Yukon Immunization Program Manual

Section 8 - Biological Products

NUVAXOVID™ XBB.1.5

SECTION 8 – BIOLOGICAL PRODUCTS

Contents

March 2024			
COVID-19 Vaccine NUVAXOVID™ XBB.1.5			
Panorama Alternate ID:	COVID-19 Spike Protein Subunit NUVAXOVID XBB.1.5 2.5mL multidose vial	**Panorama Catalogue Number (level 5)**	495
Manufacturer	Supplier: Novavax Inc.	**Biological Classification**	Recombinant protein, adjuvanted
Indications	• COVID-19 immunization for individuals 12 years of age and older.		
Schedule	**Individuals 12 years of age and older who have <u>not been vaccinated</u> with previously or currently marketed Canadian COVID-19 vaccine primary series.** **Dose 1:** 0.5mL IM **Dose 2:** 0.5mL IM 8 weeks after dose 1 **Individuals 12 years and older who have been <u>vaccinated</u> with a previously or currently marketed Canadian COVID-19 vaccine:** 1 dose given as 0.5ml IM at least 6 months after last dose of COVID-19 vaccine (minimum interval 5 months). **For moderately to severely immunocompromised individuals 12 years of age and older <u>not vaccinated</u> with previously or currently marketed Canadian COVID-19 vaccines:** NACI recommends preferentially using mRNA vaccine for primary series. In those who are not able or willing to receive an mRNA COVID-19 vaccine, Novavax Nuvaxovid XBB.1.5 should be offered as a 3 dose primary series. See table below for intervals. Informed consent should include discussion that there is currently limited evidence on the use and best dose of Novavax Nuvaxovid XBB.1.5 in people who are immunocompromised.		

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Schedule (continued)

For moderately to severely immunocompromised individuals 12 and older previously vaccinated with COVID-19 vaccine, please follow guidance for mRNA XBB.1.5 vaccine, subsituting Novavax Nuvaxovid XBB.1.5:

Recommendations for Moderately to Severly Immunocompromised Individuals			
Previous COVID-19 Vaccination History	**Number of Dose(s) of COVID-10 XBB.1.5 Vaccine**	**Recommended Interval Between Doses**	**Minimum Interval** (For optimal response, the recommended interval should be observed whenever possible)
3 or more doses	1 dose	6 months after last dose	8 weeks after last dose
2 doses	1 dose	8 weeks after last dose	28 days after last dose
1 dose	2 dose	8 weeks after last dose and between doses	
0 doses	3 doses	8 weeks between doses	

Booster Doses:

Spring 2024 Recommendations

Starting in the spring of 2024, the following individuals who are at increased risk of severe illness from COVID-19 may receive an additional dose of XBB.1.5 COVID-19 vaccine:

- Adults 65 years of age and older
- Adult residents of long term care homes and other congregate living settings for seniors
- Individuals 6 months of age and older who are moderately to severely immunocompromised (see COVID-19 vaccine eligibility) due to underlying medical conditions or treatments

If a high risk individual identified above has not recieved the dose(s) that they were eligible for in the fall of 2023, they should do so as soon as possible according to the fall 2023 schedule and reevaluate their COVID-19 vaccine eligibility in the fall of 2024.

All other non-high risk individuals that have not recieved the dose(s) that they were eligible for in fall of 2023 should so as soon as possible and reevaluate their COVID-19 vaccine eligibility in the fall of 2024. Non-high risk individuals that have recieved their fall 2023 dose(s) are not recommended to recieve another booster dose in the spring of 2024, but may proceed with a booster after an informed discussion on the risks and benefits of vaccination provided that it has been 6 months since their last dose (minimum interval 5 months).

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Interval Between Previous COVID-19 Infection and COVID-19 Immunization	• Yukon Immunization Program permits individuals to make informed decisions to receive vaccine post-infection irrespective of the intervals below, however, **all individuals** must maintain minimum intervals between vaccine doses. • **All individuals** who are recommended to receive a dose of COVID-19 vaccine and who experienced SARS CoV-2 infection may receive a dose **6 months** after COVID-19 infection symptom onset. • Residents of long term care homes and other congregate living settings for seniors that are not eligible for the spring 2024 COVID-19 vaccine campaign due to COVID-19 infection within the past 6 months may defer their next COVID-19 immunization to the fall of 2024 to ensure immunological protection against severe outcomes during anticipated peak infection periods. However, individuals or their substitute decision makers may choose to be immunized sooner with informed consent provided that minimum intervals between vaccine doses are respected.
Contraindications	• Individuals under 12 years of age. • NUVAXOVID XBB.1.5 is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container.
Precautions and Special Considerations	• Do not inject the vaccine intravascularly, subcutaneously, or intradermally. • For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted; alternately, the vaccine can be administered in an emergency room setting, also with a prolonged observation period. • There is insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.

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Precautions and Special Considerations *(continued)*	• Additional dose(s) for travel: Receiving an additional dose for travel purposes is not considered clinically necessary. It is up to the traveler to know the COVID-19 vaccine requirements for their destination and travelers should otherwise follow routine intervals for COVID-19 vaccination. • Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. • Vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.
Myocarditis and Pericarditis	• Myocarditis and pericarditis have been reported following NUVAXOVID administration. • Available data suggests that the course of myocarditis and pericarditis following NUVAXOVID administration is not different from myocarditis and pericarditis in general. • Available data from phase 3 clinical trials cannot determine a causal association between NUVAXOVID XBB.1.5. and myocarditis and pericarditis. As of fall 2023, post-marketing surveillance on the estimated risk of myocarditis or pericarditis after Novavax Nuvaxovid vaccines vary, with some research suggesting the risk approaches that of mRNA COVID-19 vaccines. • Vaccinated individuals (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.
Pregnancy and Lactation	• The safety and efficacy of NUVAXOVID in pregnant women have not yet been established. • Administration of NUVAXOVID in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus. • It is unknown if NUVAXOVID XBB.1.5 is excreted in human milk. A risk to the newborns/infants cannot be excluded. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunization against COVID-19. • **Additional resource:** Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy.pdf
Interchangeability	• There are no data available on the use of the Novavax (Nuvaxovid) COVID-19 vaccine to complete a series initiated with another COVID-19 vaccine.
Reconstitution and Dilution	• NUVAXOVID must not be reconstituted, mixed with other medicinal products, or diluted.

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Administration	• Use aseptic technique for preparation and administration. • Each multidose vial contains 5 doses of 0.5mL (5 mcg/0.5mL per dose) • Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake. • Administer IM in the deltoid.
Concurrent Administration with Other Vaccines	• Concomitant administration of NUVAXOVID with non-influenza vaccines has not been studied.
Serological Testing	• Serological testing is not recommended before or after immunization.
Vaccine Components	• One dose (0.5 mL) contains 5 mcg of SARS-CoV-2 recombinant spike protein (original [Wuhan] strain) • The Matrix-M adjuvant contains saponin, cholesterol, phosphatidylcholine, potassium dihydrogen phosphate disodium hydrogen phosphate dihydrate, sodium chloride and potassium chloride. • NUVAXOVID XBB.1.5 does not contain mRNA, antibiotics, or preservatives; there is no gelatin added in NUXAVOID XBB.1.5 as a stabilizer.
Non-medicinal ingredients	• Disodium hydrogen phosphate heptahydrate, sodium dihydrogen phosphate monohydrate, sodium chloride, polysorbate 80, sodium hydroxide, hydrochloric acid, and water for Injection
Appearance	• NUVAXOVID is colourless to slightly yellow, clear to mildly opalescent suspension, free of particles.
Blood/ Blood Products	• Contains no human blood/blood products
Bovine/ Porcine Products	• Contains no bovine/porcine products
Latex	• Does not contain latex
Expected Reactions	**Local:** tenderness, pain, redness, swelling. **Systemic:** fatigue, myalgia, headache, malaise, arthralgia, nausea, vomiting, fever.

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Storage and Handling	**Storage prior to use:** • Do not freeze. • +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. • Each multidose vial contains 5 doses of 0.5mL (5 mcg/0.5mL per dose) **During use:** • NUVAXOVID does not contain a preservative. Store the opened vial between 2°C to 8°C for up to 12 hours or at room temperature (up to 25°C) for up to 6 hours after first needle puncture. • Discard this vaccine if not used within 12 hours after first puncture of the vial.

PROGRAM NOTES

- Updated December 2023
- Spring 2024 booster recommendations added March 2024.
- Interval between COVID-19 infection and vaccination updated for long term care residents March 2024.

RELATED RESOURCES

1. Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy.pdf
2. COVID-19 Scientific Advisory Group Rapid Evidence Report.

REFERENCES

3. Canadian Immunization Guide
4. National Advisory Committee on Immunization (NACI): Statements and publication.
5. Product Monograph