The Immunisation Advisory Centre

COVID-19 EDUCATION

VERSION 5

Nuvaxovid, recombinant COVID-19 Vaccine

Information for healthcare professionals to support delivery of the Novavax COVID-19 vaccine, Nuvaxovid.

Key information

- Vaccine type: Adjuvanted recombinant spike protein subunit vaccine
- Immunisation Handbook abbreviation: rCV
- Two doses given at least 21 days apart, ideally 8 weeks apart, for use from age 12 years.
- Booster/additional booster doses from 6 months after previous COVID-19 vaccination or COVID-19 infection.

The preferred COVID-19 vaccines are Comirnaty 30mcg (for primary course) and Comirnaty 15/15mcg (for booster/additional booster doses), however Nuvaxovid (Novavax) may be offered to individuals aged 12 years or over as a primary dose to those who: are contraindicated to Comirnaty; have experienced a severe adverse event following Comirnaty; or have declined Comirnaty vaccines for personal preference.

When used as part of a mixed primary course, ie after a first dose of Comirnaty or AstraZeneca, a prescription and written consent are required.

Nuvaxovid can also be used as an alternative to Comirnaty for booster or additional booster doses to those aged 18 years and over. A prescription is not required even if the previous doses were with different vaccines.

Background

Nuvaxovid contains recombinant SARS-CoV-2 spike protein in a stabilised prefusion conformation combined with Matrix-M adjuvant to form immunogenic nanoparticles. The spike protein is produced by an insect cell-line that has been infected with an insect baculovirus expressing SARS-CoV-2 spike protein genes. The proprietary adjuvant (Matrix-M) contains two purified saponin fractions from Quillaja saponaria (soapbark tree) which enhances the innate immune response and activates the production of neutralising antibodies and T and B cell immunity.

The vaccine was designated NVX-2373 in clinical trials conducted by Novavax. It is sponsored in New Zealand by Biocelect and is approved by Medsafe for the prevention of COVID-19 in individuals aged 12 years and over.

Efficacy in clinical trials

Note that most of the clinical trials were conducted during early 2021, against predominantly Alpha not Delta nor Omicron variants. Real world data on effectiveness of Nuvaxovid is limited as the vaccine has not been used as widely as Comirnaty vaccines.

Primary course: homologous

An overall vaccine efficacy against symptomatic COVID-19 of 90% from 7 days after dose two of Nuvaxovid was shown across two phase III clinical trials involving over 45,000 participants (95% CI 82.9–94.6 in PREVENT-19 study in US/Mexico and 80.2–94.6% in a UK trial).(1,2) Protection was similar in participants aged 18-64 and 65-84 years and in those with coexisting illness. As reported by Novavax, vaccine efficacy was maintained over six months in the UK trial (from 10 November 2020 to 10 May 2021) with an overall vaccine efficacy of 82.5% (95% CI: 75.0–87.7) in protection against all COVID-19 infection – both symptomatic and asymptomatic – as measured by PCR+ or anti-N seroconversion, and efficacy against severe disease of 100% (95% CI: 17.9, 100).(3)

Primary course: heterologous/mixed

In those who have had a severe adverse reaction to their first dose of either Comirnaty or AstraZeneca, Nuvaxovid may be used for their second dose, given at least 28 days after the first dose. This is off-label use and will require prescription from an authorised provider (in accordance with Section 25 of the Medicines Act,1981).

Nuvaxovid has been shown to induce a good antibody response when given as a second dose after either a first dose of Comirnaty or AstraZeneca vaccines. A phase II study in the UK investigated safety and immunogenicity of mixed primary schedules. Between April and May 2021, 1,072 participants aged 50–78 years received a second dose of one of three COVID-19 vaccines a median of 9.4 weeks after receipt of a single dose of either the AstraZeneca or Comirnaty vaccines. (5) Although, the antibody response after a dose of Nuvaxovid was not as high as after a second dose of Comirnaty, an 18-fold rise in anti-spike antibody concentration was seen 28 days after vaccination. This was higher than after two doses of AstraZeneca vaccine. For those who received a first dose of AstraZeneca, a second dose with Nuvaxovid induced a better antibody response than a second dose of AstraZeneca.

Booster doses: homologous

Early data supports the safety and effectiveness of the use of Nuvaxovid as a booster dose.

The immune responses were enhanced when a booster dose was given approximately six months after the two-dose primary course, as shown in a phase II clinical trial assessing the immunogenicity. For both Delta and Omicron, immune responses following the booster were notably higher than those associated with high levels of efficacy in phase III studies of the vaccine.(4)

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Booster doses: heterologous/mixed

In the UK COV-BOOST study participants aged 30 years or over with no history of laboratory-confirmed SARS-CoV-2 infection were given one of six vaccines as a booster dose at least 84 days post two doses of Comirnaty or at least 70 days post two doses of AstraZeneca.(6) Following a Comirnaty primary series, the neutralising antibody titre after a dose of Nuvaxovid was 2.7–5.4 greater than the control, while a Comirnaty booster induced 5.8–8.4 higher antibody titres. Thus, for those who experience severe adverse events to their second dose of Comirnaty vaccine, Nuvaxovid would be an effective booster although it appears less immunogenic than Comirnaty as a booster dose.

Vaccine safety

Since this vaccine has not been widely used, the safety data is limited and largely based on clinical trials. Passive and active safety surveillance is underway in numerous countries, including Australia and the UK.

Contraindication: Nuvaxovid is contraindicated for individuals with a history of anaphylaxis to previous dose of this vaccine or to any component of the vaccine, including, polysorbate 80 or saponin. See the Medsafe data sheet for contents.(7)

Potential responses: The most reported responses during clinical trials were pain and swelling at the injection site (approximately 4 out of 5 dose 2 recipients), headache, muscle pain and fatigue (each, approximately 1-2 in 5 recipients). These are short in duration and more common after the second dose and in younger recipients. (2, 4) Similar frequencies in serious adverse events were observed between vaccine and placebo groups during clinical trials. When Nuvaxovid was given as a second dose after Comirnaty, the frequency of local and systemic responses were generally less than after a second dose of Comirnaty.(5) The adverse reaction profile for a booster dose is similar to that of the primary series.

Adverse events following immunisation: uncommon adverse events reported during clinical trials were lymphadenopathy and hypertension (reported one in ten older participants within three days of vaccination), rash and injection-site itching. Cases of myocarditis and pericarditis were identified in clinical trials of Nuvaxovid and have been reported during post-authorisation use: a rare but increased risk for these conditions may be present after receiving Nuvaxovid. Post-marketing experience also includes reports of decreased or painful skin sensations and tinnitus.

Use in pregnancy

Since pregnant women were excluded from the clinical trials, there is insufficient safety data to date to recommend Nuvaxovid for use during pregnancy. Comirnaty is the first line vaccine to have in pregnancy, however, Nuvaxovid is available as an alternative option for those preferring to have it. It is important that an informed consent discussion is had prior to vaccination, written consent is rcommended, outlining the risk verses benefit for its use . There is no theoretical concern for having Nuvaxovid in pregnancy however there is not the real world data to support its use that Comirnaty has.

Use when breastfeeding

There is limited data to date around the use of Nuvaxovid in lactating women. Although as with all National Immunisation Schedule vaccines, there are no concerns about giving vaccines to individuals who are lactating, the safety of Matrix M adjuvant has not yet been evaluated in human breastmilk. Prior to administration, breastfeeding women are encouraged to discuss benefit and risk with their health professional.

Coadministration with other vaccines

Nuvaxovid may be administered before, after, or at the same time as other national schedule vaccines. When using liposome adjuvant vaccines, namely Shingrix and Fluad Quad consumers should be informed of the possibility of stronger post-vaccination response where two or more of these are administered together.

References

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