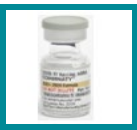
COVID-19 Vaccine – mRNA Pfizer-BioNTech Comirnaty KP.2 – Ultra frozen Vaccine 12 years of age and older

Alberta Health Services
Communicable Disease Control

BIOLOGICAL PAGE

Section 7	Biological Product Information	**Standard # 07.227**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	October 3, 2024	**Revised**	January 31, 2025

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 **Dark gray cap & dark gray label border**
Manufacturer	Pfizer-BioNTech	
Classification	mRNA vaccine	
Indications for Provincially Funded Vaccine	• Individuals 12 years of age and older (see scheduling section for specifics)	

Individuals at an increased risk of transmission or severe COVID-19 infection	While all individuals 6 months of age and older are eligible for COVID-19 vaccine, immunization is strongly recommended for the following individuals who may be at an increased risk of COVID-19 infection or severe COVID-19 disease:
	• All adults 65 years of age and older
	• Individuals 6 months of age and older who are:
	  ○ Residents of continuing care homes and senior supportive living accommodations
	  ○ Have certain moderate to severe immunocompromising conditions
	  ○ Pregnant
	  ○ First Nations, Métis, and Inuit individuals, no matter where they live
	  ○ Members of racialized and other equity-deserving communities
	  ○ Individuals who provide essential community services, including healthcare workers.	

Dose	0.3 mL (30mcg)	
Route	IM in the vastus lateralis or deltoid muscle	
Schedule for healthy immunocompetent individuals (See below Schedule for individuals with certain immunocompromising conditions)	**Individuals 12 years of age and older:** • 1 dose, at least three months from previous non-KP.2 COVID-19 vaccine dose, regardless of the number of doses received in the past.	
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-KP.2 COVID-19 vaccine:** • Immunocompromised individuals should follow the schedule below and receive the appropriate number of Pfizer KP.2 COVID-19 vaccine doses to complete a three-dose COVID-19 vaccine series. Regardless of whether they have received one or two non-KP.2 COVID-19 vaccine doses, the previous dose(s) should be counted, and the series should not be restarted. ○ Dose 1: day 0	

- Dose 2: 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-KP.2 COVID-19 vaccine:

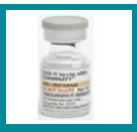
- 1 dose, at least 3 months from previous COVID-19 vaccine dose, regardless of the number of doses received in the past.

Note:

- Specific immunocompromising conditions that make an individual eligible for a COVID-19 vaccine series:
  - Solid organ transplant recipients – pre-transplant and post-transplant
  - 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
    - Child HSCT
    - Adult HSCT.
  - Individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or while receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (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 ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), or
    - alkylating agents, or
    - anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab), or
    - antimetabolites (e.g., methotrexate, azathioprine, mycophenolate), or
    - tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or
    - other agents that are significantly immunosuppressive at clinicians' discretion.
  - HIV-infected individuals without viral suppression or those with acquired immunodeficiency syndrome (AIDS).
  - Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).

Note:

- Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above should be offered a COVID-19 vaccine series.
- Immunization of immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization (initiation and interval) based on the individual's treatment and unique circumstances.

<table>
<tr><th></th><th colspan="2">COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine</th><th> 
Dark gray cap & dark gray label border</th></tr>
<tr><td>Interval between previous COVID-19 infection and COVID-19 immunization</td><td colspan="3">• For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.
Note:
• These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and risk of severe disease should also be considered. These intervals are a guide and clinical discretion is advised. Individuals can be immunized at less than the recommended intervals from infection upon request.
• For individuals who have not had any previous doses, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days).</td></tr>
<tr><td></td><td rowspan="3">Infection prior to initiation or completion of a COVID-19 immunization series.</td><td>Individuals without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C).</td><td>8 weeks after a positive test.</td></tr>
<tr><td>Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C.</td><td>4 to 8 weeks after a positive test.</td></tr>
<tr><td>History of MIS-C (regardless of immunocompromised status).</td><td>Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.</td></tr>
<tr><td></td><td>Infection after COVID-19 vaccine series.</td><td>All individuals.</td><td>3 months after a positive test.</td></tr>
<tr><td>Contraindications/ Precautions</td><td colspan="3">Contraindications:
• Known severe hypersensitivity to any component of the vaccine.
• Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products:
  ○ Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.
  ○ Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.
• Anaphylaxis to a previous dose of COVID-19 mRNA vaccine may not be an absolute contraindication. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.</td></tr>
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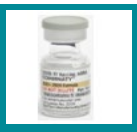
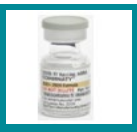
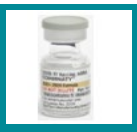
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
	Precautions: • The safety and effectiveness of Pfizer-BioNTech KP.2 is inferred from studies which evaluated the primary series and booster vaccination with Pfizer-BioNTech and supported by studies which evaluated a booster dose of Pfizer-BioNTech Original & Omicron BA.4/BA.5). ○ Safety data accrued with the COMIRNATY (Original) and COMIRNATY Original & Omicron BA.4/BA.5 formulations are relevant to the subsequent variant updated COMIRNATY vaccines because these vaccines are manufactured using the same process. • At the time of authorization, there are no known serious warnings or precautions associated with this product. • 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. • 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.	

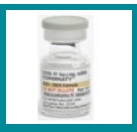
Myocarditis/Pericarditis	• Very rare cases of myocarditis and/or pericarditis following immunization with Pfizer-BioNTech vaccines have been reported during post-authorization use.
	  ○ Compared to the original monovalent primary series, the risk of myocarditis and/or pericarditis is now expected to be lower due to the use of a 1-dose schedule in most individuals.
	  ○ Post-market safety surveillance data on previous formulations of mRNA COVID-19 vaccine indicate that the risk of myocarditis following a booster dose is lower compared to that following the second dose in the primary series, and current data do not show a product-specific difference in the risks of myocarditis and/or pericarditis after a booster dose of an mRNA COVID-19 vaccine.
	• Anyone receiving an mRNA COVID-19 vaccine should be informed of the 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.
	• Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine.
	• 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 mRNA 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 vaccines.
	• Individuals with a history compatible with 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.
	  ○ If another dose of vaccine is offered, it should be a Pfizer-BioNTech KP.2 COVID-19 vaccine, if 12 years of age and over. This is due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech original (30 mcg) vaccine compared to the Moderna Spikevax original (100 mcg) vaccine among individuals 12 years of age and older.	

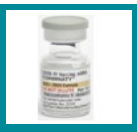
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border

	• In most circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA 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 unknown 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 mRNA COVID-19 vaccine.	

Possible Reactions	**Common:** • Pain, swelling/induration, erythema at the injection site • Fatigue • Headache • Myalgia • Arthralgia • Chills • Fever • Diarrhea • Nausea/vomiting. **Uncommon:** • Lymphadenopathy • Malaise • Asthenia • Decreased appetite • Hyperhidrosis • Lethargy • Night sweats • Hypoaesthesia (decreased sense of touch or sensation) • Paraesthesia (tingling, itching or pricking sensation). **Rare:** • Allergic reaction • Anaphylaxis • Erythema multiforme • Myocarditis/Pericarditis • Facial paralysis/Bell's palsy. Refer to the product monograph for more detailed information.	
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. An mRNA vaccine is preferred due to reassuring published data on the safety of these vaccines in pregnancy. • The safety and efficacy of Pfizer-BioNTech KP.2 vaccine in pregnant women has not yet been established. • However, data available on the original mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance. COVID-19 mRNA vaccines can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
	○ Evidence to date shows that COVID-19 immunization during pregnancy is safe and does not increase risk for miscarriage, stillbirth, low birth weight, preterm birth, NICU admission, or other adverse pregnancy/birth outcomes. ○ It is recommended that individuals consult their primary health care provider or obstetrician for any vaccine related questions or concerns. ○ However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine. **Additional resources:** Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy	
Lactation	• It is unknown whether this vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded. • Recent reports have shown that breastfeeding/chestfeeding people who have received mRNA COVID-19 vaccines have antibodies in their breastmilk, which could help protect their babies. More data are needed to determine the level of protection these antibodies might provide to the baby. • COVID-19 vaccine is recommended for individuals who are breastfeeding. It is recommended that individuals consult their primary health care provider or medical specialist for any vaccine related questions or concerns. However, consultations with a primary health care provider or medical specialist is not required to received COVID-19 vaccine.	
Composition	• Each 0.3 ml dose of Comirnaty contains 30 micrograms of mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 [Omicron KP.2] • **Non-medicinal ingredients:** ○ ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) ○ ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide ○ cholesterol ○ DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine ○ sucrose ○ tromethamine ○ tromethamine hydrochloride ○ water for injection. Does not contain any preservatives.	
Blood/Blood Products	Does not contain blood/blood products.	
Bovine/Porcine Products	Does not contain bovine/porcine products.	
Latex	Does not contain latex.	
Administration with Other Products	• Except for the Respiratory Syncytial Virus (RSV) vaccine, 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 or IGRA (QFT) tests to individuals 6 months of age and older. (In Alberta, Pfizer KP.2 vaccine is only being used for individuals 12 years of age and older). ○ Limited studies have been conducted on concurrent administration of RSV vaccine with other vaccines. Until more evidence is available, co-administration is not recommended. RSV	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
	vaccine should be given with two-week spacing before or after influenza and/or COVID-19 vaccines. ○ There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results. ○ In the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test. ○ However, repeat tuberculin skin testing or IGRA (at least 4 weeks post COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered to avoid missing persons with TB infection. • Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19. **Note:** • Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis. • mRNA COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.	
Appearance	Clear to slightly opalescent liquid. Thawed suspension may contain white to off-white amorphous particles.	
Storage	• Store in ultra-low temperature freezer between -90˚C to -60˚C . • Protect from light until thawed. • Do not refreeze after thawing. • Thawed, unpunctured vials: ○ Thawed, unpunctured vials can be stored at +2˚C to +8˚C for up to 10 weeks. ○ Thawed, unpunctured vials can be stored at +8˚C to +25˚C for up to 12 hours. Discard after 12 hours. • Thawed, punctured vials: ○ Thawed, punctured vials (first dose is withdrawn) can be stored at +2°C to +25°C for 12 hours. Discard after 12 hours. • Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vials and cartons.	
Packaging	• 6 doses per vial (Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial). • 10 vials per carton.	
Preparation	• Multidose vials are supplied as a frozen dispersion, does not contain preservative. Thaw vaccine before use: • Vaccine can be thawed in two ways: ○ From the freezer to room temperature (between +15˚C to +25˚C), thaw for 30 minutes from frozen state.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
	○ From the freezer to a vaccine fridge (+2˚C to +8˚C), thaw for 6 hours from the frozen state. • Must not be reconstituted, mixed with other medicinal product, or diluted. • No dilution is required. • Before use, mix the thawed vaccine by inverting the vial gently 10 times. • Do **not** shake vial.	
Vaccine Code	COVPBmRNAKP	
Antigen Code	COVID-19	
Licensed for	Single dose for individuals 12 years of age and older.	
Off-license use	• Three-dose series for individuals who are moderately to severely immunocompromised.	
Notes	• 2024 September 24: Licensed for use in Canada. • 2024 October: Implemented in Alberta.	
Related Resources	• Alberta Health Services Website (2024). COVID-19 mRNA Vaccine Information • COVID-19 mRNA Vaccine Information Sheet (105240)	

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