

Screening and guidance form

Pre-vaccination screening for NUVAXOVID (Novavax): Adjuvanted recombinant COVID-19 vaccine

SCREENING QUESTIONS	RATIONALE FOR QUESTIONS AND ADVICE ON ACTIONS REQUIRED
Please tell me your full name and date of birth.	Check you have the correct patient records on the CIR. Check 12 years or older (18 years for a booster or additional booster dose). Also confirm they are here for Nuvaxovid vaccine. Discuss specific risks and benefits. Prescription and written consent is only required for consumers receiving a dose of Nuvaxovid vaccine outside current Medsafe approval. Ensure that they are aware that Comirnaty vaccine is the vaccine of choice.
Are you feeling well today?	Postpone vaccine if: fever >38°C or acute systemic illness. For very frail or elderly with comorbid condition, ensure they are stable or as well as possible before vaccination and advise carer on need for post vaccination observation and hydration.
Have you had COVID-19 infection?	Anyone who has had COVID-19 infection is advised to wait 3 months before any primary dose, and 6 months before any booster or additional booster doses of Nuvaxovid vaccine. Clinical discretion can be applied for those at risk of severe infection.
Is this your first COVID-19 vaccination?	If second vaccine, check days since first COVID-19 vaccine dose to ensure a minimum of 21 days , or 28 day gap if given after a different COVID-19 vaccine. Day 0 is the vaccination day. Prescription will be required to give Nuvaxovid as 2nd dose if another COVID-19 vaccine was given first (mixed schedule), but not if 2nd dose is of same vaccine. Currently not approved for 3rd primary doses. See back page for information on 3rd primary dose, 1st boosters and additional booster doses.
Have you had a serious allergic reaction to anything including previous COVID-19 vaccine?	Contraindication: A history of anaphylaxis to previous dose of Nuvaxovid vaccine or to any component of the vaccine , including, Polysorbate 80, Adjuvant- Matrix M, Dibasic sodium phosphate heptahydrate, Monobasic sodium phosphate monohydrate. If concerned about any serious hypersensitivity reactions to previous dose of Nuvaxovid, discuss with IMAC on 0800 IMMUNE (466 863).
For any COVID-19 vaccines after initial dose: Did you/ your child have any problems after your last vaccines?	Check for any cardiac symptoms after the previous vaccine dose (particularly chest pain, palpitations, dizziness), and refer for further advice if there were any potential concerns not previously considered. Precaution: A person who has developed confirmed vaccine-induced myocarditis or pericarditis after previous COVID-19 vaccine should not have any further doses without specialist review and advice which is available from IMAC.
Do you have a bleeding problem or blood disorders?	Vaccines can be administered to people on anticoagulants. For patients with haemophilia , receiving clotting factor replacement or similar, vaccinations should be given as soon as possible after receiving the medicine. It is recommended that the platelet count is kept $\geq 30 \times 10^9/L$. Specialist advice is recommended. After vaccination, apply firm pressure over the injection site, without rubbing, for 10 minutes to reduce the risk of bruising.
Are you pregnant?	Comirnaty is the first line vaccine to have in pregnancy, however, Nuvaxovid is available as an alternative option for those preferring to have it. An informed consent discussion is needed and we recommend the use of a written consent prior to vaccination, outlining the risk versus benefit for its use. While there is no theoretical concern for having Nuvaxovid in pregnancy there is limited experience with the use of Nuvaxovid in pregnant people.

Continued overleaf

DON'T DELAY - IF IN DOUBT CALL 0800 IMMUNE (466 863)



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Immunosuppression due to disease or treatment	The antibody response to the vaccine may be reduced and protection may be suboptimal, but it is still likely to offer some protection particularly against severe disease and there are no safety concerns . Patients may have been advised on specific timing of vaccinations to fit into other treatment regimens. Where possible this should be accommodated.
Co-administration of other vaccines	The Nuvaxovid vaccine may be administered before, after, or at the same time as other national schedule vaccines. When using liposome adjuvant vaccines, namely Shingrix and Fluvad Quad consumers should be informed of the possibility of stronger post-vaccination response where two or more of these are administered together.
Bilateral axillary lymph clearance	If patients have had bilateral lymph clearance, vaccine can be given in the vastus lateralis, seek help if unsure.

Vaccine administration: Nuvaxovid specific guidance

Informed consent

Discuss risks and benefits of the vaccine including the common side effects and the rare but serious adverse events, including anaphylaxis and pericarditis.

Ensure the patient is aware that Comirnaty is usually the vaccine of choice. Offer them opportunity for questions and remind them of the need to wait 15 min.

Complete pre-vaccination screening for Nuvaxovid. A prescription is required, and written consent recommended, if vaccine is used outside the recommended schedule.

3rd Primary doses

These are not currently approved. We recommend discussing with IMAC.

Booster doses for those aged 18 years and older

- 1st booster administered 6 months after primary course
- Additional booster doses are available to those six months after a previous COVID-19 infection or COVID-19 vaccination who are:
 - aged 30 years and over
 - aged 18 years and over who meet the eligibility criteria and are at increased risk of severe disease from COVID-19 infection.

Potential vaccine reactions

The most frequent adverse reactions were injection site tenderness (75%), injection site pain (62%), fatigue (53%), myalgia (51%), headache (50%), malaise (41%), arthralgia (24%) and nausea or vomiting (15%).

Most adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. When compared with the first dose, adverse reactions after the second dose were more frequently reported. Adverse reactions were generally milder and reported less frequently in older adults (≥65 years old).

LYMPHADENOPATHY

Enlargement of lymph nodes near site of injection (eg, axillary, neck) is a known responses to vaccination. Anyone who is having a mammogram or CT scan should inform their radiologist that they have recently been vaccinated.

HYPERTENSION

During clinical trials, around 1 in 100 older adults reported an increase in blood pressure for around 3 days after vaccination.

MYOCARDITIS/PERICARDITIS

Anyone with chest pain, breathing difficulty or heart palpitations/fluttering should seek medical attention if symptoms persist for more than a day after vaccination. Cases of myocarditis and pericarditis were identified in clinical trials of Nuvaxovid and have also been reported during post-authorisation use. These findings suggest that an increased risk for these conditions may be present after receiving Nuvaxovid.

During post marketing experience there have been reports of painful or reduced skin sensation and tinnitus.

Post Vaccine advice

It is important that every consumer is given clear post vaccination advice verbally and in writing. This advice is needed for each dose of vaccine and for all ages and must include the following information:

- Discussion of potential minor side effects as well as the rare but serious ones. The advice should include expected side effect and how to manage them with the use of paracetamol or other analgesia for pain, or discomfort, and if unwell rest, drinking fluids and avoid vigorous activities, such as going to the gym.
- Awareness that anaphylaxis, although very unlikely, could occur within a few hours of vaccination and should they have any breathing difficulties, they should dial 111.
- Cardiac problems are extremely rare but can be serious, so ensure they understand the importance of seeking medical advice early for any out of character symptoms such as: Chest pain, chest heaviness or chest discomfort, heart palpitations, shortness of breath dizziness or fainting. These symptoms should not be ignored. It is important that they seek advice from a doctor or Healthline.
- Supply information on how and when to make a second appointment.
- Use **Guidance for Nuvaxovid COVID-19 Vaccine Preparation** document when preparing the vaccine.

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