Yukon

COVID-19 Vaccine Guide for Immunizers

April 2021

Table of Contents

PRODUCT INFORMATION

COVID-19 (mRNA)
COVID-19 mRNA Vaccine mRNA-1273 **Supplier: Moderna**

INDICATIONS:

- The vaccine is **not approved** for use in those less than 18 years of age.

DOSES and SCHEDULE:

Adults 18 years of age and older: 2 doses given as 0.5mL IM, 28 days apart. [1][2][3][4]

ADMINISTRATION:

- **No reconstitution required**
- After thawing, inspect the vial to ensure there is no particulate and no discoloruation. If any is observed do not administer the vaccine. **DO NOT REFREEZE THAWED VIALS!**

STORAGE AND HANDLING:

- The vaccine can be stored at:
    - -20°C (-25°C to -15°C) up to the end of its expiry date, kept in the original packaging and protected from light. Do not store on dry ice.
    - +2°C to +8°C for up to 30 days prior to first use, protected from light.
    - Room temperature (up to +25°C) for up to 12 hours.
    - After first vial puncture, the vaccine must be used within 6 hours.
    - The vaccine can be pre-loaded into a syringe for up to 6 hours.
    - Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry.
- Product should be thawed/held prior to use, in one of the following three ways:
    - From the freezer to room temperature; will require 1 hour to thaw
    - From the freezer to the refrigerator; will require 2 hours and 30 minutes to thaw, and then requires at least 15 minutes at room temperature prior to administration.
    - Swirl the vial gently after thawing and between each withdrawal. Do not shake.
- Do not refreeze thawed vials

[1] The vaccine series should be completed with the same COVID-19 vaccine product. See special considerations for interchangeability

[2] If administration of the second dose is delayed, the second dose should be provided as soon as possible and the series does not need to be restarted.

[3] The minimum interval between doses is 21 days. For optimal response, immunizers should observe recommended intervals as much as possible, however, doses given earlier than recommended may still be considered valid and need not be repeated if minimum intervals are observed.

[4] Interval accepted in clinic trials was a minimum of 21 to a maimum of 42 days apart

Summary of Vial Thawing and Storage:

<table>
<tr><td rowspan="3">Store at frozen temperature upon receiving vaccines in:
Freezer (-15°C to -25°C)
Credo Cube (-15°C to -25°C)</td><td rowspan="2">Regular Use</td><td>Step 1</td><td>Step 2</td></tr>
<tr><td>Thaw in refrigerator (+2°C to +8°C):
- Thaw for 2.5 hours
- Store in refrigerator for up to 30 days
- Label with date and time</td><td>Bring to room temperature (up to 25°C):
- May be kept at room temperature for up to 12 hours **but when brought to room temperature do not put back into fridge
- Once vial is punctured must be used within 6 hours</td></tr>
<tr><td>Immediate Use</td><td colspan="2">Step 1
Thaw to room temperature (up to +25°C) for 1 hour:
• Keep at room temperature for up to 12 hours **but when brought to room temperature do not put back into fridge
• Once vial is punctured must be used within 6 hours</td></tr>
</table>

BOOSTER DOSES:

No booster doses are recommended at this time.

SEROLOGICAL TESTING:

Serological testing is not recommended at this time.

CONTRAINDICATIONS:

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

PRODUCT COMPONENTS:

Potential allergens: 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000- DMG). **Other components**: cholesterol; 1,2-distearoyl-sn-glycerophosphocholine (DSPC); tromethamine; tromethamine hydrochloride; acetic acid, sodium acetate, sucrose

INTERCHANGEABILITY:

- Vaccine series should be completed with the same COVID-19 vaccine product. However, if a vaccine product used for a previously received dose is not known or not available, the vaccine series can be completed with a similar type of COVID-19 vaccine (eg., mRNA vaccine and mRNA vaccine).
- At this time it is not recommended that vaccines of different types (eg., mRNA vaccine and viral vector vaccine) be used in the same series.

PRECAUTIONS:

- For the following populations, a complete COVID-19 vaccine series may be offered to individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in these populations:
  - *immunosuppressed due to disease or treatment or those with an autoimmune disorder*
  - *pregnancy and breastfeeding (for more information see 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.
- Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
- 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.

SPECIAL CONSIDERATIONS:

- COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines. However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.
- Wait a period of at least 28 days after the administration of the complete two-dose vaccine series of an mRNA COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response. Wait for a period of at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine
- A complete series of COVID-19 vaccine may be offered to individuals without contraindications who have recovered from PCR-confirmed SARS-CoV-2 infection.
- 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.

ADVERSE 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.

PRODUCT INFORMATION

COVID-19 Vaccine (ChAdOx1-S [recombinant])
AstraZeneca COVID-19 Vaccine **Supplier: Astra Zeneca**
COVIDSHEILD **Supplier: Verity Pharmaceuticals**

INDICATIONS:

- Individuals 55 years of age and older[5]
- The vaccine is **not approved** for use in those less than 18 years of age.

DOSES and SCHEDULE:

Adults 55 years of age and older: 2 doses given as 0.5 mL IM, 4 weeks apart.[6,7]

ADMINISTRATION:

- **No reconstitution required**

STORAGE AND HANDLING:

Unopened multidose vial:

- +2°C to +8°C up to the end of its expiry date, kept in the original packaging and protected from light. **Do not freeze.**

Opened multidose vial:

- After first vial puncture, the vaccine is stable at room temperature (up to +30°C) for 6 hours OR at +2°C to +8°C for 48 hours.
- After the first puncture, the vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative refrigerated storage time must not exceed 48 hours. After this time, the vial must be discarded.
- The vaccine can be pre-loaded into a syringe for up to 6 hours at room temperature (up to +30°C).
- Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry.
- During use, vials/syringes may be handled in room light condition

[5] Although the vaccines are authorized for those 18 years of age and older, due to a safety signal identified in Europe following use of the AstraZeneca vaccine, NACI has recommended that neither of the ChAdOx1-S vaccines be used in people under 55 years of age. Health Canada has updated the product monographs for both products to include information about observed events of thromboembolic/ thrombocytopenia, as these vaccines are comparable.

[6] The two ChAdOx1-S vaccines are interchangeable within the vaccine series, however they are not interchangeable with other COVID-19 vaccines (e.g., mRNA vaccines).

[7] If administration of the second dose is delayed beyond 4 months, the second dose should be provided as soon as possible and the series does not need to be restarted.

BOOSTER DOSES:
No booster doses are recommended at this time.

SEROLOGICAL TESTING:
Serological testing is not recommended at this time.

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

PRODUCT COMPONENTS:
Potential allergens: polysorbate 80
Other components: disodium edetate dihydrate, ethanol, L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, sucrose.

PRECAUTIONS:
- For the following populations, a complete COVID-19 vaccine series may be offered to individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in these populations:
    - immunosuppressed due to disease or treatment or those with an autoimmune disorder (for more information see the CRA Recommendation on COVID-19 Vaccination in Persons with Autoimmune Rheumatic Disease)
    - pregnancy and breastfeeding (for more information see 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.
- Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
- 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, COVID-19 vaccination should be deferred for at least 90 days as a precautionary measure to avoid potential interference of the antibody therapy with vaccine-induced immune response.

SPECIAL CONSIDERATIONS:

- COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines. However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.
- Wait a period of at least 14 days after the administration of each ChAdOx1-S vaccine dose before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response.
- Wait for a period of at least 14 days after the administration of another vaccine before administering a COVID-19 vaccine to prevent erroneous attribution of an adverse event following immunization to a particular vaccine.
- A complete series of COVID-19 vaccine may be offered to individuals without contraindications who have recovered from PCR-confirmed SARS-CoV-2 infection.
- 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.

ADVERSE EVENTS:

Local: pain, swelling, redness, pruritus
Systemic: fatigue, headache, myalgia, chills, arthralgia, fever, nausea and malaise.
A potential increased risk of serious blood clots has been observed within 4 to 16 days following receipt of the AstraZeneca vaccine. This adverse event is being referred to as Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) and is estimated to occur in approximately 1in 100,000 to 1 in 1,000,000 vaccine recipients. Most but not all of these cases have occurred in women under 55 years of age. Symptoms warranting medical attention include: blurred vision, difficulty speaking, a seizure, difficulty moving parts of the body, shortness of breath, chest pain, new severe swelling, pain or colour change of an arm or a leg, persistent abdominal pain, or abnormal bruising, reddish or purple spots or blood blisters under the skin, or bleeding beyond the site of vaccination.

REFERENCES:

1. AstraZeneca product monograph
2. COVISHIELD product monograph
3. National Advisory Committee on Immunization: Recommendations on the use of COVID-19 Vaccine(s)