COVID-19 Vaccine (Recombinant protein, Adjuvanted)
NUVAXOVID™ Supplier: Novavax Inc.

INDICATIONS: ^
• 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:
• Primary series for individuals 12 years of age and older: 2 doses given as 0.5 mL IM, 8 weeks apart. C, D

For individuals who are moderately to severely immunosuppressed (see COVID-19 Vaccine Eligibility), a 3-dose primary series is recommended. E The 3rd dose should be provided at least 28 days after the 2nd dose. Moderna COVID-19 vaccine is preferentially recommended for all doses in the primary series. If Moderna is unavailable, Pfizer-BioNTech can be given.

• Fall booster dose for individuals 18 years of age and older: 1 dose given as 0.5 mL IM.

NOTE: A fall booster dose with a COVID-19 mRNA vaccine is recommended for individuals 5 years of age and older at least 6 months after completion of the primary series or a previous booster dose. If an individual 18 years of age and older is not able or unwilling to receive an mRNA vaccine, the Novavax COVID-19 vaccine may be provided. See BOOSTER DOSES.

ADMINISTRATION:
• No reconstitution required.

Storage and Handling:
• Unopened multidose vial:
  o +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.
• Opened multidose vial:
  o Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake.
  o After first vial puncture, the vaccine is stable at +2°C to +25°C for 6 hours. After this time, the vial must be discarded.

^ The National Advisory Committee on Immunization preferentially recommends COVID-19 mRNA vaccines for the primary series and booster dose. Novavax COVID-19 vaccine may be offered to individuals for whom COVID-19 mRNA vaccines are contraindicated or have been refused. Novavax COVID-19 vaccine is interchangeable with mRNA and viral vector COVID-19 vaccines within the primary series and/or booster dose.

C The minimum age for vaccine receipt is based on age at presentation.

D While the Health Canada authorized schedule for this product is 3 weeks between dose 1 and 2, the recommended interval is 8 weeks and is associated with optimal vaccine effectiveness. Clients requesting a shorter interval should be informed that this is not optimal for protection, but their request for an earlier dose should be granted, without need for MHO approval. If administration of the vaccine is delayed beyond 8 weeks, the series does not need to be restarted.

D The minimum interval between doses is 21 days. For optimal response, immunizers should observe recommended intervals as much as possible, however, doses given earlier than recommended may still be considered valid and need not be repeated if minimum intervals are observed.

E For individuals who received a single dose of Janssen vaccine, one additional dose of Moderna COVID-19 vaccine is recommended at least 28 days later.
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ADMINISTRATION (continued):
- The vaccine can be pre-loaded into a syringe for up to 6 hours from first vial puncture. Ensure that the vial/syringe is clearly labeled with the date and time of first vial entry.

BOOSTER DOSES:
A fall booster dose of a COVID-19 mRNA vaccine is recommended for individuals 5 years of age and older at least 6 months after completion of the primary series or a previous booster dose, regardless of the number of booster doses previously received. See COVID-19 Vaccine Eligibility for more information.

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 an mRNA COVID-19 vaccine and observed for at least 30 minutes after immunization.

PRODUCT COMPONENTS:

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 those who experienced a physician-diagnosed myocarditis or pericarditis event following a previous dose of a COVID-19 mRNA vaccine. For guidance on how to proceed with further COVID-19 vaccination, see the PRECAUTIONS section of the Pfizer-BioNTech and Moderna product pages. Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines and are no longer being followed by a medical professional for heart issues.

A minimum interval of at least 3 months between completion of the primary series or a previous booster dose and the fall booster may be considered in the context of heightened epidemiologic risk or for operational considerations.
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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.
• Deferral of COVID-19 vaccination is no longer recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19.
• COVID-19 vaccine may be offered to individuals without contraindications who have recovered from SARS-CoV-2 infection.
• COVID-19 booster doses may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 3-6 months from symptom onset or, for asymptomatic cases, from the time of the positive test. For more information refer to the NACI statement.
• Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine.

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

Pericarditis and myocarditis in association with Novavax COVID-19 vaccine have been reported internationally. There have been no reports in Canada per Public Health Agency of Canada reports to Dec. 9, 2022. The Australian Therapeutics Goods Administration reports 8 cases of myocarditis and 30 cases of pericarditis from 236,000 doses of Novavax COVID-19 vaccine administered to Dec. 18, 2022. A rate of occurrence cannot be calculated at this time due to small numbers overall of this vaccine being administered internationally. A longer interval of 8 weeks, between doses of the primary series may reduce the likelihood of pericarditis and myocarditis, particularly for males 12-39 years of age. Most cases recover fully. The exact cause of these events is not known but is thought to be related to the immune response to the spike protein which is also important in immunity against COVID-19 virus.

REFERENCES:
1. Nuvaxoid product monograph
2. National Advisory Committee on Immunization: Recommendations on the use of Novavax Nuvaxoid COVID-19 Vaccine