions, such as staying for 30 minutes of observation after having their vaccine or consulting an allergy specialist. Tell your immunisation provider if you have had:

- an allergic reaction to a previous dose or to an ingredient of the Novavax COVID-19vaccine
- **anaphylaxis to other vaccines or to other medicines**. Your provider can check to ensure there are no common ingredients with the COVID-19 vaccine you are receiving
- confirmed mastocytosis with recurrent anaphylaxis that requires treatment.

If **you have a bleeding disorder** or you are **taking a blood-thinning medication** (anticoagulant), tell your immunisation provider. Your immunisation provider can help determine whether it is safe for you to have an intramuscular injection and help decide the best timing for injection.

Special circumstances to discuss before vaccination

People with weakened immune systems (immunocompromise)

People with immunocompromise includes those who have a medical condition that weakens their immune system. It also includes those who may be taking medications that suppress their immune system. People with immunocompromise, including those living with HIV, have a higher risk of severe illness from COVID-19, including a higher risk of death. Novavax is not a live vaccine. It is safe in people with immunocompromise.

People with severe immunocompromise can have a third dose of Novavax for their primary course. Severely immunocompromised people aged 18 years and over who received a third primary dose are recommended to receive a booster dose (i.e. 4th dose) at 3 months, in line with the timing for the general population. Novavax is not currently registered for use as a booster vaccine; Pfizer or Moderna are preferred for this dose. AstraZeneca can be used if there are contraindications to Pfizer and Moderna.

Clinical trials for Novavax did not include people with immunocompromise, except for a small group of people with HIV. We do not know if Novavax is as effective in people with immunocompromise compared to the rest of the population. It is possible that Novavax might not be as effective in people with immunocompromise as it is in the general population. It is important to continue other preventive measures such as physical distancing after vaccination.

Women who are pregnant or breastfeeding

Women and adolescents who are pregnant can receive Novavax vaccine at any stage of pregnancy. If you are trying to become pregnant, you do not need to delay vaccination or avoid becoming pregnant after vaccination.

Pregnant women with COVID-19 have an increased risk of severe illness and adverse pregnancy outcomes.

There is no data about the safety of Novavax vaccine in pregnant or breastfeeding women. There are no theoretical safety concerns, however, about receiving Novavax during pregnancy because it is not a live vaccine. The Pfizer and Moderna vaccines have large amounts of realworld data to show that they are safe for pregnant and breastfeeding women.

If you are breastfeeding, you can have Novavax. You do not need to stop breastfeeding after vaccination.

People with a history of COVID-19

If you have had COVID-19 in the past, tell your doctor or immunisation provider. COVID-19 vaccination can be given after recovery from the infection, or can be deferred for up to 4 months after the acute illness in those who have had confirmed SARS-CoV-2 infection, as evidence suggests that past infection reduces the risk of reinfection for at least 4 months.

Novavax and children

Novavax has only been provisionally approved for use in people aged 18 years and over and cannot be given to people younger than 18.

Ensuring the safety of Novavax

The Therapeutic Goods Administration (TGA) assesses all vaccines in Australia. This ensures that, in order for a vaccine to be approved, it is safe, effective and manufactured to a very high quality standard. A description of the process for approval of COVID-19 vaccines is available at: www.tga.gov.au/covid-19-vaccine-approval-process.

The safety of COVID-19 vaccines will continue to be monitored closely throughout the COVID-19 vaccination program.

You can report suspected side effects to your vaccination provider or other healthcare professional. They will then make a formal report on your behalf to your state or territory health department or directly to the TGA.

If you would prefer to report it yourself, please visit <u>www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine</u> and follow the directions on the page.