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

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.227**	
Created and approved by	Provincial Immunization Program Standards and Quality		
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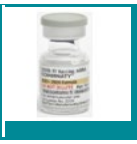
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine  Dark gray cap & dark gray label border
Manufacturer	Pfizer-BioNTech
Classification	mRNA vaccine
Indications for Provincially Funded Vaccine	Individuals 12 years of age and older (see scheduling section for specifics).
Dose	0.3 mL (30mcg)
Route	IM in the vastus lateralis or deltoid muscle
Schedule for healthy immunocompetent individuals (See below for the schedule for individuals with certain immunocompromising conditions)	**Individuals 12 years of age and older:** • 1 dose, at least 3 months from previous non-KP.2 COVID-19 vaccine dose, regardless of the number of doses received in the past.
Additional KP.2 COVID-19 vaccine dose	**Biannual Dose Implementation Date: April 28, 2025** The following individuals who are at an increased risk of severe illness from COVID-19 may receive an additional (biannual) dose of KP.2 COVID-19 vaccine: • Individuals 65 years of age and older • Adults 18 years of age and older who reside in continuing care homes and senior supportive living accommodations • Individuals 12 years of age and older who have certain moderate to severe immunocompromising conditions • First Nations, Métis, and Inuit individuals who are 12 years of age and older, no matter where they live ○ One dose, at least 3 months from previous KP.2 COVID-19 dose

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. Count the previous dose(s) and do not restart the series regardless of whether they have received one or two non-KP.2 COVID-19 vaccine doses.
	  ○ Dose 1: day 0
	  ○ Dose 2: 28 days after dose 1
	  ○ Dose 3: 8 weeks after dose 2

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

- 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 three-dose COVID-19 vaccine series include:
  - Solid organ transplant recipients:
    - Child SOT Before 18 Months
    - Child SOT After 18 Months
    - Adult SOT
  - 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 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 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)
    - 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 without viral suppression or those with acquired immunodeficiency syndrome (AIDS).
  - Individuals with moderate to severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome).
- 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 physician on the 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.

<table>
<tr><th></th><th colspan="3">COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine</th><th>  </th><th>Dark gray cap & dark gray label border</th></tr>
<tr><td>Additional KP.2 COVID-19 vaccine dose</td><td colspan="4">Biannual Dose Implementation Date: April 28, 2025
Moderately to severely immunocompromised individuals 12 years of age and older who are at an increased risk of severe illness from COVID-19 may receive an additional dose of KP.2 COVID-19 vaccine.
1 dose, at least 3 months from previous KP.2 COVID-19 vaccine dose.</td></tr>
<tr><td rowspan="5">Interval between previous COVID-19 infection and COVID-19 immunization</td><td colspan="4">The following guidance is provided on suggested intervals between COVID-19 infection and COVID-19 immunization.
Note:
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.
Consider biological and social risk factors for exposure (such as, local epidemiology, circulation of VOCs, living settings) and risk of severe disease, when deciding whether to administer vaccine doses following the suggested interval in the table below.
These intervals are a guide and clinical discretion is advised.
Individuals can be immunized at less than the recommended intervals from infection upon request.
Individuals who have not had any previous doses, 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.
Exception: Wait at least 90 days before immunizing individuals with multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A).</td></tr>
<tr><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 MIS-C or MIS-A.</td><td colspan="2">8 weeks after a positive test.</td></tr>
<tr><td>Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C or MIS-A.</td><td colspan="2">4 to 8 weeks after a positive test.</td></tr>
<tr><td>History of MIS-C or MIS-A (regardless of immunocompromised status).</td><td colspan="2">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.</td></tr>
<tr><td>Infection after COVID-19 vaccine series.</td><td>All individuals.</td><td colspan="2">3 months after a positive test.</td></tr>
<tr><td>Contraindications/ Precautions</td><td colspan="4">Contraindications:
Known severe hypersensitivity to any component of the vaccine.
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.
Precautions:</td></tr>
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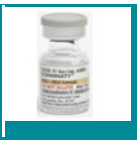
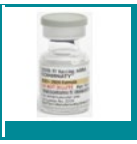
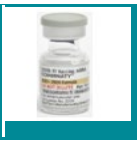
	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
	• There are no known serious warnings or precautions associated with this product at the time of authorization. • Individuals who have had a serious allergic reaction to another vaccine, drug or 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. • 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.	

Myocarditis/Pericarditis	• 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.
	  ○ 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.
	• Inform individuals receiving an mRNA COVID-19 vaccine 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.
	• 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 they 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.
	• In most circumstances, defer further doses of mRNA COVID-19 vaccines for people who experienced **myocarditis and/or 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.
	  ○ If another dose of vaccine is offered, it should be Pfizer-BioNTech KP.2 COVID-19 vaccine, if 12 years of age and older. 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
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	May use during pregnancy. • Offer vaccine to pregnant individuals regardless of trimester of pregnancy due to 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. • 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. • 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. • Consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine. **Additional resources:**		

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
	Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy	
Lactation	May use for people who are lactating and feeding their milk to infants and children. • 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 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 indicated 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. • 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	• 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. ○ Pfizer KP.2 vaccine is only being used for individuals 12 years of age and older in Alberta. ○ **Exception:** Respiratory Syncytial Virus (RSV) vaccine ▪ Limited studies have been conducted on concurrent administration of RSV vaccine with other vaccines and is not recommended until more evidence is available. ▪ Give RSV vaccine with **two weeks spacing** before or after influenza and/or COVID-19 vaccines. • TST and COVID-19 vaccines: ○ Currently there is no data on the impact of the COVID-19 mRNA vaccines on tuberculin skin testing or IGRA (QFT) test results. 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.	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
	▪ 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, 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. • 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:** • Consult the primary health care provider or medical specialist as 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. • Give mRNA COVID-19 vaccines 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: ○ Can be stored at +2˚C to +8˚C for up to 10 weeks. ○ Can be stored at +8˚C to +25˚C for up to 12 hours. Discard after 12 hours. • Thawed, punctured vials: ○ Can be stored at +2˚C to +25˚C for 12 hours. Discard after 12 hours. • Do not use vaccine after the expiration date printed on the vials and cartons regardless of storage condition.	
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 and do not contain preservative. • **Thaw vaccine before use:** ○ From the freezer to room temperature (between +15˚C to +25˚C): Thaw for 30 minutes from frozen state. ○ 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. • Mix the thawed vaccine by inverting the vial gently 10 times before use. • Do **not** shake vial.	
Vaccine Code	COVPBmRNAKP	

	COVID-19 Vaccine – mRNA Pfizer Comirnaty KP.2 Ultra frozen Vaccine	 Dark gray cap & dark gray label border
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. • 2025 March 14: Indications for an additional (biannual) COVID-19 KP.2 vaccine dose for eligible individuals as of April 28, 2025.	
Related Resources	• Alberta Health Services Website (2024). COVID-19 mRNA Vaccine Information • COVID-19 mRNA Vaccine Information Sheet (105240)	

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