March 2023

COVID-19 mRNA Vaccine (Comirnaty®)

(Adult Bivalent [BA4/5] Presentation 30mcg/0.3mL) ***Supplier: Pfizer***

Grey Vial Cap; Grey Label Border (identified by Omicron)

INDICATIONS ①

COVID-19 vaccine booster for:

(1) Adolescents or adults 12 years of age and older

PRIMARY SERIES

Pfizer Comirnaty Bivalent (BA.4/5) presentation is **not** approved for use in the primary COVID-19 vaccination series. See other Spikevax and Comirnaty product pages for primary series indications.

BOOSTER DOSES ②③④⑤

Bivalent Omicron-containing COVID-19 vaccines are the preferred products for booster doses.

Fall 2022 Booster:

Individuals ages 12 and older should have received a fall 2022 Omicron-containing bivalent COVID-19 booster dose according to recommended intervals, regardless of the number of booster doses previously received. Individuals ages 5-11 should have received one booster dose according to recommended intervals by the fall of 2022.

Spring 2023 Booster:

The individuals below **should** receive a spring 2023 COVID-19 booster dose according to recommended intervals, regardless of the number of booster doses previously received:

- Individuals ages 5 and older with moderately to severely immunocompromising conditions or chronic conditions, as outlined below in 'REINFORCEMENTS'.
- All adults ages 65 and older.
- All adults living in long term care or other congregate living settings for seniors or those with complex medical needs.

The individuals below **may** receive a spring 2023 COVID-19 booster dose according to recommended intervals, regardless of the number of booster doses previously received:

- All other individuals ages 12-64.

The individuals below **may** receive a spring 2023 COVID-19 booster dose according to recommended intervals if they did not receive a fall 2022 COVID-19 vaccine booster:

- Individuals ages 5-11 not perceived to be at higher risk of severe COVID-19.

The individuals below are **not eligible** for a spring 2023 COVID-19 booster dose:

- Individuals ages 5-11 that received a fall 2022 COVID-19 booster and are not perceived to be at higher risk of severe COVID-19.
- All individuals ages 6 months – 4 years.

Recommended interval: 6 months following their primary series or last booster.
Minimum interval: 5 months following their primary series or last booster.

Dose:

i. All individuals 12 and older: **0.3mL**

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INTERVAL BETWEEN PREVIOUS COVID-19 INFECTION AND COVID-19 IMMUNIZATION ⑥

Individuals who are recommended to receive a booster dose and who experienced SARS CoV-2 infection after completing their primary COVID-19 vaccine series may receive a booster dose **6 months after infection.**

REINFORCEMENTS ⑦⑧⑨⑩

Moderately to severely immunocompromising conditions eligible for spring 2023 booster:

- Active treatment for solid tumour or hematologic malignancies, or treatment for these conditions
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome) 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/uL or CD4%<15%, or without HIV viral suppression
- Active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (e.g., prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive (e.g., cancer chemotherapy, radiation therapy, cytotoxic drugs, calcineurin inhibitors, biological response modifiers and antibodies that target lymphocytes).
- Chronic kidney disease on dialysis

Chronic conditions eligible for spring 2023 booster: ⑦

- Cancer
- Cerebrovascular disease
- Chronic kidney disease
- Chronic liver diseases (limited to: cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease, and autoimmune hepatitis)
- Chronic lung diseases (limited to: bronchiectasis, chronic obstructive pulmonary disease, interstitial lung disease, pulmonary hypertension, pulmonary embolism)
- Cystic fibrosis
- Diabetes mellitus, type 1 and type 2
- Disabilities (e.g. Down syndrome, learning, intellectual, or developmental disabilities; ADHD; cerebral palsy; congenital disabilities; spinal cord injuries)
- Heart conditions (e.g., cardiomyopathies, coronary artery disease, heart failure, etc.)
- HIV infection
- Individuals with complex medical needs
- Mental health disorders (limited to: mood disorders, including depression; schizophrenia spectrum disorders)
- Neurodevelopmental and other chronic neurological conditions including epilepsy and cerebrovascular disease
- Obesity
- Pregnancy and recent pregnancy
- Primary immunodeficiency diseases

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- Sickle cell disease or thalassemia
- Smoking, current or former
- Solid organ or blood stem cell transplant
- Substance use disorders
- Tuberculosis

Additional dose(s) for travel: Receiving an additional dose for travel purposes is not considered clinically necessary. It is up to the traveler to know the COVID-19 vaccine requirements for their destination.

SEROLOGICAL TESTING

Serological testing is not recommended at this time.

CONTRAINDICATIONS

History of anaphylactic reaction to a previous dose of the vaccine or to any component of the vaccine.

ADMINISTRATION

- No reconstitution required.
- Vial contains 6 doses of 0.3mL
- After thawing, inspect the vial to ensure there is no particulate and no discoloration. If any is observed do not administer the vaccine.
- The withdrawal of 6 doses from a single vial is dependant, in part, on the type of syringes and needles used to withdraw doses from the vials; low dead-volume syringes and/or needles should be used if available, as standard syringes and needles may not facilitate the extraction of a 6th dose from a single vial. Additional strategies for extraction of 6 doses:
  - Allow contents to settle for 20 seconds after final inversion.
  - Go slow: withdrawing the diluted vaccine too quickly may result in fizzing.
  - Adjustments to remove air bubbles and dose calibration should be done with the needle still in the vial to avoid loss of vaccine.
  - When drawing the 6th dose, place the needle tip just inside the rubber stopper; slightly tilt vial and ensure the needle bevel is facing down and close to the vial neck.
- Administer IM in the deltoid site.
- **DO NOT REFREEZE THAWED VIALS.**

VACCINE COMPONENTS

Potential allergens: 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide.
Other components: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate); 1,2- distearoyl-sn-glycero-3-phosphocholine; cholesterol; sodium chloride; sucrose; tromethamine; tromethamine hydrochloride.

INTERCHANGABILITY

Current evidence shows that interchanging mRNA COVID-19 vaccine products is safe and effective for subsequent doses. Moderna Spikevax Bivalent (0.1mg/mL), Moderna Spikevax original (0.2mg/mL), and Pfizer-BioNTech Comirnaty (30 mcg/0.3mL) are all authorized by Health Canada as booster doses in individuals ≥18 years of age.

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ADVSERSE EVENTS

Local: pain, swelling, redness, delayed localized reactions, with onset on or after day 8 following vaccination, may occur in a small percentage of vaccine recipients, mostly after the first dose.

Systemic: fatigue, headache, myalgia, chills, arthralgia, fever, nausea and vomiting.

Pericarditis and myocarditis in association with the mRNA vaccines have been observed in Israel and the US, where these vaccines have been used in younger people longer than in Canada, especially after the second dose. In the US data, they have noted that the observed rates exceed what would be expected (given that these are inflammatory disorders of the lining of the heart and heart muscle, respectively, and occur for a variety of reasons including in association with viral infections). These events have occurred more frequently after the second dose at a rate of about 1 per 100,000 second doses, and have been observed mostly in males under 30 years of age. Most cases recover fully with conservative treatment.

PRECAUTIONS

- Vaccination against COVID-19 is recommended for individuals who are pregnant, breastfeeding, immunocompromised, or have an autoimmune condition. If clients have questions, have an informed discussion with them. Further information is available in the SOGC Statement on COVID-19 Vaccination in Pregnancy.
- For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted; alternately, the vaccine can be administered in an emergency room setting, also with a prolonged observation period.
- There is insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.
- Future doses of mRNA COVID-19 vaccine should be deferred in those who experienced a physician-diagnosed myocarditis or pericarditis event following the first dose with no other cause identified, until further information about the risk of recurrence is available. Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines.
- Post-market surveillance safety data to date have not shown product-specific differences in the risks of myocarditis and/or pericarditis after a booster dose of an mRNA COVID-19 vaccine. Therefore adults 18 to 29 years of age can receive a booster dose with any available mRNA COVID-19 vaccine for which they are currently eligible.
- Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time.

STORAGE AND HANDLING

Storage prior to use:

- The date printed on the vial and carton reflects the date of manufacture. The vaccine should not be used after 18 months from the date printed.
- -90°C to -60°C up to the end of its expiry date (18 months from manufacture date), kept in the original packaging and protected from light. Do not store on dry ice.
- **Do not store vials at -25°C to -15°C.**

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- +2°C to +8°C for up to 10 weeks (70 days) within the 18 month shelf life, prior to first use, protected from light.
- Room temperature (up to +25°C) for up to 12 hours before the first vial puncture.

Thawing:

- From the ultra low freezer to room temperature; will require up to 30 minutes to thaw
- From the ultra low freezer to the refrigerator; will require up to 6 hours to thaw, and then requires at least 15 minutes at room temperature prior to administration.
- Invert the vial gently 10 times after thawing. Do not shake

During use:

- After first vial puncture, the vaccine must be used within the next 12 hours.
- The vaccine can be pre-loaded into a syringe for up to 12 hours.
- Thawed vials and filled syringes can be handled in room light conditions. Avoid exposure to direct sunlight and ultraviolet light.
- Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry.
- Swirl gently between each withdrawal. Do not shake.

Do not refreeze thawed vials

① The Pfizer BA.4/5 Bivalent COVID-19 vaccine (Original and Omicron BA.4/BA.5) is approved as a booster for people who are 12 years of age and older. Its safety and effectiveness in younger people has not yet been established.

② A bivalent Omicron-containing mRNA COVID-19 vaccine is the preferred vaccine product for booster doses in the eligible populations.

③ Individuals should not delay their planned vaccination in anticipation of a new formulation of mRNA vaccine. Individuals choosing to delay a booster dose should carefully assess their individual risks (i.e., risks of SARS-CoV2 infection and severe outcomes from COVID-19) and benefits associated with deferring a booster dose.

④ COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live vaccine.

⑤ It is recommended that a booster dose is administered 6 months following the primary series or last booster; however, the minimum interval for booster doses is 5 months.

⑥ If an individual makes an informed decision to get vaccinated post-infection irrespective of the intervals outlined, this is permitted. However, recommended intervals between doses must be met as per the Yukon Immunization Manual (i.e. 8 weeks between dose 1 and 2; and 6 months for booster dose following completion of primary series).

⑦ **YIP recommends the following groups receive a spring 2023 booster, following recommended intervals:**

- individuals who are not up to date on fall 2022 booster recommendations.
- adults 65 years of age and older.
- adults living in long term care and other congregate living settings for seniors or those with complex medical needs.
- those 5-11 years of age with chronic conditions and whose provider or family perceive is at risk for severe disease receive a spring booster.
- those 12 to 64 years of age with chronic or moderate/severely immunocompromising conditions listed above.

⑧ YIP **does not** strongly recommend a spring 2023 booster for individuals 5 to 64 years of age that do not have immunocompromising or chronic conditions, as listed above, if they were up to date on immunizations in fall 2022. YIP recommends that these individuals reassess their COVID-19 vaccine booster needs in Fall 2023. However, YIP permits

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these individuals to receive a spring COVID-19 vaccine booster, based on their preferences, while following recommended intervals.

⑨ There is strong evidence that hybrid immunity from a confirmed COVID-19 infection AND primary series or booster dose of COVID-19 vaccine prevent greater than 90% of severe COVID-19 outcomes for at least 8 months after the infection or booster. This information could help healthy individuals under 65 years of age (without listed chronic or moderate/severe immunocompromising conditions) with decision to not receive a spring 2023 booster

⑩ Expert opinion and evidence suggests that individuals with these chronic conditions are at higher risk of experiencing severe disease from COVID-19 infection.

REFERENCES

1. Canadian Immunization Guide
2. National Advisory Committee on Immunization (NACI): Statements and publications
3. Product Monograph