Renfrew County and District Health Unit

"Optimal Health for All in Renfrew County and District"

AstraZeneca COVID-19 Vaccine

RENFREW COUNTY & DISTRICT HEALTH UNIT

April 2021

Outline

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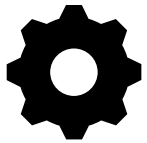
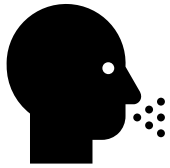
ICONS

More Information

Check Product Monograph



Tool



Client Education

About the Vaccine

- **Indications:**
  - AstraZeneca COVID-19 Vaccine (COVID-19 Vaccine (ChAdOx1-S [recombinant])) is indicated for active immunization of individuals 18 years of age and over for the prevention of coronavirus disease 2019 (COVID-19).
  - NACI recommends that AstraZeneca COVID-19 vaccine should not be used in adults under 55 years of age at this time while the safety signal of Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) following vaccination with AstraZeneca COVID-19 vaccine is investigated further.
- **Contraindications:**
  - AstraZeneca COVID-19 Vaccine is contraindicated in individuals who are hypersensitive to the active substance or to any ingredient in the formulation.
- **Dose:**
  - The AstraZeneca COVID-19 Vaccine has a vaccination course that consists of two separate doses of 0.5 mL each. The second dose should be administered between 4 and 12 weeks after the first dose.
- **# of Doses per Multi-dose Vial:**
  - 8 or 10
- **Dilution Required:**
  - No

Check Product Monograph

AstraZeneca vs. COVISHIELD®

- COVISHIELD® (manufactured by Serum Institute of India) and AstraZeneca COVID-19 VACCINE (manufactured by AstraZeneca) are ChAdOx1-S recombinant vaccines developed by AstraZeneca and the University of Oxford.
- Health Canada has reviewed the manufacturing information for these vaccines and found them to be comparable.
- Often referred to together in documents.
- Two separate vaccines.

What is a non-replicating viral vector COVID-19 vaccine?

- ✓ AstraZeneca, COVISHIELD®, and Janssen are non-replicating viral vector COVID-19 vaccines.
- ✓ A viral vector is a harmless, attenuated (weakened) virus that has been modified to act as a delivery system for transferring genetic instructions to our cells.
- ✓ Non-replicating (or replication-incompetent or replication-deficient) viral vector-based vaccines are genetically modified so that they are unable to produce new viral particles. The viral vector enters our cells where our cell machinery is used to produce viral antigen; once this is accomplished, the viral vector is cleared.
- ✓ COVID-19 viral vector-based vaccines authorized for use in Canada are non-replicating vaccines.

How does a non-replicating viral vector vaccine work?

- ✓ COVID-19 vaccines based on viral vector platforms use a modified virus to carry genes that encode SARS-CoV-2 spike proteins into the host cells.
- ✓ The vector virus is a type of adenovirus that has been modified to carry COVID-19 genes and to prevent replication. These modifications are intended to prevent the viral vector from causing disease. (i.e., they are non-replicating).
- ✓ Once inside the cell, the SARS-CoV-2 spike protein genes are transcribed into mRNA in the nucleus and translated into proteins in the cytosol of the cell.
- ✓ The AstraZeneca vaccine uses a modified chimpanzee adenovirus vector (ChAd).

COVID-19 Vaccines: Viral Vector-based Vaccines

Storage and Handling

- ✓ Unopened multidose vial:
  1. Store in a refrigerator or pre-conditioned cooler (+2 to +8°C).
  2. Do not freeze.
  3. Store in outer carton in order to protect from light.
  4. Use the product before the expiration date on the vial label.
- ✓ Opened multidose vial:
  - ✓ After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than:
    - 6 hours at room temperature, up to 30°C, or
    - 48 hours in a refrigerator (2 to 8°C).
- ✓ The vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours.

Check Product Monograph

Special Handling Instructions

Disposal:

- AstraZeneca COVID-19 Vaccine contains genetically modified organisms (GMOs).
- Any unused vaccine or waste material should be disposed of in accordance with local requirements.
- Spills should be disinfected with an appropriate antiviral disinfectant.
- No specific guidance; use normal practices until further notice

Special Considerations

- Rare cases of serious blood clots have been recently reported in Europe following post-licensure use of AstraZeneca COVID-19 vaccine.
- Cases identified so far have been primarily in women under the age of 55 years; although cases in men have also been reported and have mostly occurred between 4 and 16 days after receipt of vaccine.
- This adverse event is being referred to as Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT).
- This reaction is associated with the development of antibodies that "activate" platelets, which stimulate the formation of clots and result in thrombocytopenia. The mechanism of action is similar to heparin-induced thrombocytopenia (HIT).
- The exact mechanism by which the AstraZeneca vaccine triggers VIPIT is still under investigation.
- The rate of occurrence of this adverse event is still to be confirmed.

NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults

Client Education

- Anyone receiving the AstraZeneca COVID-19 vaccine should be informed of this potential adverse event and advised to seek immediate medical attention if they develop symptoms of thromboembolism and/or thrombocytopenia between days 4 and 20 following receipt of the AstraZeneca vaccine.
- Symptoms to be vigilant for include:
  - shortness of breath;
  - chest pain;
  - leg swelling;
  - persistent abdominal pain;
  - neurological symptoms, including sudden onset of severe or persistent worsening headaches or blurred vision;
  - skin bruising (other than at the site of vaccination) or petechiae.
- In addition, healthcare professionals should be aware of VIPIT including how to diagnose and treat the condition.

AstraZeneca Fact Sheet

Precautions

- The components of the AstraZeneca COVID-19 vaccine include polysorbate 80 and, due to potential cross reactivity, polyethylene glycol.
  - Polysorbate 80 can rarely cause allergic reactions and is found in products such as medical preparations (such as vitamin oils, tablets, and anticancer agents) or cosmetics
  - PEG can rarely cause allergic reactions and is found in products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, cosmetics, skin creams, medical products used on the skin and during operations, toothpaste, contact lenses and contact lens solution. PEG also can be found in foods or drinks but is not known to cause allergic reactions from foods or drinks.

COVID-19 Vaccination Recommendations for Special Populations

Check Product Monograph

Side Effects

Very common side effects	May affect more than 1 in 10 people	• Pain, tenderness, warmth at the injection site • Fatigue • Chills (common after second dose) • Headache • Muscle pain • Nausea (common after second dose) • Joint pain • Fever (uncommon after second dose), Feverishness
Common	May affect 1 to less than 10 in 100 people	• Localized redness, swelling, and pruritis • Induration (uncommon after second dose) • Vomiting (uncommon after second dose)
Uncommon side effects	May affect up to 1 in 100 people	• Enlarged lymph nodes

Adverse Event Following Immunization (AEFI)

- There is a remote chance that AstraZeneca COVID-19 Vaccine could cause a severe allergic reaction.
- A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the AstraZeneca COVID-19 Vaccine. For this reason, clients are asked to wait 15-30 minutes after they receive their vaccine for monitoring.
- Symptoms of an allergic reaction include:
  - hives (bumps on the skin that are very itchy)
  - swelling of the face, tongue or throat
  - difficulty breathing
  - a fast heartbeat
  - dizziness and weakness

Client Education

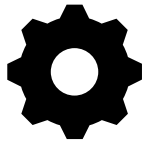
- Clients should be advised of the side effects of the vaccine.
- Clients should be advised of what an adverse event is and the steps to take once they leave the clinic.
  - Review signs and symptoms of a severe allergic reaction.
  - Advise clients to call 9-1-1, or go to the nearest hospital.
- Clients should be provided with instructions to report any other adverse events to their health care provider (if they occur after leaving the clinic).
- Clients should be advised to wait at least 15 minutes after they receive the vaccine for observation.

What you need to know about your COVID-19 vaccine appointment

AstraZeneca Fact Sheet

AEFI Reporting

- Vaccine providers are asked to report AEFIs through local public health departments and to follow AEFI reporting requirements that are specific to their province or territory.
- In general, any serious (defined as resulting in hospitalization, permanent disability or death) or unexpected adverse event that is temporally related to vaccination should be reported.
- To report an AEFI to Renfrew County and District Health Unit, please completely and as accurately as possible, fill out the AEFI reporting form and fax it to 613-735-3067.



AEFI reporting form

Administration of AstraZeneca Vaccine

Point-of-care Guidance:

- This is a two dose series; maximum protection will be attained in up to 2 weeks following the completion of the vaccine series.
- Do not mix the AstraZeneca COVID-19 vaccine with other vaccines/products in the same syringe.
- The AstraZeneca COVID-19 vaccine should not be given simultaneously with other live or inactivated vaccines.
- The vaccine series should be completed with the same COVID-19 vaccine product as the interchangeability of vaccines is not known at this time

Administration of AstraZeneca COVID-19 /COVISHIELD Vaccine

Administration of AstraZeneca Vaccine

Vaccine Preparation:

- AstraZeneca COVID-19 Vaccine must not be reconstituted, mixed with other medicinal products, or diluted.
- The unopened multidose vial can be stored in a refrigerator (+2 to +8°C). Do not freeze. Store in outer carton in order to protect from light. Use the product before the expiration date on the vial label.
- AstraZeneca COVID-19 Vaccine is packaged in (not all pack sizes may be available):
  - 5 mL of solution in a 10-dose vial (clear type I glass) with stopper (elastomeric with aluminium overseal).
  - 4 mL of solution in an 8-dose vial (clear type I glass) with stopper (elastomeric with aluminium overseal).
- The vaccine does not contain any preservative. After first opening, use the vial within:
  - • 6 hours when stored at room temperature (up to +30°C), or
  - • 48 hours when stored in a refrigerator (+2 to +8°C).

Administration of AstraZeneca COVID-19 /COVISHIELD Vaccine

Administration of AstraZeneca Vaccine

- Vaccines should be mixed with a careful swirling motion until a uniform suspension is achieved prior to administration. **Do Not Shake**
- Each vaccine dose of 0.5mL is withdrawn into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual.
- Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose.
- Care should be taken to ensure a full 0.5 ml dose is observed depending on which product is used.
  - Where a full dose cannot be extracted, the remaining volume should be discarded.
- Strict adherence to aseptic techniques must be followed.

Administration of AstraZeneca COVID-19 /COVISHIELD Vaccine

Client Education

- All clients should be reminded to continue to practice recommended public health measures for prevention and control of COVID-19 infection and transmission regardless of receipt of COVID-19 vaccine.
- Clients should be provided with information regarding the extended dose interval.
  - National Advisory Committee on Immunization(NACI) has recommended that the interval between the first and second dose be extended up to 4 months.

AstraZeneca Fact Sheet

Vaccine Clinical Advisory Group (VCAG) Recommendations on Exceptions to Extended Dose Intervals for COVID-19 Vaccines (Mar 26, 2021)

Documentation

- COVax
  - Inventory – Select AstraZeneca
  - Will NOT need to enter a diluent
- Consent Form
  - Ensure all information is properly recorded for entry into COVax
- Data Entry Form
  - For use if COVax is not available

COVID-19 Vaccine Data Entry Form (AstraZeneca)

Resources

- RCDHU website
- Administration of AstraZeneca COVID-19 /COVISHIELD Vaccine (Mar 11, 2021)
- NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults (Mar 29, 2021)
- AstraZeneca COVID-19 Vaccine Product Monograph (Feb 26, 2021)
- Vaccine Clinical Advisory Group (VCAG) Recommendations on Exceptions to Extended Dose Intervals for COVID-19 Vaccines (Mar 26, 2021)

Questions