Yukon Immunization Program Manual

Section 8 - Biological Products

COVID-19 Vaccines

SECTION 8 – BIOLOGICAL PRODUCTS

Contents

<table>
<tr><td colspan="5">September 2024</td></tr>
<tr><td colspan="5">Covid-19 Vaccine MODERNA SPIKEVAX ® Omicron KP.2</td></tr>
<tr><td>Manufacturer</td><td>Moderna Therapeutics</td><td>Biological Classification</td><td colspan="2">mRNA vaccine</td></tr>
<tr><td rowspan="6">INDICATIONS</td><td colspan="2">Publicly Funded Indication</td><td colspan="2">Standard Schedule</td></tr>
<tr><td rowspan="3">1. Individuals 6 months and older who are moderately to severely immunocompromised (Table 1) and have not previously received a COVID-19 vaccine.</td><td>6 months -11 years</td><td>12 yrs and older</td></tr>
<tr><td><u>2 Dose Series:</u>
Dose 1:
0.25mL (25mcg) IM
and
Dose 2:
0.25mL (25mcg) IM</td><td><u>2 Dose Series:</u>
Dose 1:
0.5mL (50mcg) IM
and
Dose 2:
0.5mL (50mcg) IM</td></tr>
<tr><td colspan="2">Give doses 8 weeks apart
Minimum spacing is 4 weeks</td></tr>
<tr><td rowspan="3">2. All individuals (healthy and immunocompromised) ages 6 months and older who have previously received COVID-19 vaccine.</td><td>6 months -11 years</td><td>12 yrs and older</td></tr>
<tr><td>1 Dose:
0.25mL (25mcg) IM</td><td>1 Dose: 0.5mL (50mcg) IM</td></tr>
<tr><td colspan="2">Minimum spacing is 3-months from any previous covid vaccine</td></tr>
<tr><td rowspan="2">3. Healthy individuals aged 6 months of age and older who have not previously received a COVID-19 vaccine.</td><td>6 months -11 years</td><td>12 yrs and older</td></tr>
<tr><td>1 Dose:
0.25mL (25mcg) IM</td><td>1 Dose:
0.5mL (50mcg) IM</td></tr>
</table>

September 2024
Covid-19 Vaccine MODERNA SPIKEVAX ® Omicron KP.2
Table 1. Moderately to Severely Immunocompromised
• Immunocompromised due to solid tumour or hematologic malignancies or treatments for these conditions • Solid-organ transplant and taking immunosuppressive therapy • Hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy) • Immunocompromise due to chimeric antigen receptor (CAR) T cell therapy targeting lymphocytes • Moderate to severe primary immunodeficiency with associated humoral and/or cell-mediated immunodeficiency or immune dysregulation • HIV with AIDS-defining illness or TB diagnosis in last 12 months before starting vaccine series, **or** severe immune compromise with CD4<200 cells/μL **or** CD4%<15%, **or** without HIV viral suppression • Recent treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids, alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive • Chronic kidney disease on dialysis

CONTRAINDICATIONS	• Clients with history of hypersensitivity to this vaccine or to any ingredient in the formulation or component of the container. • Individuals 5 months of age and younger.
PRECAUTIONS & SPECIAL CONSIDERATIONS	• The presence of a minor infection, such as a cold, should not result in the deferral of vaccination. • Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination. • Individuals are recommended to wait 3 months after COVID-19 infection symptom onset before receiving a COVID-19 vaccine, however, the Yukon Immunization Program permits individuals to make informed decisions to receive vaccine post-infection irrespective of the recommended interval. • Individuals with a history compatible with myocarditis or pericarditis within 6 weeks of receiving a dose of an mRNA 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.

	September 2024
Covid-19 Vaccine MODERNA SPIKEVAX ® Omicron KP.2	
PREGNANCY AND LACTATION	• Vaccination against COVID-19 is recommended for individuals who are pregnant, breastfeeding. • NACI strongly recommends that individuals who are pregnant should be offered a fall COVID-19 vaccine booster dose at any stage of pregnancy, regardless of the number of previously received booster doses. Further information is available in the SOGC Statement on COVID-19 Vaccination in Pregnancy.
INTERCHANGEABILITY	• Pfizer and Moderna COVID-19 products are considered interchangeable; there is no longer preference of one product over the other
RECONSTITUTION AND DILUTION	• Do not reconstitute or dilute.
ADMINISTRATION	• The preferred site for injection is the anterolateral aspect of the thigh in infants or the deltoid muscle of the upper arm in children greater than one year of age. The vaccine should not be injected in the gluteal area or areas where there may be a major nerve trunk and/or blood vessel.
CONCURRENT ADMINISTRATION WITH OTHER VACCINES	• SPIKEVAX ® KP.2 may be administered at the same time, or anytime before or after another inactivated or live vaccine.
SEROLOGICAL TESTING	• Serologic testing is not recommended before or after SPIKEVAX ® KP.2.
VACCINE COMPONENTS	• 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), Acetic acid, Cholesterol, Lipid SM-102, PEG2000 DMG 1,2-dimyristoyl-rac glycerol, methoxy-polyethyleneglycol, SM-102 (Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), Sodium acetate trihydrate, Sucrose, Tromethamine, Tromethamine hydrochloride, Water for injection.
APPEARANCE	• SPIKEVAX ® KP.2 is a white to off-white dispersion. • Visually inspect Spikevax KP.2 vials for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
BLOOD/ BLOOD PRODUCTS	• SPIKEVAX ® KP.2 does not contain any blood or blood products.
BOVINE/ PORCINE PRODUCTS	• SPIKEVAX ® KP.2 does not contain any bovine or porcine products.
LATEX	• SPIKEVAX ® KP.2 does not contain latex.

	September 2024
Covid-19 Vaccine MODERNA SPIKEVAX ® Omicron KP.2	
EXPECTED REACTIONS	• **Local:** pain, swelling, redness, axillary swelling/ tenderness. • **Systemic**: fatigue, myalgia, headache, arthralgia, chills, nausea/vomiting, fever, irritability/ crying (infants/ children), loss of appetite (infants/ children).

STORAGE AND HANDLING	**Storage:**
	• Protect from light until thawed. Store in original package.
	• Do not refreeze after thawing.
	• Moderna SPIKEVAX® KP.2 can be stored.
	  ○ -20°C (-50°C to -15°C) up to the end of its expiry date
	  ○ +2°C to +8°C for up to 50 days prior to first use
	  ○ At room temperature (up to +25°C) for up to 12 hours
	• Record date/time when product is moved from freezer to fridge.
	• Thawed, punctured vials (first dose is withdrawn) can be stored at +2°C to +8°C for 24hours. Discard after 24 hours
	• Thawed, punctured vials (first dose is withdrawn) can be stored at +8°C to +25°C for 12 hours. Discard after 12 hours.
	• The vaccine can be pre-loaded into a syringe for up to 24 hours from first vial puncture if stored refrigerated (+2°C to +8°C) or 12 hours if stored at room temperature (up to +25°C).
	Thawing for use:
	• Always record the date and time of each vial being moved from fridge/freezer to room temperature.
	• Allow vial(s) to thaw from frozen in the refrigerator +2°C to +8°C for 2 hours.
	• Allow vial(s) thaw from frozen at room temperature between +15˚C to +25˚C for 45 minutes.
	Preparation:
	• Let each refrigerated/thawed vial stand at room temperature for 15 minutes before administering.
	• Swirl gently after thawing and before each withdrawal; **do not shake.**
	• Record time when vial is first punctured.
	• Cleanse the vial stopper with a single-use antiseptic swab and withdraw each dose of vaccine from the vial using a new sterile needle and syringe and/or needles for each injection.
	• Once a dose is withdrawn from the vial, it should be administered immediately but vaccine can be pre-loaded into a syringe for up to 12 hours.

REFERENCES AND RESOURCES	National Advisory Committee on Immunization Statements Canadian Immunization Guide Product Monograph

<table>
<tr><td colspan="4">September 2024</td></tr>
<tr><td colspan="4">Covid-19 Vaccine PFIZER COMIRNATY ® Omicron KP.2</td></tr>
<tr><td>Manufacturer</td><td>BioNTech Manufacturing GmbH Imported by Pfizer Canada ULC</td><td>Biological Classification</td><td>mRNA vaccine KP.2</td></tr>
<tr><td rowspan="4">INDICATIONS</td><td colspan="2">Publicly Funded Indication</td><td>Standard Schedule</td></tr>
<tr><td colspan="2">1. Individuals 12 years of age and older who are moderately to severely immunocompromised (Table 1) and have not previously completed a COVID-19 vaccine series</td><td><u>2 Dose Series</u>
Dose 1: 0.3 mL (30mcg) IM
and
Dose 2. 0.3 mL (30mcg) IM
Give 8 weeks apart
(4 week minimum spacing)</td></tr>
<tr><td colspan="2">2. All individuals (healthy and immunocompromised) ages 12 years and older who have previously received COVID-19 vaccine.</td><td>1 Dose: 0.3 mL (30mcg) IM
Minimum 3-month interval since last COVID-19 vaccine</td></tr>
<tr><td colspan="2">3. Healthy individuals ages 12 years and older who have not previously received a COVID-19 vaccine.</td><td>1 Dose: 0.3 mL (30mcg) IM</td></tr>
</table>

	September 2024
Covid-19 Vaccine PFIZER COMIRNATY ® Omicron KP.2	
Table 1. Moderately to Severely Immunocompromised	
• Immunocompromised due to solid tumour or hematologic malignancies or treatments for these conditions • Solid-organ transplant and taking immunosuppressive therapy • Hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy) • Immunocompromise due to chimeric antigen receptor (CAR) T cell therapy targeting lymphocytes • Moderate to severe primary immunodeficiency with associated humoral and/or cell-mediated immunodeficiency or immune dysregulation • HIV with AIDS-defining illness or TB diagnosis in last 12 months before starting vaccine series, **or** severe immune compromise with CD4<200 cells/μL **or** CD4%<15%, **or** without HIV viral suppression • Recent treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids, alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive • Chronic kidney disease on dialysis	
CONTRAINDICATIONS	• PFIZER COMIRNATY ® KP.2 is contraindicated in individuals who are hypersensitive to the active substance or to any ingredient in the formulation • Individuals less than 12 years of age
PRECAUTIONS & SPECIAL CONSIDERATIONS	• The presence of a minor infection, such as a cold, should not result in the deferral of vaccination. • Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination. • Individuals are recommended to wait 3 months after COVID-19 infection symptom onset before receiving a COVID-19 vaccine, however, the Yukon Immunization program permits individuals to make informed decisions to receive vaccine post-infection irrespective of the recommended interval. • Individuals with a history compatible with myocarditis or pericarditis within 6 weeks of receiving a dose of an mRNA 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.
PREGNANCY AND LACTATION	• Vaccination against COVID-19 is recommended for individuals who are pregnant, breastfeeding. • NACI strongly recommends that individuals who are pregnant should be offered a fall COVID-19 vaccine booster dose at any stage of pregnancy, regardless of the number of previously received booster doses. Further information is available in the SOGC Statement on COVID-19 Vaccination in Pregnancy.

	September 2024
Covid-19 Vaccine PFIZER COMIRNATY ® Omicron KP.2	
INTERCHANGEABILITY	• Pfizer and Moderna COVID-19 products are considered interchangeable; there is no longer preference of one product over the other as long as indications are met.
RECONSTITUTION AND DILUTION	• PFIZER COMIRNATY ® KP.2 multiple dose vial with a gray cap and gray label border MUST NOT BE DILUTED prior to administration.
ADMINISTRATION	• The preferred site for injection is the deltoid muscle of the upper arm. The vaccine should not be injected in the gluteal area or areas where there may be a major nerve trunk and/or blood vessel.
CONCURRENT ADMINISTRATION WITH OTHER VACCINES	• PFIZER COMIRNATY ® KP.2 may be administered at the same time, or anytime before or after another inactivated or live vaccine.
SEROLOGICAL TESTING	• Serologic testing is not recommended before or after PFIZER COMIRNATY ® KP.2.
VACCINE COMPONENTS	• ALC-0315(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159=2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, cholesterol, dibasic sodium phosphate dihydrate, monobasic potassium phosphate, potassium chloride, sodium chloride, sucrose, water for injection.
APPEARANCE	• PFIZER COMIRNATY ® KP.2 is a white to off-white frozen suspension. • The liquid is a clear to slightly opalescent suspension and may contain white to off-white opaque amorphous particles • Visually inspect PFIZER COMIRNATY ® vials for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
BLOOD/ BLOOD PRODUCTS	• PFIZER COMIRNATY ® KP.2 does not contain any blood or blood products.
BOVINE/ PORCINE PRODUCTS	• PFIZER COMIRNATY ® does not contain any bovine or porcine products.
LATEX	• PFIZER COMIRNATY ® does not contain latex.
EXPECTED REACTIONS	• **Local:** pain, swelling, redness at injection site, axillary (or groin) swelling/ tenderness. • **Systemic**: fatigue, myalgia, headache, arthralgia, chills, nausea/vomiting, fever, irritability/ crying (infants/ children), loss of appetite (infants/ children).

	September 2024
Covid-19 Vaccine PFIZER COMIRNATY ® Omicron KP.2	

STORAGE AND HANDLING	**Storage:**
	• Protect from light until thawed. Store in original package.
	• Do not refreeze after thawing.
	• PFIZER COMIRNATY ® can be stored:
	  ○ -90°C to -60°C up to the end of its expiry date.
	  ○ +2°C to +8°C for up to 10 weeks.
	  ○ room temperature up to +25°C for up to 12 hours
	• Record date/time when PFIZER COMIRNATY ® product is moved from freezer to fridge.
	Thawing for use:
	• Always record the date and time of each vial being moved from fridge/freezer to room temperature.
	• Allow vial(s) to thaw from frozen in the refrigerator 2°C to 8°C for 6 hours.
	• Allow vial(s) thaw from frozen at room temperature up to 25°C for 30 .minutes.
	• Avoid exposure to direct sunlight and ultraviolet light. PFIZER COMIRNATY ® can be handled in room light conditions.
	Preparation:
	• Let each refrigerated/thawed vial stand at room temperature for 15 minutes before administering.
	• Prior to use and after thawing, gently invert the vial 10 times to mix; **do not shake.**
	• Record time when vial is first punctured. Multi-dose vials contain 6 doses.
	• Cleanse the vial stopper with a single-use antiseptic swab and withdraw each dose of vaccine from the vial using a new sterile needle and syringe (preferentially using low dead-volume syringes) and/or needles for each injection.
	• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL discard the vial and any excess volume.
	• Once a dose is withdrawn from the vial, it should be administered immediately but can be pre-loaded into a syringe for up to 12 hours
	• Ensure that the vial of vaccine/pre-loaded syringe is clearly labelled with the date and time of first vial puncture.

REFERENCES AND RESOURCES	National Advisory Committee on Immunization Statements Canadian Immunization Guide Product Monograph