COVID-19 Vaccine (Recombinant protein, Adjuvanted)
NUVAXOVID® XFG Supplier: Sanofi Pasteur Limited

INDICATIONS: [A]

- Individuals 12 years of age and older. See COVID-19 Vaccine Eligibility.

The vaccine is not approved for use in those less than 12 years of age.

DOSES AND SCHEDULE:

- Individuals 12 years of age and older:
  - Previously vaccinated with 1 or more dose(s): 1 dose given as 0.5 mL **IM** at least 3 months[B] after last dose of COVID-19 vaccine.
  - NOT previously vaccinated: 1 dose given as 0.5 mL **IM**.
- Individuals 12 years of age and older who are immunocompromised: Individuals who are immunocompromised should have a total of at least 2 doses of COVID-19 vaccine per age-appropriate dosing recommendations above, with at least one of these doses being the COVID-19 XFG formulation. Refer to intervals in table below. Those who self-declare a recommendation by their health care provider are eligible to receive a 3-dose series, at a recommended interval of 8 weeks between doses.[C] New recipients of HSCT or CART should receive a 3-dose series, at a recommended interval of 8 weeks between doses.

Recommendations for Immunocompromised Clients		
COVID-19 Vaccination History	**Number of Dose(s) of COVID-19 XFG Vaccine**	**Recommended Interval Between Doses**
2 or more doses	1 dose	3 months after last dose [B]
1 dose	1 dose	8 weeks after last dose *and* between doses [D]
0 doses	2 doses	8 weeks between doses [D]

ADMINISTRATION:

- The vaccine is supplied as single dose 0.5 mL prefilled syringes (PFS).
- The vaccine can be stored at +2°C to +8°C up to the end of its expiry date, kept in the original packaging and protected from light. Do not freeze.
- The vaccine should not be stored at room temperature for any length of time.
- NUVAXOVID® is a colourless to slightly yellow, clear to mildy opalescent suspension, free of particles. Syringes should be visually inspected for foreign particulate matter and/or discoloration prior to administration. Do not use if either of these conditions exists.

[A] NUVAXOVID® COVID-19 vaccine is interchangeable with COVID-19 mRNA vaccines.
[B] An interval of at least 3 months can be used due to the unknown seasonality of SARS-CoV-2 and the expected duration of protection from vaccine.
[C] Additional doses above the authorized schedule are intended to improve the immune response in individuals who are severely immunocompromised. This may be especially important in individuals who have not had a prior SARS-CoV-2 infection as they do not benefit from hybrid immunity. For such individuals, a total of 3 doses may be provided to enhance protection.
[D] A 28 day minimum interval may be considered. For optimal response, the recommended interval should be observed.

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BOOSTER DOSES:
No further doses are recommended following COVID-19 vaccination with the XFG formulation at this time.

SEROLOGICAL TESTING:
Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:
1. History of anaphylactic reaction to a previous dose of the vaccine or to any component of the vaccine. These individuals should be offered a COVID-19 mRNA vaccine and observed for at least 30 minutes after immunization.

PRODUCT COMPONENTS:
Potential allergens: polysorbate 80.
Other components: disodium hydrogen phosphate heptahydrate, hydrochloric acid, sodium chloride, sodium dihydrogen phosphate monohydrate, sodium hydroxide, cholesterol, disodium hydrogen phosphate dihydrate, phosphatidylcholine, potassium chloride, potassium dihydrogen phosphate, Matrix-M adjuvant (*Quillaja saponaria* saponins fraction-A and fraction-C).

PRECAUTIONS:
- For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the vaccine should be administered in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation post-vaccination of at least 30 minutes.
- Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
- Individuals diagnosed with Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A) should delay COVID-19 vaccination until they have recovered from Illness and for 90 days after the date of diagnosis of MIS-C or MIS-A.
- Additional doses of a COVID-19 vaccine should be deferred in individuals who experienced a physician-diagnosed myocarditis or pericarditis event following a previous dose of a COVID-19 vaccine. However, those with a history compatible with pericarditis who had no cardiac workup or had normal investigations may proceed to further vaccination once symptoms have resolved and 90 days have passed since receipt of the dose associated with the event. For those with confirmed myocarditis (with or without pericarditis), an individual risk/benefit discussion between the patient and their healthcare provider should occur so that the patient (with their parent/guardian as applicable) can make an informed decision about proceeding with a subsequent dose. If another dose is offered, informed consent should include the unknown rates of recurrence of myocarditis and/or pericarditis following receipt of additional doses of COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop. Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 vaccines and are no longer being followed by a medical professional for heart issues. For more information refer to the NACI summary.

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SPECIAL CONSIDERATIONS:

- COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live vaccine.
- COVID-19 vaccine may be offered to individuals without contraindications who have recovered from SARS-CoV-2 infection.
- For previously vaccinated individuals, COVID-19 vaccine may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 3 months from symptom onset or, for asymptomatic cases, from the time of the positive test.
- For individuals that have not yet completed their primary series, COVID-19 vaccine may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 8 weeks from symptom onset or, for asymptomatic cases, from the time of the positive test. If these individuals are immunocompromised, a 4-8 week interval may be considered.

ADVERSE EVENTS:
Local: tenderness, pain, redness, swelling.
Systemic: fatigue, myalgia, headache, malaise, arthralgia, nausea, vomiting, fever.

Rare cases of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining around the heart) have been reported following vaccination with prior formulations of COVID-19 vaccines. These are more often seen after the 2nd dose received, when spacing between the first and second dose was less than 8 weeks, in males, in those 12-29 years old, and with use of SPIKEVAX® 100 mcg dose. The risk of myocarditis and/or pericarditis is now expected to be lower due to the use of a single dose of COVID-19 vaccine in most individuals in this age group starting vaccination. Typical onset of symptoms is within the first week after vaccination. An increase in myocarditis and/or pericarditis has not been observed in younger children. Follow-up studies of those who experienced myocarditis continues, but the majority of individuals respond well to conservative therapy such as anti-inflammatory treatment and recover quickly.