Ministry of Health

Administration of AstraZeneca COVID-19 /COVISHIELD Vaccine

Version 1.0 March 8, 2021

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment or legal advice.

In the event of any conflict between this guidance document and any applicable emergency orders, or directives issued by the Minister of Health, Minister of Long-Term Care, or the Chief Medical Officer of Health (CMOH), the order or directive prevails.

- Please check the Ministry of Health (MOH) COVID-19 website regularly for updates to this document.

What is COVID-19?

COVID-19 is a novel coronavirus disease 2019 that is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Anyone can be infected with SARS-CoV-2 (COVID-19). However, some populations are at increased risk of exposure to the virus (e.g., due to living or work settings), and some populations are at increased risk of severe disease and death due to biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., low socioeconomic status, belonging to a racialized population) factors.

Additional information about the AstraZeneca COVID-19 vaccine can be found in the product monograph. Additional information about the COVISHIELD vaccine can be found in the product monograph.

General Clinic Precautions

All staff working in the clinic must take appropriate infection prevention and control measures, including donning appropriate personal protective equipment (PPE) when interacting with clients as they move through the immunization clinic and when responding to any adverse events following immunization (AEFI).

The Vaccine

AstraZeneca COVID-19 Vaccine/COVISHIELD Vaccine (COVID-19 (ChAdOx1-S [recombinant])	
Type of vaccine	Non-replicating viral vector (ChAd)

Date of authorization in Canada	February 26 2021	
Authorized ages for use	18 years of age and older. The safety and efficacy in children under 18 years of age have not yet been established.	
Dose	0.5 mL(5×10^{10} viral particles)	
Schedule	2 doses	
	Minimum Interval	28 days
	Recommended Interval	4 months* To increase the number of individuals benefiting from the first dose of vaccine, the province is following recommendations from the National Advisory Committee on Immunization (NACI) to extend the second dose of COVID-19 vaccine to **4 months** after receipt of the first dose.
Booster doses	At present, no evidence for additional boosters after the 2-dose series	
Route of administration	Intramuscular (IM) into the deltoid muscle	
Nature of the antigen	Transmembrane spike protein	
Adjuvant (if present)	None	
Storage requirements		
Primary storage requirements, pre-puncture	+2 to +8 °C	

Diluent	No
Formats available	Multi-dose vial (8- and 10- dose presentations). Preservative free.
Usage limit post-puncture	6 hours when stored at room temperature (up to +25 or +30°C depending on product) OR 48 hours when stored in a refrigerator (+2 to +8°C).
Drug Interactions	No interaction studies have been performed.

Considerations For Administration

- In alignment with the recommendations from NACI, Ontario will be offering the AstraZeneca/COVISHIELD vaccine to all healthy Ontarians aged 18-64 years, without contraindications if:
    - the advantages of earlier vaccination outweigh the limitations of vaccinating with a less efficacious vaccine;
    - the ease of transport, storage and handling of this vaccine facilitates access to vaccination which may otherwise be challenging; and
    - informed consent is provided which includes discussion about current vaccine options (e.g. efficacy) and the timing of future vaccine options.
- There is insufficient evidence of efficacy in adults 65 years of age and older at this time. In addition, there was a relatively small proportion of participants between 55 and 64 years of age included in the trial (NACI).
- In Ontario, beginning with populations aged 60-64 years and decreasing in age, the AstraZeneca/COVISHIELD vaccine will be offered with informed consent.
- In Ontario, individuals over 65 years may also choose to receive this vaccine product with informed consent.

Summary of reported and estimated vaccine efficacy for COVID-19 vaccines currently approved in Canada:

Vaccine	14 days after dose 1 and before dose 2 (95% CI)	> 7-14 days after dose 2 (95% CI)
Pfizer BioNTech	93% (69-98%)	95% (90-98%)
Moderna	92% (69-99%)	94% (89-97%)
AstraZeneca/COVISHIEL	76% (59-86%)*	81.6% (47.0 to 93.6%)^

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CI = confidence interval; *from day 22 up to day 90 after dose 1. ^Estimate of vaccine efficacy for dose interval of >12 weeks

- All individuals must provide informed consent that includes a discussion about current vaccine options and the timing of future vaccine options.

Who Should Delay Receiving the Vaccine

- Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, those with an acute illness, or those with symptoms of COVID-19 in order to avoid attributing any complications resulting from infection with SARS-CoV-2 or other illnesses to vaccine-related adverse events and to minimize the risk of COVID-19 transmission at an immunization clinic. It would be prudent to wait for all symptoms of an acute illness to completely resolve before receiving vaccine.

- Individuals who have been advised to self-isolate due to suspected or confirmed SARS-CoV-2 infection or due to close contact with a COVID-19 positive case should not attend a vaccine clinic and should wait to get their vaccine until their isolation period is over.
  Note: Please refer to Guidance for COVID-19 Immunization in Long-Term Care Homes and Retirement Homes for specific guidance on vaccinating high risk contacts , those with symptoms or confirmed SARS-CoV-2 infection in long-term care and retirement homes.
- Individuals who have recently (within the past 14 days) received another a vaccine
- Individuals who intend to receive a vaccine within 4 weeks of receiving the COVID-19 vaccine.
  - Anyone who receives a COVID-19 vaccine should wait 28 days after completing their COVID-19 vaccine series before receiving another vaccine (except in the case when another vaccine is required for post-exposure prophylaxis).

Considerations for Other Patient Groups

- The AstraZeneca and COVISHIELD COVID-19 vaccine can safely be given to persons with evidence of a prior SARS-CoV-2 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
- Having prolonged COVID–19 symptoms (sometimes called “Long COVID”) is not a contraindication to receiving the COVID-19 vaccine.

    - If the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. Common side effects of the vaccine (e.g., fatigue, myalgia, arthralgia) may be similar to ongoing prolonged COVID-19 symptoms.
- Information on immunizing special populations, including breastfeeding or pregnant individuals, individuals with allergies, individuals with autoimmune conditions, or individuals who are immunocompromised due to disease or treatment, is available in the Vaccination Recommendations for Special Populations guidance document. Point of care guidance for these individuals can be found in the COVID-19 Vaccine – Pre-Screening Assessment Tool for Health Care Providers (gov.on.ca).

Precautions During Vaccination Should Be Taken For:

- Refer to Vaccination Recommendations for Special Populations for information on vaccination for all patients with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).
    - The components of the AstraZeneca COVID-19/COVISHIELD 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.

- Individuals who fainted or became dizzy after receiving a vaccine or medical procedure, or those with high levels of fear about injections. These individuals can receive the vaccine. To reduce injuries due to fainting, people should be immunized while seated, or if considered at high-risk, while lying down. These individuals are also advised they may bring a support person.
    - Patients who have a bleeding disorder, bruise easily or use a blood-thinning medicine can safely receive the vaccine. Individuals receiving long-term anticoagulation with either warfarin or heparin are not

considered to be at higher risk of bleeding complications following immunization and may be safely immunized through the intramuscular route as recommended, without discontinuation of their anticoagulation therapy. In individuals with bleeding disorders, the condition should be optimally managed prior to immunization to minimize the risk of bleeding.
    - There is some evidence to suggest that IM administration with a small gauge needle (23 gauge or smaller) may be preferred, with firm pressure applied to the injection site for 5 to 10 minutes
- For more detailed recommendations on people with allergies, please consult the Vaccination Recommendations for Special Populations guidance document.

Side Effects

The AstraZeneca and COVISHIELD COVID-19 vaccines, like other medicines and vaccines can cause 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

Source: National Advisory Committee on Immunizations, Appendix D

In clinical trials most of the side effects experienced were mild to moderate and on average did not last longer than three days. Please see the product monographs for AstraZeneca COVID-19 vaccine and COVISHIELD for a complete list of reported side effects/ adverse reactions.

Adverse Events Following Immunization

All health care providers administering vaccines must be familiar with the anaphylaxis protocols for their clinic sites.

Those administering vaccines should ensure that the vaccine recipients or their parents/guardians are advised to notify clinic staff, or if they have left the clinic, call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop any of the following:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40˚C or 104˚F)
- Convulsions (seizures)
- Other serious reactions

Guidance on reporting adverse events following immunization (AEFI)

- Health care providers administering vaccines should ensure that vaccine recipients or their parent/guardian are informed of the need to report adverse events after vaccination to their health care provider. They may also contact their local public health unit to ask questions or to report an adverse event.
- Health care providers who administer immunizations (e.g., physicians, nurses and pharmacists) are required under the *Health Protection and Promotion Act*, s. 38 to report all reportable adverse events following immunizations (AEFIs), as defined in s. 38 of the HPPA to their local public health unit. Reports should be made using the Ontario AEFI Reporting Form.
- See PHO's Fact Sheet - Adverse Event Following Immunization Reporting For Health Care Providers In Ontario (publichealthontario.ca) for additional guidance.
- The Ontario Ministry of Health in collaboration with Public Health Ontario monitors reports of adverse events after immunization. This monitoring is done in collaboration with the Public Health Agency of Canada and Health Canada.

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 or COVISHIELD with other vaccines/products in the same syringe.
- The AstraZeneca COVID-19 vaccine or COVISHIELD 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.

- There are no data available on the interchangeability of AstraZeneca COVID-19 Vaccine or COVISHIELD with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of AstraZeneca COVID-19 Vaccine or COVISHIELD should receive a second dose of AstraZeneca COVID-19 Vaccine or COVISHIELD to complete the vaccination series
- In the context of limited COVID-19 vaccine supply and the absence of evidence on interchangeability of COVID-19 vaccines, the previous dose may be counted, and the series need not be restarted

Vaccine Preparation:

Additional information on vaccine preparation can be found in the product monographs for AstraZeneca COVID-19 vaccine and COVISHIELD.

AstraZeneca COVID-19 vaccine	**COVISHIELD**
AstraZeneca COVID-19 Vaccine must not be reconstituted, mixed with other medicinal products, or diluted	COVISHIELD 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.	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.
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). 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. After this time, the vial must be discarded.	The vaccine does not contain any preservative. After first opening, use the vial within: • 6 hours when stored at room temperature (up to +**25°C**), or • 48 hours when stored 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. After this time, the vial must be discarded.
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	COVISHIELD is packaged in: • 5 mL of solution in a **10-dose vial** (clear type I glass) with stopper (elastomeric with aluminium overseal).

(elastomeric with aluminium overseal). • 4 mL of solution in an **8-dose vial** (clear type I glass) with stopper (elastomeric with aluminium overseal).	

- Vaccines should be mixed with a careful swirling motion until a uniform suspension is achieved prior to administration. Unless otherwise instructed by the manufacturer, the vaccine should not be shaken before use.
- 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.

Vaccine Administration:

- It is important the proper sized syringes (e.g., to ensure the correct volume is accurately drawn up) and safety engineered needles are used when administering the vaccine
- Visually inspect each dose in the dosing syringe prior to administration.

AstraZeneca COVID-19 vaccine	COVISHIELD
• clear to slightly opaque, colourless to slightly brown, sterile, particle free, preservative-free, solution for intramuscular injection	• clear to slightly opaque, colourless to slightly opaque solution essentially free from visible particles, preservative-free, solution for intramuscular injection

- Discard the vial if the solution is discoloured or visible particles are observed.
- During the visual inspection:
    - Verify the final dosing volume of **0.5 mL** and
    - Confirm there are no particulates and that no discolouration is observed.
- **If the visual inspection fails, do not administer the vaccine**.
- Administer the vaccine intramuscularly in the deltoid muscle.
- Do not inject the vaccine intravascularly, subcutaneously or intradermally.

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.

Information on vaccine storage, stability and disposal can be found in the product monographs for AstraZeneca COVID-19 vaccine and COVISHIELD or the Vaccine Storage and Handling Guidance document