**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.  
  For individuals who are moderately to severely immunosuppressed (see [COVID-19 Vaccine Eligibility](#)), a 3-dose primary series is recommended. The 3rd dose should be provided at least 28 days after the 2nd dose.

- **Booster dose for individuals 18 years of age and older:** 1 dose given as 0.5 mL IM.

**ADMINISTRATION:**
- No reconstitution required.

**Storage and Handling:**
- **Unopened multidose vial:**
  - +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:**
  - Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake.
  - After first vial puncture, the vaccine is stable at +2°C to +8°C for 12 hours or at room temperature (up to +25°C) for 6 hours. Once punctured, the vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 12 hours. After these times, the vial must be discarded.

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**Notes:**
- 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.
- The minimum age for vaccine receipt is based on age at presentation.
- 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.
- 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.
- See [COVID-19 Vaccine Eligibility](#) for additional dose recommendations with COVID-19 XBB.1.5 formulation. If an individual 18 years of age and older is not able or unwilling to receive an mRNA vaccine, a booster dose of Novavax COVID-19 vaccine may be provided; however, the client should be counselled that receipt of a dose of an original Novavax COVID-19 vaccine is expected to be less effective against the current circulating strains of COVID-19 compared to the XBB.1.5 formulation and will delay their receipt of the XBB.1.5 formulation due to interval recommendations.
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ADMINISTRATION (continued):
  o The vaccine can be pre-loaded into a syringe provided the preceding storage
temperatures and times following first vial puncture are adhered to.
  o Ensure that the vial/syringe is clearly labeled with the date and time of first vial entry.

BOOSTER DOSES:
No further doses are recommended following COVID-19 vaccination with the XBB.1.5
formulation at this time. See COVID-19 Vaccine Eligibility.

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:
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 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 COVID-19 mRNA vaccine 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.

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
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SPECIAL CONSIDERATIONS (continued):
  prevention of COVID-19.
  • COVID-19 vaccine may be offered to individuals without contraindications who have
    recovered from SARS-CoV-2 infection.
  • 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 and there has been 1 report in Canada per Public Health Agency of Canada
reports to May 26, 2023 meeting the Brighton Case Definition Levels 1-3. Data from Japan,
Australia and Europe report approximately 0-4 cases of myocarditis and 13 cases of pericarditis
per 100,000 doses administered, per the Canadian Immunization Guide. 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. Nuvaxovid product monograph
2. National Advisory Committee on Immunization: Recommendations on the use of Novavax
   Nuvaxovid COVID-19 Vaccine