

Ministry of Health

# **COVID-19 Vaccine Information for Individuals that received a first dose of the AstraZeneca COVID-19 vaccine/COVISHIELD vaccine**

Version 1.0 – May 21, 2021

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

As of May 11<sup>th</sup>, Ontario paused the rollout and administration of first doses of the AstraZeneca COVID-19 vaccine. This decision was made out of an abundance of caution due to an observed increase after first dose in the rare blood clotting condition, known as Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT), associated with the AstraZeneca COVID-19 vaccine\*.

A second dose of COVID-19 vaccine is needed for optimal protection against COVID-19 by all people who received AstraZeneca as their first dose of vaccine. Individuals who received the AstraZeneca COVID-19 vaccine or COVISHIELD COVID-19 vaccine have two options to discuss with their health care provider when considering their second vaccine dose:

- 1. Receive AstraZeneca COVID-19 vaccine for my second dose 12 weeks following my first dose**
- 2. Receive an mRNA vaccine (Pfizer or Moderna) for my second dose 16 weeks following my first dose, if mixing vaccines is recommended**

**To understand your options - please read this information sheet carefully and make sure any questions you may have are answered by a health care professional.**

Please tick the box to indicate you have read each statement below.

**Option 1: Receive AstraZeneca COVID-19 vaccine for my second dose**

- The second dose of the AstraZeneca COVID-19 vaccine is currently offered on or after 12 weeks following the first dose. Under some conditions and to make best use of available vaccine at the end of May, second doses will be offered at an interval of 10-12 weeks (not shorter) to those who would like to get their 2nd dose sooner during this time. Your healthcare provider will let you know if you are eligible for this shortened dose interval.
- Clinical trials showed that AstraZeneca works best when the two doses are spread out by 12 weeks. When the doses were spread out by 12 weeks, it provided an estimated 80% protection against symptomatic disease. When the two doses were given closer together (9-12 weeks), protection was estimated at 69%\*\*.
- AstraZeneca has been associated with a type of blood clot called Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). **The reported risk of VITT after the second dose of AstraZeneca/ COVISHIELD vaccine is lower than after the first dose.**
- The rate of VITT in Canada after a 1st dose have been estimated to be approximately 1 per 55,000 doses\*.
  - Data from the United Kingdom (UK) suggests that the rate of VITT following the second dose is approximately 1 in 600,000 doses administered. This is based 15 events of VITT following approximately 9 million second doses of AstraZeneca vaccine administered in the UK.\*\*\*

\*To learn more about VITT consult the Science Briefs of the Ontario COVID-19 Science Advisory Table: [Vaccine-Induced Immune Thrombotic Thrombocytopenia \(VITT\) Following Adenovirus Vector COVID-19 Vaccination: Lay Summary - Ontario COVID-19 Science Advisory Table](#)

\*\* To learn more about the protection AstraZeneca COVID-19 vaccine provides against COVID-19 see the National Advisory Committee on Immunization's (NACI) [Recommendations on the use of COVID-19 vaccines - Canada.ca](#)

\*\*\* To learn more about what is currently known about the risk of VITT after a second dose of AstraZeneca COVID-19 vaccine, see this report from the United Kingdom: <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting>

**Option 2: Receive an mRNA vaccine for my second dose, if recommended**

- I received a first dose of AstraZeneca/COVISHIELD vaccine and I may choose to wait until 16 weeks from my first dose when more is known about the safety and efficacy of mixing vaccine products in a series. At that time, I can choose to receive a second dose of the AstraZeneca/COVISHIELD vaccine or, if proven to be a safe and effective option, receive an mRNA vaccine for my second dose.
- I acknowledge that, while the National Advisory Committee on Immunization (NACI) is not currently recommending that vaccines of different types (e.g., mRNA vaccine and viral vector vaccine) be used given a lack of data, a large clinical trial is underway that is addressing this question with final results anticipated to be available in June 2021.
- The study of mixed vaccine schedules that is underway has published early data on side effects from their trial. Study participants who received mixed product schedules (Astra Zeneca followed by Pfizer-BioNTech vaccine, and Pfizer-BioNTech followed by Astra Zeneca vaccine) were more likely to experience side effects such as fever, than the study participants who received the same vaccine for both doses. There were no serious side effects and no hospitalizations reported in these study data.\*
- There is further emerging international data on mixed vaccines series with a recent Spanish study which provided a first dose of the AstraZeneca COVID-19 vaccine followed by a second dose of the Pfizer vaccine where participants mounted a robust immune response following the second dose, and demonstrated mild to moderate side effects commonly observed after COVID-19 vaccines and with no hospital admissions.\*

\* To learn more about what is known about mixing vaccines so far, see this correspondence from the Lancet: [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(21\)01115-6.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(21)01115-6.pdf) and this article from [Nature: Mix-and-match COVID vaccines trigger potent immune response](#)

- I have had the opportunity to ask questions regarding the vaccine I am receiving and to have them answered to my satisfaction.
- I understand that I may withdraw this consent at any time and I may choose Option 1 instead of Option 2.

To be filled in only if direct entry into COVAX<sub>ON</sub> is not possible:

<b>Last Name</b>	<b>First Name</b>
<b>Date of Birth</b>	<b>Identification number (e.g., health card, passport, birth certificate, driver's license)</b>
<p>----- / ----- / -----</p> <p>month      day      year</p>	