

COVID-19 Vaccine – non-mRNA

BIOLOGICAL PAGE

Section 7	Biological Product Information	Standard # 07.229
Created and approved by	Provincial Immunization Program	
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	Novavax Nuvaxovid Vaccine
Manufacturer	Sanofi Vaccines Canada Ltd.
Classification	Non-live: recombinant protein, adjuvanted
COVID-19 vaccine strain	XFG
Indications for use	Individuals 12 years of age and older.
Fall/Winter 2026 – 2027 Eligibility for Provincially Funded COVID-19 vaccine	A dose of XFG COVID-19 vaccine will be available, free of charge, to individuals who are at an increased risk of severe illness from COVID-19 infection or at an increased risk of exposure and transmission to others. This includes: • All adults 65 years of age and older • Individuals 12 years of age and older who are: ○ Residents of continuing care homes and senior supportive living accommodations ○ Individuals with underlying medical conditions including immunocompromising conditions and individuals experiencing houselessness ○ First Nations, Métis and Inuit individuals, no matter where they live ○ Eligible healthcare workers ○ Teachers, as eligible under the Back to School Act. • Individuals 12 years of age and older who are not eligible may be able to access COVID-19 through community pharmacies at a cost. Note: • There is no longer a preference for mRNA vaccines over protein subunit vaccines for those 12 years of age and older. The previous product preference has been removed because of the increasing amount of data available regarding the Nuvaxovid products. Eligible healthcare workers include: • Individuals actively registered with one of the regulatory colleges in Alberta. • Union members (for example, UNA, HSAA, AUNP, AUPE, CUPE) as well as individuals who work in patient-facing settings such as: ○ Hospital staff (including students in health disciplines, contract workers and volunteers) ○ Staff in community health settings (for example, clinical labs, home care and shelters) ○ Medical first responders ○ Staff in continuing care and supportive living ○ Disability support workers and staff working in recovery settings ○ Healthcare aides on the provincial registry

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	Students training in facilities such as hospitals, clinics, pharmacies and continuing care homes and supportive living accommodations
Dose	12 years of age and older 0.5 mL (5 mcg)
Route	IM
Schedule for healthy immunocompetent individuals	Individuals 12 years of age and older 1 dose, at least 3 months from previous non-XFG COVID-19 vaccine, regardless of the number of previous doses.
Schedule for individuals with certain moderate to severe immunocompromising conditions	Individuals 12 years of age and older Unimmunized/Previously received fewer than 3 doses of non-XFG COVID-19 vaccine - Immunocompromised individuals should follow the schedule below and receive the appropriate number of doses of COVID-19 vaccine to complete a three-dose COVID-19 vaccine series. Regardless of whether they have received one or two non-XFG COVID-19 vaccine doses, the previous dose(s) should be counted, and the series should not be restarted. - Dose 1: day 0 - Dose 2: at least 28 days after dose 1 - Dose 3: 8 weeks after dose 2; however, a minimum interval of 4 weeks may be considered. Previously received 3 or more doses of non-XFG COVID-19 vaccine 1 dose, at least 3 months from previous COVID-19 vaccine dose, regardless of the number of doses received in the past. Specific immunocompromising conditions that make an individual eligible for provincially funded COVID-19 vaccine include: - Solid organ transplant recipients. See: Immunization for Children Expecting Solid Organ Transplant Before 18 Months of Age Immunization for Children Expecting Solid Organ Transplant After 18 Months of Age Immunization for Adult Solid Organ Transplant (SOT) Candidates and Recipients - Hematopoietic stem cell transplants recipients –pre-transplant and post-transplant while in immunosuppressed state and individuals receiving Chimeric Antigen Receptor (CAR) T-Cell therapy. See: Standard for Immunization of Transplant Candidates and Recipients Immunization for Child HSCT Transplant Recipients Immunization for Adult HSCT Transplant Recipients - Individuals with malignant hematologic disorders and non-hematologic malignant solid tumors while receiving active treatment. Active treatment includes chemotherapy, targeted therapies, and immunotherapy, but does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention. - Individuals with chronic kidney disease on peritoneal dialysis or hemodialysis. - Individuals on: - Long term high-dose systemic steroid treatment (prednisone equivalent of greater than or equal to 2 mg/kg/day or 20 mg/day if weight greater than 10 kg, for greater than or equal to 14 days)

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	○ Alkylating agents ○ Anti-B-cell therapies (including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies such as rituximab, ocrelizumab, and ofatumumab) ○ Antimetabolites such as methotrexate, azathioprine, mycophenolate ○ Tumor-necrosis factor (TNF) inhibitors such as adalimumab, certolizumab, etanercept, golimumab, infliximab. • Individuals with HIV infection without viral suppression or those with acquired immunodeficiency syndrome (AIDS). • Individuals with moderate to severe primary immunodeficiency such as DiGeorge syndrome, Wiskott-Aldrich syndrome. Note: • Documentation of immunocompromising conditions is not required. • Offer a COVID-19 vaccine series to individuals who identify themselves as meeting at least one of the criteria above. • Consult the physician on timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances. ○ Immunize individuals who are immunocompromised at a time when the individual is most likely to mount an immune response.
Eligible underlying medical conditions	Individuals with the following underlying medical conditions are eligible for provincially funded COVID-19 vaccine and should follow the schedule outlined for healthy immunocompetent individuals: • Cancer (currently receiving treatment) • Cerebrovascular disease • Chronic kidney disease and not on peritoneal dialysis or hemodialysis • Chronic liver diseases • Chronic lung diseases • Cystic fibrosis • Diabetes mellitus • Disabilities such as Down syndrome; learning, intellectual, or developmental disabilities; ADHD; cerebral palsy; congenital disabilities; spinal cord injuries • Heart conditions such as cardiomyopathies, coronary artery disease, heart failure • HIV infection • Mental health disorders (limited to: mood disorders, including depression, schizophrenia spectrum disorders) • Obesity • Pregnancy • Tuberculosis • Primary immunodeficiency diseases that are not mentioned above • Use of corticosteroids or other immunosuppressive medications that are not mentioned above.
Interval between previous COVID-19 infection and COVID-19 immunization	• Individuals who have had a recent COVID-19 infection may receive COVID-19 vaccine after acute symptoms of COVID-19 have resolved and they are no longer infectious, unless there is a history of multisystem inflammatory syndrome in children or adults (MIS-C or MIS-A). • Individuals with a history of MIS-C or MIS-A, regardless of immunocompromised status, should receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C or MIS-A, whichever is longer.
Contraindications/Precautions	Contraindications • Known severe hypersensitivity to any component of the vaccine.

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	- One non-medicinal ingredient in the vaccine that has the potential to cause type 1 hypersensitivity reactions is polysorbate 80. Polysorbate 80 may be found in medication preparations such as, vitamin oils, tablets, anticancer agents and cosmetics. - Anaphylaxis to a previous dose of Nuvaxovid COVID-19 vaccine. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations. Precautions - At the time of authorization, there are no known serious warnings or precautions associated with this product. - Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration. - Administration should be postponed in individuals suffering from acute severe febrile illness.
Myocarditis/Pericarditis	- Very rare cases of myocarditis and/or pericarditis following immunization with Nuvaxovid COVID-19 vaccine have been reported, and available data cannot determine a causal association with Nuvaxovid XFG. - Anyone receiving a COVID-19 vaccine should be informed of the potential risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. - Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 vaccines. - If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccine. - Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization. - In most circumstances, further doses of COVID-19 vaccine should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of COVID-19 vaccine. - However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician. - Informed consent should discuss the lower risk of recurrence of myocarditis and/or pericarditis following additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of COVID-19 vaccine. - Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine.
Possible Reactions	Common - Pain, tenderness, redness, swelling at injection site - Pain or discomfort in the arm, hand, leg and/or foot (pain in the extremity) - Fever - Fatigue

	Novavax Nuvaxovid Vaccine - Headache, myalgia, arthralgia - Nausea, vomiting Uncommon - Chills Rare - Allergic reaction - Anaphylaxis - Hypoaesthesia or paraesthesia - Myocarditis/pericarditis - Unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	May use during pregnancy. - COVID-19 vaccine should be offered to pregnant individuals regardless of trimester of pregnancy because of the increased risk that infection poses in pregnancy. - COVID-19 vaccine is recommended for pregnant individuals and can be offered at any trimester. There have been no safety concerns with receiving a COVID-19 vaccine during pregnancy. - Either Nuvaxovid or mRNA vaccines may be used for pregnant individuals. However, there is more data available for mRNA vaccines than Nuvaxovid vaccine for people who are pregnant. Additional resources Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy
Lactation	May use for individuals who are lactating and feeding their milk to infants and children. COVID-19 vaccines may be offered while breastfeeding. There have been no safety concerns with receiving a COVID-19 vaccine during lactation.
Composition	One dose (0.5 mL) contains 5 mcg of SARS-CoV-2 recombinant spike protein - Non-medicinal ingredients: - Disodium hydrogen phosphate heptahydrate - Hydrochloric acid (for adjustment of pH) - Polysorbate 80 - Sodium chloride - Sodium dihydrogen phosphate monohydrate - Sodium hydroxide (for adjustment of pH) - Water for Injection - For adjuvant: - Cholesterol - Disodium hydrogen phosphate dihydrate - Phosphatidylcholine - Potassium chloride - Potassium dihydrogen phosphate - Sodium chloride
Blood/Blood Products	Does not contain blood/blood products.
Bovine/Porcine Products	Does not contain bovine/porcine products.
Latex	Does not contain latex.

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Administration with Other Products	- COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines including, live, inactivated, adjuvanted, or unadjuvanted vaccines, tuberculin skin tests (TST) or IGRA (QFT) tests. - TST/IGRA (QFT) and COVID-19 vaccines: - There is no current data on the impact of the COVID-19 Nuvaxovid XFG vaccines on TST or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA (QFT) test results. - In the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, COVID-19 vaccines may be given at the same time, before, or after the TST or IGRA test. - Re-testing (at least 28 days after a dose of COVID-19 vaccine) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be prudent in order to avoid missing cases due to potentially false-negative results. Consult with TB services. - Do not defer COVID-19 immunization in individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19. Note: - Consult the primary health care provider or medical specialist on a case-by-case basis about the spacing and timing of administration of COVID-19 vaccine. The potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis of COVID-19 infection are currently unknown. - Give Nuvaxovid XFG COVID-19 vaccines any time before or after an immunoglobulin preparation (including Rhlg) or blood product.
Additional Preparation Instructions	Pre-filled syringe - Prior to administration, visually inspect the contents of the syringe or vial for visible particulate matter and/or discolouration prior to administration. Also, visually inspect the syringe or vial for cracks or any abnormalities, such as evidence of tampering. If any of these conditions exists, the vaccine should not be administered. - With tip cap upright, remove tip cap by twisting counterclockwise until tip cap releases. - The package does not include a needle. Use a sterile needle of the appropriate size for intramuscular injection and administer the entire volume to deliver a 0.5 mL dose.
Appearance	The liquid is colourless to slightly yellow, clear to mildly opalescent suspension, free of particles.
Storage	Store NUVAXOVID prefilled syringes and multidose vials between 2°C to 8°C and keep within the outer carton to protect from light.
Packaging	12 years and older Pre-filled syringe: 10 doses per package.
Vaccine Codes	COVIDrSpike
Antigen Code	COVID-19
Licensed for	Individuals 12 years of age and older.
Off-license use	- An interval of less than 6 months from previous COVID-19 vaccine dose. - An interval of less than 4 months from previous COVID-19 vaccine dose for immunocompromised individuals who previously completed a COVID-19 vaccine series.

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	3 dose series for individuals who are moderately to severely immunocompromised.
Program Notes	2023 December 05: Licensed for use in Canada. 2024 January 05: Implemented in Alberta. 2024 January 29: Updated to include CAR T-cell therapy. 2024 April 15: -Updated to include indications for an additional COVID-19 XFG vaccine dose for eligible individuals. Decrease from two-dose series to single dose for unimmunized individuals who are not moderately to severely immunocompromised. Three-dose series for unimmunized post-HSCT and/or CAR T-cell therapy recipients. 2026 September 16: NUVAXOVID XFG COVID-19 vaccine authorized for use in Canada. 2026 October 1: Implemented in Alberta.
Related Resources	Health Professional Immunization Information COVID-19 website
References Canada Society of Obstetricians and Gynecologists of Canada. (2022 March 14). SOGC Statement on COVID-19 Vaccination in Pregnancy. National Advisory Committee on Immunization. (2026). <i>Guidance on an additional dose of COVID-19 vaccines starting fall 2026: An advisory committee statement</i>. Public Health Agency of Canada. National Advisory Committee on Immunization. (2023). <i>Updated guidance on the use of COVID-19 vaccines in individuals who have not previously been vaccinated against COVID-19: An advisory committee statement</i>. Public Health Agency of Canada. Novavax Inc. Nuvaxovid XFG (2026 June 19). Product Monograph. 202. Available from: https://pdf.hres.ca/dpd_pm/00086089.PDF Primary and Preventative Health Services. (2026 October 1). COVID-19 Vaccine - Novavax (Nuvaxovid) Recombinant protein, adjuvanted. In <i>Alberta Immunization Policy: Biological Products</i>. Government of Alberta. Public Health Agency of Canada. (2024). <i>Canadian Immunization Guide</i>. Government of Canada. Public Health Agency of Canada. (2022). <i>COVID-19 signs, symptoms and severity of disease: A clinician guide</i>. Government of Canada.	