

Yukon Immunization Program Manual

Section 8 — Biological Products

COVID-19 Vaccines

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COVID-19 Vaccines			SPIKEVAX®
Manufacturer	Moderna Biopharma Canada Corp	Biological classification	mRNA vaccine
Current Formulation	Targets the Omicron XFG variant, 2026 to 2027 formulation.		
INDICATIONS	SCHEDULE		
	6 months to 11 years old: (Immunocompetent)	1 Dose: 0.25 mL (25 mcg) IM per calendar year	
	12 years and older: (Immunocompetent)	1 Dose: 0.5 mL (50 mcg) IM per calendar year	
	6 months to 11 years who are moderately to severely immunocompromised: (see Table 1 for eligible conditions)	2 doses per calendar year: - Dose 1: 0.25mL (25 mcg) IM - Dose 2: 0.25mL (25 mcg) IM	
	12 years and older who are moderately to severely immunocompromised: (see Table 1 for eligible conditions):	2 doses per calendar year: - Dose 1: 0.5 mL (50 mcg) IM - Dose 2: 0.5 mL (50 mcg) IM	
	Adults in long-term care homes/congregate care living settings:		
	Adults 65 years of age and older:		
MINIMUM SPACING	The minimum spacing between doses is 3 months. 6 months is preferred.		
AVAILABLE FORMATS	- Multi-Dose Vial: 25 mcg / 0.25 mL (ages 6 months to 11 years old) or 50 mcg/ 0.5 mL (ages 12 years and older) - Single-dose Prefilled Syringe: 50 mcg / 0.5 mL (ages 12 years and older)		

COVID-19 Vaccines		SPIKEVAX®
CONTRAINDICATIONS	• Infants younger than 6 months of age • Severe allergic reaction (e.g., anaphylaxis or hypersensitivity) to a previous dose of this vaccine, or to any component of the formulation or container	
PRECAUTIONS & SPECIAL CONSIDERATIONS	• Minor illness: The presence of a mild infection (e.g., cold) is not a reason to defer vaccination. • History of infection: Testing for prior SARS-CoV-2 infection is not required. A 3-month interval after infection may be considered, but vaccination is not contraindicated sooner. • History of myocarditis/pericarditis: Individuals with symptoms within 6 weeks of a previous mRNA vaccine may be re-immunized after consultation with YIP. • Counsel on myocarditis risk: Inform all vaccine recipients of the rare risk and advise them to seek medical care if they develop symptoms such as chest pain, shortness of breath, or abnormal/rapid heart rhythm.	
PREGNANCY AND LACTATION	NACI and the SOGC advise offering the dose at any stage of pregnancy, regardless of prior doses.	
INTERCHANGEABILITY	• mRNA COVID-19 vaccines (COMIRNATY® and SPIKEVAX®) are considered interchangeable. • SPIKEVAX® is offered as the routine product in the territory due to operational considerations.	
RECONSTITUTION AND DILUTION	Do not reconstitute or dilute.	
ADMINISTRATION	• Administer by intramuscular (IM) injection ONLY • Infants under 12 months of age: IM injection into the anterolateral aspect of the thigh (vastus lateralis). • Individuals 12 months of age and older: IM injection into the deltoid muscle of the upper arm.	

COVID-19 Vaccines		SPIKEVAX®
CONCURRENT ADMINISTRATION WITH OTHER VACCINES	SPIKEVAX® may be administered at the same time as other vaccines. No minimum interval is required before or after giving another inactivated or live vaccine.	
SEROLOGICAL TESTING	Serologic testing is not recommended before or after SPIKEVAX®.	
VACCINE COMPONENTS	Medicinal ingredients: • Each 0.5 mL dose: contains 50 mcg of mRNA encoding SARS-CoV-2 spike protein, 5'(m7G-5'-ppp-5'-Gm) cap, 100 nucleotide 3' poly(A) tail of the strain listed below. • Each 0.25 mL dose: contains 25 mcg of mRNA encoding SARS-CoV-2 spike protein, 5'(m7G-5'-ppp-5'-Gm) cap, 100 nucleotide 3' poly(A) tail of the strain listed below. Non-medicinal ingredients: Acetic acid, Cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), PEG2000-DMG (1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000), SM-102 (Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), Sodium acetate trihydrate, Sucrose, Trometamol, Trometamol hydrochloride, Water for injection	
APPEARANCE	• SPIKEVAX® is a white to off-white dispersion. • SPIKEVAX® may contain white or translucent product-related particulates. • Visually inspect product for foreign particulate matter and/or discoloration prior to administration. If either is present, the vaccine should not be administered.	
BLOOD/ BLOOD PRODUCTS	Does not contain human blood/blood products.	
BOVINE/ PORCINE PRODUCTS	Does not contain human bovine or porcine products.	
LATEX	Does not contain latex.	

COVID-19 Vaccines		SPIKEVAX®
COMMON SIDE EFFECTS	Local: Pain, swelling or redness at the injection site. Systemic: Dizziness, tiredness, sleepiness, headache, fever, chills muscle ache and stiffness, decreased appetite, nausea and/or vomiting, enlarged lymph nodes.	
STORAGE AND HANDLING	MULTIDOSE VIALS (MDV):	
	STORAGE:	
	UNPUNCTURED MDV VIALS: Frozen Storage: • Store at -50°C to -15°C until the labelled expiry date. • Store vaccine in the original carton to protect from light. • Do not refreeze once thawed. Refrigerated Storage: • Store at +2°C to +8°C for up to 60 days (not exceeding the expiry date). • Transport time at 2°C to 8°C counts toward the 60-day refrigerated limit. • Relabel refrigerated expiry. Record the date and time when the product is moved from the freezer to the refrigerator. • Do not refreeze once thawed. Room Temperature Storage: • May be stored at +8°C to +25°C for up to 12 hours. • Cumulative time at room temperature must not exceed 12 hours.	
	POST-PUNCTURE MDV VIALS: • Record the date and time of first puncture. • Relabel refrigerated expiry. Refrigerated Storage • Store at +2°C to +8°C for up to 24 hours of continuous refrigeration after first puncture. Room Temperature Storage • Store at +8°C to +25°C for up to 12 hours after first puncture. • Cumulative time at room temperature must not exceed 12 hours. • If pre-loaded into a syringe from a multidose vial, use within 12 hours. Note: Once thawed, they may be handled under normal room-light conditions.	

COVID-19 Vaccines	SPIKEVAX®
	THAWING:
	Record the date and time vial(s) moved from frozen to room temperature. <u>MDV Thawing time from Frozen :</u> • In refrigerator (+2°C to +8°C): 2 hours • At room temperature (+15°C to +25°C): 45 minutes
	PREPARATION & HANDLING:
	• Ensure the vial is fully thawed before use. Do not dilute. • Swirl gently after thawing and between each withdrawal. Do not shake. • Visually inspect before use. Vaccine should be white to off-white and may contain white or translucent product-related particulates. Do not use if discoloured or if other particulate matter is present. • The multidose vial is used for both: ○ 0.25 mL, 25 mcg doses for individuals 6 months to 11 years ○ 0.5 mL, 50 mcg doses for individuals 12 years and older ○ Verify the correct dose volume before withdrawal. ○ Document the dose volume administered and reconcile doses withdrawn when the vial is finished • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab before each withdrawal. • Use a new sterile needle and syringe for each dose. Low dead-volume syringes and/or needles are preferred when available. • Puncture the stopper at a different site whenever possible. • If insufficient vaccine remains for a complete dose, discard the remaining vaccine. Do not combine vaccine from multiple vials. • Once withdrawn, administer the dose as soon as feasible.
	TRANSPORT:
	• Preferred: Transport frozen at -50°C to -15°C. • If frozen transport is not feasible, thawed vials may be transported at 2°C to 8°C for up to 36 hours. • Transport time at 2°C to 8°C counts toward the 60-day refrigerated limit. • Use qualified refrigerated shipping containers and minimize shaking and vibration. • After thawed transport, do not refreeze. Keep at 2°C to 8°C until use or expiry.

COVID-19 Vaccines		SPIKEVAX®
	PRE-FILLED SYRINGES (PFS):	
	STORAGE:	
	Frozen Storage - Store at -50°C to -15°C until the expiry date. - Store in the original carton to protect from light. - Never refreeze thawed vaccine.	
	Refrigerated Storage Store at +2°C to +8°C for up to 60 days (not exceeding the expiry date).	
	Room Temperature Storage - May be stored at +8°C to +25°C for up to 12 hours following removal from refrigeration. - Do not return to refrigerator after being thawed at room temperature.	
	Note: Once thawed, they may be handled under normal room-light conditions.	
	THAWING:	
	Record the date and time each vial or pre-filled syringe is moved from frozen storage to room temperature.	
	<u>PFS Thaw time under refrigeration (+2°C to +8°C):</u> - Individual Syringe: 1 hours 40 minutes - Carton of 10 syringes 2 hours 40 minutes	
	<u>PFS Thaw time at room temperature (+15° to +25°C):</u> - Individual Syringe: 40 minutes - Carton of 10 syringes: 1 hours 20 minutes - No 15-minute warm-up period is required following refrigerated storage.	
	PREPARATION & HANDLING:	
	- Ensure the syringe is fully thawed before use. Do not dilute or shake. - Visually inspect before use. Vaccine should be white to off-white and may contain white or translucent product-related particulates. Do not use if discoloured or if other particulate matter is present. - Use a sterile needle appropriate for intramuscular injection, 21-gauge or thinner. - Hold the syringe with the tip cap upright. Twist the cap counterclockwise and remove slowly. Do not pull the cap while twisting.	

COVID-19 Vaccines		SPIKEVAX [®]
	• Attach the needle by twisting clockwise until secure. • Uncap the needle when ready to administer. • Administer the entire contents intramuscularly. • Discard the syringe after use.	
	TRANSPORT:	
	• May be transported frozen at -50°C to -15°C. • Thawed PFS may be transported at 2°C to 8°C. • After thawed transport, do not refreeze. Keep at 2°C to 8°C until use or expiry. • There is no separate 36-hour transport limit for the PFS.	
REFERENCES AND RESOURCES		
National Advisory Committee on Immunization Statements Canadian Immunization Guide Product Monograph		

COVID-19 Vaccines			COMIRNATY®
Manufacturer	BioNTech Manufacturing GmbH (imported by Pfizer Canada ULC)	Biological Classification	mRNA vaccine
Current Formulation	Targets the Targets the XFG strain. (2026-2027 formula)		
INDICATIONS	SCHEDULE		
	5 to 11 years old: (Immunocompetent)	1 Dose: 0.3 mL (10 mcg) IM per calendar year	
	12 years and older: (Immunocompetent)	1 Dose: 0.3 mL (30 mcg) IM per calendar year	
	12 years and older, moderately to severely immunocompromised: (see Table 1 for eligible conditions)	2 doses per calendar year: - Dose 1: 0.3 mL (30 mcg) IM - Dose 2: 0.3 mL (30 mcg) IM	
	Adults in long-term care homes/congregate care living settings:		
	Adults 65 years of age and older:		
MINIMUM SPACING	The minimum spacing between doses is 3 months. 6 months is preferred.		
AVAILABLE FORMATS	- Single-dose Vial: 10 mcg / 0.3 mL (ages 5 to 11 years old) - Single-dose Prefilled Syringe: 30 mcg / 0.3 mL (ages 12 years and older)		
CONTRAINDICATIONS	Severe allergic reaction (e.g., anaphylaxis or hypersensitivity) to a previous dose of this vaccine, or to any component of the formulation or container		
PRECAUTIONS & SPECIAL CONSIDERATIONS	- Minor illness: The presence of a mild infection (e.g., cold) is not a reason to defer vaccination. - History of infection: Testing for prior SARS-CoV-2 infection is not required. A 3-month interval after infection may be considered, but vaccination is not contraindicated sooner.		

COVID-19 Vaccines	COMIRNATY®
	• History of myocarditis/pericarditis: Individuals with symptoms within 6 weeks of a previous mRNA vaccine may be re-immunized after consultation with YIP. • Counsel on myocarditis risk: Inform all vaccine recipients of the rare risk and advise them to seek medical care if they develop symptoms such as chest pain, shortness of breath, or abnormal/rapid heart rhythm.
PREGNANCY AND LACTATION	NACI and the SOGC advise offering the dose at any stage of pregnancy, regardless of prior doses.
INTERCHANGEABILITY	• mRNA COVID-19 vaccines (COMIRNATY® and SPIKEVAX®) are considered interchangeable. • SPIKEVAX® is offered as the routine product in the territory due to operational considerations.
RECONSTITUTION AND DILUTION	Do not reconstitute or dilute.
ADMINISTRATION	• Children 5–11 years (single-dose vial 10 mcg/0.3 mL): IM injection into the deltoid muscle of the upper arm. • Individuals 12 years and older (prefilled syringe 30 mcg/0.3 mL): IM injection into the deltoid muscle of the upper arm. • Do not administer intravascularly, subcutaneously, or intradermally
CONCURRENT ADMINISTRATION WITH OTHER VACCINES	COMIRNATY® may be administered at the same time as other vaccines. No minimum interval is required before or after giving another inactivated or live vaccine.
SEROLOGICAL TESTING	Serologic testing is not recommended before or after COMIRNATY®.
VACCINE COMPONENTS	Medicinal Ingredients: mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 • Single Dose Vial contains 10 mcg/0.3 mL • Single Dose Prefilled Syringe 30 mcg/0.3 mL

COVID-19 Vaccines		COMIRNATY®
		Non-Medicinal Ingredients: ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[(polyethylene glycol)-2000]-N, Nditetradecylacetamide, cholesterol, DSPC = 1,2-distearoyl-sn-glycero-3- phosphocholine, sodium chloride, sucrose, tromethamine, tromethamine hydrochloride, water for injection
APPEARANCE		• Single-dose vial (ages 5 to 11 years old): ○ Before mixing: clear to slightly opalescent; may show white to off-white opaque amorphous particles. ○ After mixing (prior to administration): clear to slightly opalescent with no visible particles. • Single-dose prefilled syringe (ages 12 years and older): Off-white suspension. • Do not use either product if discoloured, or if particles are present.
BLOOD/ BLOOD PRODUCTS		Does not contain any blood or blood products.
BOVINE/ PORCINE PRODUCTS		Does not contain any bovine or porcine products.
LATEX		Does not contain latex.
COMMON SIDE EFFECTS		Local: Pain, swelling or redness at the injection site Systemic: Dizziness, tiredness, sleepiness, headache, fever, chills muscle ache and stiffness, decreased appetite, nausea and/or vomiting, enlarged lymph nodes
STORAGE AND HANDLING		Protect from light; keep in original packaging. Do not shake the product.
		STORAGE:
		• <u>Single-dose vials:</u> ○ Freezer: -90°C to -60°C until expiry date (depo only). ▪ Always record date/time product is moved from freezer to fridge. ▪ Do NOT store COMIRNATY® vaccine at -25°C to -15°C.

COVID-19 Vaccines	COMIRNATY®
	○ Refrigerator: +2°C to +8°C for up to 10 weeks of continuous refrigeration (not exceeding expiry). ○ Room temperature (up to 25°C): for up to 12 hours, discard after 12 hours ● Prefilled syringes: ○ DO NOT FREEZE. If prefilled syringe has been frozen, discard. ○ Unopened prefilled syringes: store 2–8°C until expiry. ● Transport PFS and SDV at 2 to 8°C. THAWING FOR USE: Always record the date and time of each vial being moved from fridge/freezer to room temperature. PREPARATION: ● Single-dose vials: ○ Ensure vial is thawed prior to use. ○ Mix by gently inverting the vial 10 times after thawing. Do not shake. ○ Record the time of first puncture. ○ Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw a single 0.3 mL dose. ○ Discard vial and any excess volume. Do not pool excess vaccine from multiple vials ● Prefilled syringes: ○ If prefilled syringe has been frozen, discard. ○ Thaw at room temp for 15 minutes prior to use. ○ Do not shake. ○ Remove tip cap by slowly turning counterclockwise and holding luer lock. ○ Attach a needle for IM injection and proceed with administration. After needle attachment: use immediately; if not discard after 4 hours.
REFERENCES AND RESOURCES	
National Advisory Committee on Immunization Statements Canadian Immunization Guide Product Monograph	

Table 1. Moderate to Severe Immunocompromised Conditions for COVID-19 Vaccination

- **Active cancer** (solid tumour or hematologic malignancy) or current treatment for these conditions
- **Solid-organ transplant** with ongoing immunosuppressive therapy
- **Hematopoietic stem cell transplant** (≤ 2 years post-transplant or on immunosuppressive therapy)
- **CAR T-cell therapy**
- **Moderate to severe primary immunodeficiency** (humoral and/or cell-mediated)
- **HIV infection** with:
 - AIDS-defining illness, or
 - TB diagnosis in past 12 months before starting vaccine series, or
 - Severe immune compromise (CD4 < 200 cells/ μ L or CD4% $< 15\%$, or without viral suppression)
- **Recent use of immunosuppressive therapies**, including:
 - Anti-B cell therapies (e.g., mAbs targeting CD19, CD20, CD22)
 - High-dose systemic corticosteroids
 - Alkylating agents
 - Antimetabolites
 - TNF inhibitors or other significantly immunosuppressive biologics
- **Chronic kidney disease on dialysis**