

COVID-19 VACCINATION

NUVAXOVID (NOVAVAX) FACT SHEET

Version 1 - July 2023

This fact sheet is for Primary Care sites who are participating in the Novavax roll-out as part of the COVID-19 Vaccination Program. It provides information and guidance about the administration and storage of the Novavax COVID-19 vaccine which is approved for use as a primary course dose for people aged **12 years and over**.

Eligible population

The Australian Technical Advisory Group on Immunisation (ATAGI) **recommends** the Novavax COVID-19 vaccine can be used as a vaccine for primary course dose in people aged **12 years or older**.

Booster Dose

Although not preferred, this vaccine can be used as a **booster dose** for people aged <u>18</u> <u>years and over</u> in line with the current **ATAGI recommendation for booster doses**.

Novavax is not registered by the Therapeutic Goods Administration (TGA) for use as a booster dose in adolescents aged 12-17 years. However, **ATAGI** have advised that Novavax can be used as a booster in this age group if no other COVID-19 vaccine brand is suitable for that person. Where vaccines are not registered by the TGA it is important to consider relevant State/territory guidance relating to vaccine registration and administrations (relevant for pharmacies only).

NUVAXOVID (NOVAVAX)

The Novavax vaccine is a protein-based vaccine and contains part of the coronavirus spike protein. For most people, the Novavax primary course dose interval is given 8 weeks apart. The dose interval can be reduced to a minimum of 3 weeks, for people at higher risk of severe COVID-19, including older adults and people with underlying medical conditions.

ATAGI has **recommended** that individuals who are severely immunocompromised, may have a 3rd primary dose of COVID-19.

While there is no evidence on extended dosing intervals for Novavax, the extended interval of 8 weeks is consistent with other COVID-19 vaccines and evidence from other COVID-19 vaccines has suggested a longer dose interval may improve vaccine effectiveness.

The longer dose interval may also reduce the risk of myocarditis and pericarditis, particularly for those most at risk of these side effects (males aged 12-39 years).

The Novavax vaccine comes in a **blue-capped** multi-dose vial, with 10 doses per vial and **does not require dilution**.

The Novavax vaccine is a **thawed vaccine** and **cannot be frozen**. **An unopened vial** can be stored at 2°C to 8°C for up to 9 months.

Please refer to the TGA, Novavax Training Module, the Product Information or ATAGI's Clinical Guidance for the most up to date information.

Novavax (Blue Cap) Pack Dimensions

Each box contains 10 vials of 10 doses each.

Box Dimensions (L x W x H) are: 36 x 92 x 62 (mm)

Novavax vaccine can be ordered in multiples of 100 doses, up to your maximum allocation.



Novavax (Blue Cap) Vial

The vial has a blue cap.

Vial size is approx. 35mm x 12mm.



Novavax (Blue Cap) Consumables

The Novavax paired consumables that will be delivered separately to your vaccine (if an order for consumables is placed include (or similar):

- 1mL low dead volume Luer slip syringe with 0.1mL graduations (includes a separately packed 25 gauge 25mm needle) (pack of 100)
- Low dead space 25 gauge 25mm [1 inch] Orange Long needle (pack of 100)
- Injection Syringe 1mL Tuberculin (pack of 100)

Disposal of Vials

Vaccines that are considered wastage (either due to expiry, damage, cold chain breach, or excess vaccine remaining in a used vial) must be disposed of in accordance with local requirements for disposal of Schedule 4 medication, the Product Information and Safety Data Sheets for the COVID-19 vaccine type being disposed of.

Vaccines cannot be disposed of in the sink, toilet, or through the regular garbage disposal processes.

Site declaration

Sites who would like to participate in this roll-out must complete the **Novavax Site Readiness Declaration.** Sites **will be required** to complete this in the COVID-19 Vaccine Administrative System (CVAS) before being able to order the Novavax COVID-19 vaccine.

Training

All clinical staff must complete the 6 core modules as part of the COVID-19 Vaccination Training Program (CVTP) before administering the Novavax COVID-19 vaccine. They must also complete the vaccine specific module, called Additional module 5: Novavax vaccine.

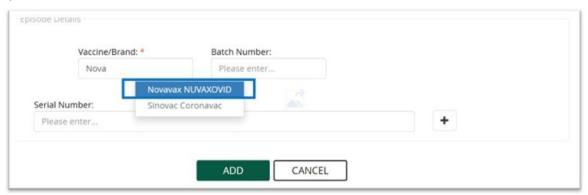
Non-clinical staff, especially those who receive or handle vaccines, should also complete the 3 core modules as part of the CVTP. The training modules are updated regularly to reflect the latest advice on COVID-19 vaccines.

Read more on the COVID19 vaccination training page COVID-19 vaccination training program | Australian Government Department of Health and Aged Care.

Reporting a Novavax COVID-19 vaccination to the Australian Immunisation Register

When reporting the administration of a **Novavax COVID-19 vaccine** to the AIR, vaccination providers should use the vaccine code **NOVNUV**.

The **Novavax COVID-19** vaccine is available to report to the AIR using Practice Management Software (PMS), however if this vaccine is not displayed, we recommend vaccination providers contact their software provider in the first instance. Alternatively, vaccination providers can report the vaccine to the AIR using the **AIR site**. Please see an example below:



It is mandatory under the *Australian Immunisation Register Act 2015*, for vaccination providers to report all vaccinations administered in Australia to the AIR. Vaccination providers should use the latest version of their PMS to make sure they meet reporting requirements.

It is the responsibility of the vaccination provider to upload the COVID-19 vaccination into the patients AIR either within **24 hours** and no later than 10 working days after vaccination.

Please note: It is important that vaccination providers enter the <u>correct vaccine and batch</u> <u>number</u> when reporting information to the AIR. Healthcare providers should check each patient's immunisation history and <u>Medicare reference numbers</u> before administering any COVID-19 vaccine.

Consent

Informed consent is required before administering any COVID-19 vaccine dose and providers are required to document consent in a patient's medical record. Verbal or written consent is acceptable. Vaccination providers can access interpreters from Translating and Interpreting Service (TIS National) on 131 450 to assist in their consultations with patients and ensure informed consent is given for COVID-19 vaccines.

An example form for vaccination providers to obtain patient consent prior to COVID-19 vaccination can be found **here**. This form should be used in combination with the ATAGI COVID-19 **ATAGI COVID-19 Clinical guidance**, which will assist in discussions around consent and any medical contraindications or issues that may arise in your conversations with patients.

Reporting in COVID-19 Vaccine Administrative System (CVAS)

A reminder that it is **mandatory** to complete a **Delivery Acceptance Report** on the day of vaccine delivery and the **Vaccine Stock Management Report** for all vaccine stock held in the clinic is due by 9pm on Friday local time each week.

You will need to complete a Stock Management report for each vaccine your site is approved to administer, **even if you do not receive any deliveries or administer any doses in that week.** Any wastage involving 10 or more vials in one incident should be reported immediately after the wastage event via the Wastage reporting tab in CVAS.

Useful Links

The **ATAGI** website contains:

- ATAGI's recommendation for 3rd Primary Dose Severely immunocompromised
- ATAGI recommendation for booster doses
- ATAGI Clinical Guidance

The **TGA** website contains the:

- Information on the Novavax vaccine
- Novavax Product Information
- Consumer Medicine Information.

The **Department of Health and Aged Care** website contains the:

- COVID-19 Vaccines in Australia A3 poster
- ATAGI recommended COVID-19 doses and vaccines Poster.