

Ministry of Health

COVID-19 Vaccine Administration

Version 3.0 November 22, 2021 (amended on November 26, 2021)

Highlights of changes

- Added Chapters on Janssen COVID-19 Vaccine (page 38) and Pediatric Pfizer-BioNTech COVID-19 Vaccine (page 45)
- Inserted an ingredient list for all COVID-19 vaccines (page 14-15)

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

This document can be used as a reference for vaccine clinics and vaccine administrators to support immunization for COVID-19. Complementary resources include the individual vaccine product monographs and the COVID-19: [Vaccine Storage and Handling Guidance](#).

Evidence on vaccine effectiveness for COVID-19 vaccines currently authorized for use in Canada continues to evolve. For up to date information on vaccine efficacy and effectiveness, please consult the National Advisory Committee on Immunization (NACI) statements and publications on the [Government of Canada webpage](#).

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Quick Reference: Health Canada Authorized COVID-19 Vaccines Available for Use in Ontario

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Pediatric Pfizer-BioNTech COVID-19 Vaccine
Product Generic Name	BNT162b2	mRNA-1273	ChAdOx1-S [recombinant] /AZD1222	Ad26.COV2.S, recombinant	BNT162b2
Date of authorization in Canada	December 9, 2020 (May 2, 2021 for ages 12-15)	December 23, 2020 (August 27, 2021 for ages 12-17)	February 26, 2021	March 5, 2021	November 19, 2021
Manufacturer	Pfizer-BioNTech	Moderna	AstraZeneca/Verity Pharmaceuticals &	Janssen (Johnson & Johnson)	Pfizer-BioNTech
Type of Vaccine	Messenger ribonucleic acid (mRNA)	Messenger ribonucleic acid (mRNA)	Non-replicating viral vector (ChAd)	Non-replicating viral vector (Ad26)	Messenger ribonucleic acid (mRNA)
Link to Health Canada Product Monograph	pfizer-biontech-covid-19-vaccine-pm1-en.pdf (canada.ca)	moderna-covid-19-vaccine-pm1.pdf (canada.ca)	astrazeneca-covid-19-vaccine-pm1-en.pdf	Janssen-covid-19-vaccine-pm1.pdf (Canada.ca)	pfizer-biontech-covid-19-vaccine-pm1-en.pdf (canada.ca)

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Pediatric Pfizer-BioNTech COVID-19 Vaccine
Nature of antigen	Transmembrane prefusion spike protein	Transmembrane prefusion spike protein	Transmembrane spike protein	Transmembrane prefusion spike protein	Transmembrane prefusion spike (S) glycoprotein
Adjuvant	None	None	None	None	None
Format	Multi-dose vial: 6 doses/vial	Multi-dose vial: 10 and 14 doses/vial *Canada has received foreign labelled product from the US. Please read the vial label closely.	Multi-dose vial: 8 and 10 doses/vial	Multi-dose vial: 5 doses/vial	Multi-dose vial: 10 doses/vial
Preservative	None	None	None	None	None
Dose	0.3 mL (30 mcg of mRNA) following reconstitution	0.5 mL (100 mcg of mRNA)	0.5 mL (5 x 10 ¹⁰ viral particles)	0.5 mL (5 x 10 ¹⁰ viral particles)	0.2mL (10 mcg of mRNA) following reconstitution

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Pediatric Pfizer-BioNTech COVID-19 Vaccine
Health Canada Authorized Interval	2 doses, 21 days apart	2 doses, 28 days apart	2 doses, 4 to 12 weeks apart	1 dose	2 doses, 21 days apart
Minimum Interval ¹	19 days apart	21 days apart	28 days apart	N/A	19 days apart
Recommended Interval ²	8 weeks apart	8 weeks apart	At least 8 weeks apart	N/A	8 weeks apart
Reconstitution	Yes: each vial diluted with 1.8 mL sterile 0.9% Sodium Chloride Injection, USP, supplied by Pfizer. See product monograph for more information.	None	None	None	Yes: each vial diluted with 1.3 mL sterile 0.9% Sodium Chloride Injection, USP, (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. See product monograph for more information.

¹ NACI's Minimum Interval Recommendation ([Table 3: Immunization schedule, by COVID-19 vaccine](#)).

² There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response, higher vaccine effectiveness and may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults. See [NACI's statement](#) for more information.

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Pediatric Pfizer-BioNTech COVID-19 Vaccine
Route	Intramuscular (IM)	Intramuscular (IM)	Intramuscular (IM)	Intramuscular (IM)	Intramuscular (IM)
Authorized Age Indication	12 years of age and older ³	12 years of age and older ³	18 years of age and older	18 years of age and older	5 years of age to <12 years of age
Potential allergen included in vaccine and/or its container ⁴	Polyethylene glycol (PEG) ⁵	Polyethylene glycol (PEG) ⁵ Tromethamine (tromethamol or Tris)	Polysorbate 80 ⁵	Polysorbate 80 ⁵	Polyethylene glycol (PEG) ⁵ Tromethamine (tromethamol or Tris)

³ Ontario has made a preferential recommendation for use of the Pfizer-BioNTech vaccine for individual's ages 12-24 years. See [Vaccination Recommendations for Special Populations](#) for details.

⁴ This table identifies ingredients of the authorized, available COVID-19 vaccines that have been associated with allergic reactions in other products ([NACI](#)). This is not a complete list of substances. Any component of the COVID-19 vaccine or its container could be a potential allergen.

⁵ [Potential cross-reactive hypersensitivity between PEG and polysorbates has been reported in the literature.](#)

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Pediatric Pfizer-BioNTech COVID-19 Vaccine
Vaccine Product for booster or third doses ⁶	Eligible individuals should receive a third dose of an mRNA vaccine (Pfizer-BioNTech or Moderna).	Eligible individuals should receive a third dose of an mRNA vaccine (Pfizer-BioNTech or Moderna).	Individuals eligible for a third dose are recommended to receive an mRNA vaccine (Pfizer-BioNTech or Moderna) unless there are contraindications to receiving an mRNA vaccine.	Individuals eligible for a booster dose are recommended to receive an mRNA vaccine (Pfizer-BioNTech or Moderna) unless there are contraindications to receiving an mRNA vaccine.	No

⁶ See [COVID-19 Vaccine Third Dose Recommendations](#) for details on eligibility and dose intervals.

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Pediatric Pfizer-BioNTech COVID-19 Vaccine
Very common and common side effects ⁷	Pain, swelling, or redness/erythema at the injection site Fatigue Headache Muscle pain Chills Fever Joint pain Diarrhea Nausea/vomiting	Pain, swelling, or redness/erythema at the injection site Fatigue Headache Muscle pain Chills Joint pain Nausea/Vomiting Lymphadenopathy	Pain, swelling, or redness/erythema at the injection site Fatigue Headache Muscle pain Chills Joint pain Fever Nausea/ Vomiting	Pain, swelling, or redness/erythema at injection site Fatigue Headache Muscle Pain Chills Joint pain Nausea/Vomiting Fever	Pain, redness, swelling at the injection site Fatigue Headache Muscle Pain Chills Fever Joint pain Diarrhea Nausea/vomiting
Uncommon side effects ⁸	Lymphadenopathy	Fever (very common after second dose)	Lymphadenopathy		Lymphadenopathy

⁷ Very common side effects occur in 10% or more of vaccine recipients, while common side effects occur in 1 to less than 10% of vaccine recipients ([NACI](#)).

⁸ Uncommon side effects occur in 0.1% to less than 1% of vaccine recipients ([NACI](#))

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Pediatric Pfizer-BioNTech COVID-19 Vaccine
Rare or very rare adverse events ⁹	Pericarditis/Myocarditis	Pericarditis /Myocarditis	Vaccine-Induced Thrombotic Thrombocytopenia (VITT) Capillary Leak Syndrome (CLS) Guillain-Barré syndrome (GBS)	Vaccine-Induced Thrombotic Thrombocytopenia (VITT) Capillary Leak Syndrome (CLS) Guillain-Barré syndrome (GBS)	
Primary Storage Requirements Pre-Puncture	Ultracold -90°C to -60°C Guidance on short term storage can be found in the COVID-19: Vaccine Storage and Handling Guidance document	Frozen -25°C to -15°C	Refrigerated +2°C to +8°C	Refrigerated +2°C to +8°C	Ultracold -90°C to -60°C
Storage Requirements Pre-Puncture	Up to 31 days at +2°C to +8°C OR at room temperature (up to +25°C) for no more than 2 hours	Up to 30 days at +2°C to +8°C OR 24 hours at +8°C to +25°C	+2°C to +8°C	+2°C to +8°C	Up to 10 weeks at +2°C to +8°C OR at room temperature (up to +25°C) for no more than 12 hours

⁹ Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients respectively ([NACI](#))

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Pediatric Pfizer-BioNTech COVID-19 Vaccine
Post-Puncture Shelf Life	6 hours from time of reconstitution at +2°C to +25°C	24 hours at +2°C to +25°C	6 hours at room temperature (up to +30°C) OR 48 hours at +2°C to +8°C	3 hours at room temperature (up to +25°C) OR 6 hours at +2°C to +8°C	12 hours from time of reconstitution at +2°C to +25°C

COVID-19 Vaccine Precautions & Population Specific Considerations

Group	Context	Action
All individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine or vaccine components).	<p>Consult: Vaccination Recommendations for Special Populations</p> <ul style="list-style-type: none"> Components that may rarely cause type I hypersensitivity reactions found in COVID-19 vaccines include polyethylene glycol (PEG), polysorbate 80 and tromethamine (tromethamol or Tris). Details for each vaccine can be found in: <ul style="list-style-type: none"> Chapter 1: Pfizer-BioNTech COVID-19 Vaccine. Chapter 2: Moderna COVID-19 Vaccine Chapter 3: AstraZeneca COVID-19 Vaccine. Chapter 4: Janssen (Johnson & Johnson) COVID-19 Vaccine. and Chapter 5: Pediatric Pfizer-BioNTech COVID-19 Vaccine 	<p>Point-of-care guidance for these individuals can be found in the COVID-19 Vaccine – Pre-Screening Assessment Tool for Health Care Providers</p> <p>See the Vaccination Recommendations for Special Populations for further details.</p>

Group	Context	Action
History of fainting/dizziness, or fear of injections/needles	See CARDS resources to support immunization	Can receive the vaccine <ul style="list-style-type: none"> • Immunize while seated to reduce injuries due to fainting, • If considered high-risk, immunize while lying down. • These individuals may bring a support person.
Individuals who have a bleeding disorder, bruise easily, or are taking blood-thinners	<ul style="list-style-type: none"> • Individuals taking long-term anticoagulation (e.g., warfarin or heparin therapy) are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy (NACI). • In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding (NACI). 	Can receive the vaccine <ul style="list-style-type: none"> • There is some evidence to suggest that IM administration with a small gauge needle (23 gauge or smaller) may be preferred to minimize the risk of bleeding, with firm pressure applied to the injection site for 5 to 10 minutes.
Breastfeeding or Pregnant	Consult: Vaccination Recommendations for Special Populations See Vaccination in Pregnancy & Breastfeeding Decision Making Support Tool to support immunization	Can receive the vaccine See the Vaccination Recommendations for Special Populations for further details.
Autoimmune Conditions Immuno-compromised due to disease or treatment	Consult: Vaccination Recommendations for Special Populations	See the Vaccination Recommendations for Special Populations for further details.

Group	Context	Action
<p>Prior SARS-CoV-2 infection</p>	<p>Vaccine should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection, as per NACI recommendations.</p> <p>Having prolonged COVID-19 symptoms (sometimes called Long COVID or Post-Acute COVID-19 Syndrome) is not a contraindication to receiving the COVID-19 vaccine.</p>	<p>Can receive the vaccine</p> <ul style="list-style-type: none"> 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. <p>Common side effects of the vaccine (e.g., fatigue, myalgia, arthralgia) may be similar to ongoing prolonged COVID-19 symptoms.</p>
<p>Symptoms, either current or displayed recently, of chest pain or shortness of breath</p>	<p>Vaccine should not be offered to persons displaying current or recent history of chest pain or shortness of breath.</p>	<p>Defer vaccination</p> <ul style="list-style-type: none"> Consult with a health care provider prior to vaccination and/or if symptoms are severe, should be directed to the emergency department or instructed to call 911
<p>Confirmed or suspected SARS-CoV-2 infection Symptoms of COVID-19 Other acute illnesses</p>	<p>To avoid attributing any complications resulting from infection with SARS-CoV-2 or other illnesses to vaccine-related adverse events</p> <p>Risk of COVID-19 transmission at an immunization clinic/venue</p>	<p>Defer vaccination</p> <ul style="list-style-type: none"> It would be prudent to wait for all symptoms of an acute illness to completely resolve before receiving the vaccine.

Group	Context	Action
Symptomatic and asymptomatic individuals who have been advised to self-isolate due to: <ul style="list-style-type: none"> Suspected or confirmed SARS-CoV-2 infection Close contact with a COVID-19 positive case	Risk of COVID-19 transmission at an immunization clinic/venue	Defer vaccination <ul style="list-style-type: none"> Should not attend a vaccine clinic and should wait to get their vaccine until their isolation period is over. Follow specific Guidance for COVID-19 Immunization in Long-Term Care (LTC) Homes and Retirement Homes (RH) for individuals living and working in LTC homes and RHs.

COVID-19 Vaccine Ingredient List

Ingredients	Pfizer-BioNTech	Pediatric Pfizer-BioNTech	Moderna	AstraZeneca	Janssen (Johnson & Johnson)
Active	<ul style="list-style-type: none"> tozinameran (mRNA) 	<ul style="list-style-type: none"> tozinameran (mRNA) 	<ul style="list-style-type: none"> elasomeran (mRNA) 	<ul style="list-style-type: none"> ChAdOx1-S (recombinant) 	<ul style="list-style-type: none"> Ad26.COV2.S (recombinant)

Ingredients		Pfizer-BioNTech	Pediatric Pfizer-BioNTech	Moderna	AstraZeneca	Janssen (Johnson & Johnson)
Non-medical	Lipids	<ul style="list-style-type: none"> • ALC-0315 • ALC-0159 – a polyethylene glycol (PEG) • 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) • Cholesterol 	<ul style="list-style-type: none"> • (4- hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) • hexane-6,1-diyl bis(2-hexyldecanoate) • 2[(polyethylene glycol)-2000]- N,N-ditetradecylacetamide • 1,2-distearoyl-sn-glycero-3-phosphocholine • cholesterol 	<ul style="list-style-type: none"> • 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) • Lipid SM-102 • Cholesterol • PEG2000 DMG SM-102 	<ul style="list-style-type: none"> • Disodium edetate dihydrate (EDTA) • Ethanol • L-Histidine • L-Histidine hydrochloride monohydrate • Polysorbate 80 	<ul style="list-style-type: none"> • 2-hydroxypropyl-β-cyclodextrin (HBCD) • Citric acid monohydrate • Ethanol • Hydrochloric acid • Polysorbate-80 • Trisodium citrate dihydrate

Ingredients		Pfizer-BioNTech	Pediatric Pfizer-BioNTech	Moderna	AstraZeneca	Janssen (Johnson & Johnson)
Non-medical	Salts	<ul style="list-style-type: none"> • Dibasic sodium phosphate dihydrate • Monobasic potassium phosphate • Potassium chloride • Sodium chloride 	<ul style="list-style-type: none"> • Tromethamine • Tromethamine hydrochloride • Sodium chloride 	<ul style="list-style-type: none"> • Acetic acid • Sodium acetate trihydrate • Tromethamine • Tromethamine hydrochloride 	<ul style="list-style-type: none"> • Magnesium chloride hexahydrate • Sodium chloride 	<ul style="list-style-type: none"> • Sodium chloride • Sodium hydroxide
	Sugar	<ul style="list-style-type: none"> • Sucrose 	<ul style="list-style-type: none"> • Sucrose 	<ul style="list-style-type: none"> • Sucrose 	<ul style="list-style-type: none"> • Sucrose 	
	Other	<ul style="list-style-type: none"> • Water for injection 	<ul style="list-style-type: none"> • Water for injection 	<ul style="list-style-type: none"> • Water for injection 	<ul style="list-style-type: none"> • Water for injection 	<ul style="list-style-type: none"> • Water for injection

Adverse Events Following Immunization

All health care providers administering vaccines must be familiar with the anaphylaxis protocols for their clinic sites and ensure availability of anaphylaxis management kits. For additional information:

- Public Health Ontario resource on the [Management of Anaphylaxis Following Immunization in the Community](#)
- The [Canadian Immunization Guide](#)

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 symptoms:

- Hives
- Swelling of the face, throat or mouth
- Altered level of consciousness/Serious drowsiness
- Trouble breathing, hoarseness or wheezing
- High fever (over 40 °C or 104 ° F)
- Convulsions or seizures
- Other serious reactions (e.g., "pins and needles" or numbness)

Guidance on reporting adverse events following immunization (AEFI) for health care providers

- Health care providers administering vaccines are required to inform vaccine recipients or their parent/guardian of the importance of immediately reporting adverse events following immunization (AEFIs) to a physician or nurse in accordance with Section 38 of the *Health Protection and Promotion Act* (HPPA). Vaccine recipients or their parent/guardian may also contact their [local public health unit](#) to ask questions or to report an AEFI.
- Specified health care providers (e.g., physicians, nurses and pharmacists) are required under s.38(3) of the HPPA to report AEFIs to their local [public health unit](#). Reports should be made using the [Ontario AEFI Reporting Form](#).
- See Public Health Ontario's [vaccine safety webpage](#) and [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 AEFIs. This monitoring is done in collaboration with the Public Health Agency of Canada and Health Canada.

Out of Province Vaccines

For guidance on managing and documenting individuals who have received COVID-19 vaccines outside of Ontario, please consult [COVID-19 Guidance for Individuals Vaccinated outside of Ontario/Canada \(gov.on.ca\)](https://www.gov.on.ca/covid19/guidance/individuals-vaccinated-outside-of-ontario/canada).

Point-of-Care Guidance for COVID-19 Vaccines

- Do not mix the COVID-19 vaccines with other vaccines/products in the same syringe.
- NACI recommends that COVID-19 vaccines for individuals 12 years of age and older may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines.
- NACI recommendations for vaccine co-administration differ for individuals 5-11 years of age. See Chapter 5: Pediatric Pfizer-BioNTech for ages 5-11 for further details.
- NACI [recommendations](#) on the use of a different COVID-19 vaccine product to complete a two-dose COVID-19 vaccine series are being followed in Ontario:

NACI recommends that if readily available*, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a two-dose vaccine series started with an mRNA COVID-19 vaccine.

- However, when the same mRNA COVID-19 vaccine product is not readily available*, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group should be offered as the second dose in the vaccine series.
- The previous dose should be counted, and the series need not be restarted.

*readily available has been defined by NACI as easily available at the time of vaccination without delay or vaccine wastage

Where a different vaccine product is used to complete the two-dose primary vaccine series, the second dose should be given at a recommended dose interval of 8 weeks for mRNA vaccines and at least 8 weeks for AstraZeneca. There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in a more robust and durable immune response and higher vaccine effectiveness (NACI). The decision to use the longer recommended dose interval should consider local epidemiology and transmission of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), individual risk of exposure, and need for a second dose for earlier protection.

Vaccine for first dose	Vaccine for second dose	Health Canada Authorized Interval between first and second doses	Recommended Interval
Pfizer	Pfizer	21 days†	8 weeks*
Pediatric Pfizer	Pediatric Pfizer	21 days†	8 weeks*
Pfizer	Moderna	21 days†	8 weeks*
Moderna	Moderna	28 days†	8 weeks*
Moderna	Pfizer	28 days†	8 weeks*
AstraZeneca	Pfizer	8-12 weeks [∞]	At least 8 weeks*
AstraZeneca	Moderna	8-12 weeks [∞]	At least 8 weeks*
AstraZeneca	AstraZeneca	8-12 weeks [∞]	At least 8 weeks*

† Health Canada authorized interval as per product monograph of the vaccine used for the first dose.

*The Ministry of Health is recommending an interval of 8 weeks between first and second doses. There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response, higher vaccine effectiveness and may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults.

[∞] The AstraZeneca COVID-19 vaccine may be provided at the Health Canada authorized interval of 4-12 weeks as per the product monograph. An interval of at least 8 weeks is recommended. See the [Q&A for Health Care Providers on Mixed \(Heterologous\) COVID-19 Vaccine Schedules](#) for more information

Third Doses for Special Populations

Third doses of an mRNA COVID-19 vaccine is now recommended for select populations.

Please see the [COVID-19 Vaccine Third Dose Recommendations](#) for population descriptions and details.

COVID-19 Vaccine Errors and Deviations

For guidance on managing COVID-19 vaccine administration errors and deviations, please see [COVID-19 Vaccine Errors and Deviations](#).

Chapter 1: Pfizer-BioNTech COVID-19 Vaccine ≥ 12 formulation (purple cap)

Considerations for Administration

Based on advice from Ontario's Vaccine Clinical Advisory Group, the Ministry of Health has issued a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 12-24 (including those turning 12 in 2021)**. This recommendation stems from an observed increase in the number of reports in Ontario of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in the 18-24 year old age group, particularly among males. See [Vaccination Recommendations for Special Populations for more details](#).

Warnings & Precautions

Myocarditis & Pericarditis

There have been Canadian and international reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines. [Global experience](#) to date has indicated that the majority of reported cases have responded well to conservative therapy (rest, treatment with non-steroidal anti-inflammatory drugs (NSAIDs)) and tend to recover quickly. Symptoms have typically been reported to start within one week after vaccination. Providers are encouraged to consult the enhanced epidemiologic surveillance summary from [Public Health Ontario](#) for trends and risk of myocarditis/pericarditis following mRNA vaccines in Ontario.

[NACI](#) continues to strongly recommend that a complete series with an mRNA COVID-19 vaccine be offered to all eligible individuals in Canada, including those 12 years of age and older, in the authorized age group without contraindications to the vaccine. In the context of adequate Pfizer-BioNTech COVID-19 vaccine supply, the preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 12-24 (including those turning 12 in 2021) is anticipated to reduce the rare number of events of myocarditis/pericarditis in Ontario. Evidence on this topic continues to evolve and this recommendation may be amended as more

information becomes available. Vaccines are safe, effective, and continue to be the best way to protect young adults, their families, and our community from COVID-19.

The benefits of vaccination with COVID-19 vaccines continue to outweigh the risks of COVID-19 illness and related, possibly severe outcomes for all age groups.

mRNA COVID-19 vaccines also continue to be recommended internationally. This situation is being monitored closely in Canada and internationally.

- Anyone receiving an authorized mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis, and advised to seek medical attention if they develop symptoms including chest pain, shortness of breath, palpitations (pounding or heart racing), or feeling of rapid or abnormal heart rhythm ([NACI](#)).
- As a precautionary measure, [NACI](#) has recommended that individuals who have experienced myocarditis or pericarditis following vaccination following a first dose of an mRNA COVID-19 vaccine defer their second dose in the vaccination series until more information is available. Additionally, individuals aged 12-17 years with history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations ([NACI](#)). The National Advisory Committee on Immunization, Public Health Ontario and The Ministry of Health continue to follow this closely and will update this recommendation as more evidence becomes available
 - For more information consult Public Health Ontario's [Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines](#) resource.
 - [Interim clinical guidance and an algorithm](#) for the identification and management of myocarditis and pericarditis following mRNA COVID-19 vaccination in children is available from the Hospital for Sick Children.
 - A clinical framework is also available from the Canadian Journal of Cardiology [Myocarditis and Pericarditis following COVID-19 mRNA Vaccination: Practice Considerations for Care Providers](#)

Allergies

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).

Vaccine components include the potential allergen Polyethylene Glycol (PEG). Allergic reactions to PEG are rare. PEG is found in products such as prescription medications, bowel preparation products for colonoscopy, over the counter products (e.g., laxatives, cough syrups), cosmetics, dermal fillers, skin care products, products such as ultrasound gel, and contact lens care solution. PEG also can be

found in foods or drinks but is not known to cause allergic reactions from foods or drinks. Due to potential cross-reactivity with PEG, allergies to polysorbate must also be considered. Allergic reactions to polysorbates are rare. Polysorbates can be found in products such as medical preparations (such as vitamin oils, tablets, and anticancer agents) or cosmetics among others.

Any component of the COVID-19 vaccine or its container could be a potential allergen. The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for people with a latex allergy. For a full list of vaccine components, please consult the [product monograph](#).

People who experienced a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine may receive future doses of the same or another mRNA COVID-19 vaccine after consulting with an allergist/immunologist or another appropriate physician. This group should also be observed for 30 minutes, instead of 15 minutes, after getting the vaccine. See [NACI's recommendations on the use of COVID-19 vaccines](#) for more information.

Side effects

The Pfizer-BioNTech COVID-19 vaccine, like medicines and other vaccines, may cause side effects. In clinical trials, most of the side effects experienced were mild to moderate, and usually resolved within a few days. Please see the [product monograph](#) for a complete list of reported side effects.

Very common side effects	Occur in 10% or more of vaccine recipients	<ul style="list-style-type: none"> • Pain at injection site • Fatigue • Headache • Muscle pain • Chills • Fever (common after first dose for adults)
Common side effects	Occur in 1 to less than 10% of vaccine recipients	<ul style="list-style-type: none"> • Localized redness/erythema or swelling at injection site • Joint pain (very common after second dose) • Diarrhea • Nausea and/or vomiting (common after second dose for adults)

Uncommon side effects	Occur in 0.1% to less than 1% of vaccine recipients	<ul style="list-style-type: none"> Enlarged lymph nodes (Lymphadenopathy)
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Source: [National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.](#)

See the Warnings and Precautions section above for information about the very rare reports of myocarditis and pericarditis following vaccination with mRNA COVID-19 vaccines. See the [product monograph](#) for further details on post-market adverse reactions.

Vaccine Preparation for Pfizer-BioNTech COVID-19 Vaccine \geq 12 formulation

Detailed information on vaccine preparation and transport can be found in the [product monograph](#) and the [COVID-19: Vaccine Storage and Handling Guidance](#).

- The Pfizer-BioNTech COVID-19 vaccine multiple dose vial contains a frozen suspension that does not contain preservatives and **must be thawed and diluted prior to administration**. See the Preparation for Immunization Clinics section of the [COVID-19: Vaccine Storage and Handling Guidance](#) and [product monograph](#) for detailed thawing instructions.
- Once thawed, unpunctured vials may be stored for up to 31 days at +2 °C to +8 °C or at room temperature (up to +25 °C) for no more than 2 hours.
 - During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.
 - Appropriate labelling including “must use by dating/timing” can provide visual cues to indicate product viability of use.
- Before dilution and after thawing, the vial must be inverted gently 10 times to mix the vaccine. **Do not shake.**
- Prior to dilution, the thawed suspension is a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if liquid is discoloured or if other particles are observed.
- Strict adherence to aseptic techniques must be followed.

- The contents of the vial must be diluted with sterile 0.9% Sodium Chloride Injection, USP. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. Do **not** use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- Using aseptic technique, withdraw 1.8 mL of 0.9% Sodium Chloride Injection, USP into a transfer syringe (21 gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.
- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8mL air into the empty diluent syringe.
- After dilution, the vial containing the Pfizer-BioNTech COVID-19 vaccine should be gently inverted 10 times to mix. **Do not shake.**
- To minimize the risk of contamination, never use the same diluent vial more than once. Make sure to discard any remaining saline in the diluent vial in a sharps container ([Pfizer-BioNTech COVID-19 Vaccine Resources](#)). In Ontario, Pfizer-BioNTech vaccine is shipped with a diluent to vaccine ratio that supports single use of diluent.
- After dilution, the vaccine will be an off-white suspension. Inspect vial to confirm there are no particulates and no discolouration is observed. Do not use if the vaccine is discoloured or contains particulate matter.

Record the time and date of dilution on the vial label and store the vial between +2°C to +25°C. Any unused vaccine must be discarded 6 hours after dilution.

- During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
- Thawed and diluted vials can be handled in room light conditions.

Preparation of an Individual Dose for Pfizer-BioNTech COVID-19 Vaccine ≥ 12 formulation

- The vaccine is authorized as a 6-dose vial.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab and withdraw 0.3mL of vaccine, preferentially using low dead-volume syringes and/or needles
- Each dose must contain 0.3mL of vaccine

- For guidance on what to do when there is leftover solution in the vial or if more than 6 doses can be obtained from a vial, please see the [COVID-19: Vaccine Storage and Handling Guidance](#) document

Vaccine Administration for Pfizer-BioNTech COVID-19 Vaccine > 12 formulation

- It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up.
- Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.
- Visually inspect each dose in the dosing syringe prior to administration. The diluted vaccine will be an off-white suspension.
- During the visual inspection:
 - Verify the final dosing volume of **0.3 mL**, and
 - Confirm there are no particulates and that no discolouration is observed.
- **If the visual inspection fails, do not administer the vaccine.**
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw each 0.3 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection. Pierce the stopper preferably at a different site each time.
- Administer Pfizer-BioNTech COVID-19 vaccine immediately, and no later than 6 hours after dilution
- Administer Pfizer-BioNTech COVID-19 vaccine intramuscularly in the deltoid muscle.
 - Do not inject the vaccine intravascularly, subcutaneously, or intradermally.
- Any non-viable/unused vaccine or waste material should be disposed of in accordance with local requirements. See Appendix G of the [COVID-19: Vaccine Storage and Handling Guidance](#) for details.

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 [COVID-19: Vaccine Storage and Handling Guidance](#)

Chapter 2: Moderna COVID-19 Vaccine

Considerations for Administration

Based on advice from Ontario's Vaccine Clinical Advisory Group, the Ministry of Health issued a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 12-24 (including those turning 12 in 2021)**. This recommendation stems from an observed increase in the number of reports in Ontario of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in the 18-24 year old age group, particularly among males. Should individuals aged 12 to 24 request Moderna, they can access it with informed consent, which should include a review of the [Vaccine Information Sheet](#) that outlines the possible elevated risk of myocarditis/pericarditis. See [Vaccination Recommendations for Special Populations](#) for more details.

Warnings & Precautions

Myocarditis & Pericarditis

There have been Canadian and international reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining of the heart) following vaccination with COVID-19 mRNA vaccines ([Public Health Agency of Canada](#)). Cases have occurred more frequently in males than in females, most frequently in adolescents and young adults, and more commonly after the second dose of vaccine. There has been an observed increase in the number of reports in Ontario of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in the 18-24 year old age group, particularly among males, leading to a preferential recommendation for the use of Pfizer-BioNTech vaccine in this age group. See [Vaccination Recommendations for Special Populations](#) for more details. [Global experience](#) to date has indicated that the majority of reported cases have responded well to conservative therapy (rest, treatment with non-steroidal anti-inflammatory drugs (NSAIDs)) and tend to recover quickly. Symptoms have typically been reported to start within one week after vaccination. Further information on trends in myocarditis/pericarditis following mRNA vaccines in Ontario are summarized in an enhanced epidemiologic surveillance summary from [Public Health Ontario](#).

NACI continues to strongly recommend that a complete series with an mRNA COVID-19 vaccines be offered to all eligible individuals in Canada, including those 12 years of age and older, in the authorized age group without contraindications to the vaccine. mRNA COVID-19 vaccines also continue to be recommended in other

countries where mRNA vaccines are being used. This situation is being monitored closely in Canada and internationally. Evidence on this topic continues to evolve and this recommendation may be amended as more information becomes available. Vaccines are safe, effective and continue to be the best way to protect young adults, their families and our community from COVID-19.

The benefits of vaccination with COVID-19 vaccines continue to outweigh the risks of COVID-19 illness and related, possibly severe consequences/outcomes for all age groups.

- Anyone receiving an authorized mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop symptoms including chest pain, shortness of breath, palpitations (pounding or heart racing), or feeling of rapid or abnormal heart rhythm ([NACI](#)).
- As a precautionary measure, the [NACI](#) has recommended that individuals who have experienced myocarditis or pericarditis following vaccination with a first dose of an mRNA COVID-19 vaccine defer their second dose in the vaccination series until more information is available. Additionally, individuals aged 12-17 years with history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations ([NACI](#)). The National Advisory Committee on Immunization, Public Health Ontario and The Ministry of Health continue to follow this closely and will update this recommendation as more evidence becomes available.
 - For more information consult Public Health Ontario's [Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines](#) resource
 - [Interim clinical guidance and an algorithm](#) for the identification and management of myocarditis and pericarditis following mRNA COVID-19 vaccination in children is available from the Hospital for Sick Children
 - A clinical framework is also available from the Canadian Journal of Cardiology [Myocarditis and Pericarditis following COVID-19 mRNA Vaccination: Practice Considerations for Care Providers](#)

Allergies

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).

Vaccine components include the potential allergen Polyethylene Glycol and Tromethamine (trometamol or Tris). Allergic reactions to PEG are rare. PEG is found in products such as prescription medications, bowel preparation products for colonoscopy, over the counter products (e.g., laxatives, cough syrups), cosmetics, dermal fillers, skin care products, products such as ultrasound gel, and contact lens care solution. PEG also can be found in foods or drinks but is not known to cause allergic reactions from foods or drinks. Due to potential cross-reactivity with PEG, allergies to polysorbate must also be considered. Allergic reactions to polysorbates are rare. Polysorbates can be found in products such as medical preparations (such as vitamin oils, tablets, and anticancer agents) or cosmetics among others.

Allergic reactions to Tromethamine are rare. Tromethamine is found in products such as contrast media, oral, and parenteral medications.

Any component of the COVID-19 vaccine or its container could be a potential allergen. The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for people with a latex allergy. For a full list of vaccine components, please consult the [product monograph](#).

People who experienced a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine may receive future doses of the same or another mRNA COVID-19 vaccine after consulting with an allergist/immunologist or another appropriate physician. This group should also be observed for 30 minutes, instead of 15 minutes, after getting the vaccine. See [NACI's recommendations on the use of COVID-19 vaccines](#) for more information.

Side effects

The Moderna COVID-19 vaccine, like medicines and other vaccines can cause side effects. 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 monograph](#) for a complete list of reported side effects.

<p>Very common side effects</p>	<p>Occur in 10% or more of vaccine recipients</p>	<ul style="list-style-type: none"> • Pain at injection site • Lymphadenopathy/ Axillary swelling and tenderness (enlarged lymph nodes) • Fatigue • Headache • Joint pain • Muscle pain • Chills
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Common side effects	Occur in 1 to less than 10% of vaccine recipients	<ul style="list-style-type: none"> Localized redness/erythema and swelling at injection site (very common after second dose) Nausea and/or vomiting (very common after second dose)
Uncommon side effects	Occur in 0.1% to less than 1% of vaccine recipients	<ul style="list-style-type: none"> Fever (very common after second dose)

Source: [National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.](#)

See the Warnings and Precautions section above for information about the very rare cases of myocarditis and pericarditis that have been reported following vaccination with mRNA COVID-19 vaccines.

Vaccine Preparation

Detailed information on vaccine preparation and transport can be found in the [product monograph](#) and [the COVID-19: Vaccine Storage and Handling Guidance](#).

- The COVID-19 vaccine Moderna **must be thawed prior to administration. No reconstitution is required.**

Thaw each vial before use:

- Thaw in refrigerated conditions between +2°C to +8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.
- Alternatively, vials can be thawed at room temperature between +15°C to +25°C for 1 hour.
- Do not re-freeze vials after thawing.
- Swirl the vial gently after thawing and between each withdrawal. **Do not shake.**
- The vaccine is authorized as a 10-dose vial.
 - Canada has received foreign labelled product from the US, some of which comes in a 14 dose per vial format. Please read the vial label carefully prior to administration to determine the number of doses available per vial.
- For guidance on what to do when there is leftover solution in the vial or if more than the stated number of doses can be obtained, please see the [COVID-19: Vaccine Storage and Handling Guidance](#) document.

Vaccine Administration

- Moderna COVID-19 vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Inspect vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The vaccine should be administered by the intramuscular (IM) route only. Do not inject the vaccine intravascularly, subcutaneously or intradermally. The preferred site is the deltoid muscle of the upper arm.
- It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up.
- Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw each 0.5 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection. Pierce the stopper preferably at a different site each time. The dose in the syringe should be used as soon as feasible and no later than 24 hours after the vial was first entered (needle-punctured).
- Moderna COVID-19 vaccine is preservative free. Once the vial has been entered (needle-punctured), it should be discarded after 24 hours. Do not refreeze. Thawed vials and filled syringes can be handled in room light conditions.
- Any non-viable/unused vaccine or waste material should be disposed of in accordance with local requirements. See Appendix G of the [COVID-19: Vaccine Storage and Handling Guidance](#) for details.

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 [COVID-19: Vaccine Storage and Handling Guidance](#) document.

Chapter 3: AstraZeneca COVID-19 Vaccine

Considerations For Administration

As of May 11th, 2021, Ontario has 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 in reports of a rare, serious blood clotting condition called Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) following vaccination with the AstraZeneca COVID-19 vaccine. More information on the decision can be found in the press release: [Ontario Pauses Administration of AstraZeneca Vaccine | Ontario Newsroom](#). At this time, first doses should only be given in extenuating circumstances (i.e., on the recommendation of an allergist/immunologist or another specialist where a confirmed allergy exists to components of the mRNA vaccines).

Individuals that received AstraZeneca COVID-19 vaccine for their first and second doses are recommended to receive an mRNA COVID-19 vaccine for their third dose unless contraindicated. Individuals who are unable to receive an mRNA vaccine due to contraindications may be offered a viral vector vaccine. Informed consent for an additional dose of viral vector vaccine should include discussion of potential risks with a health care provider. Informed consent for an additional dose of viral vector vaccine should include discussion about the lack of evidence on the use of an additional dose of viral vector COVID-19 vaccine in immunocompromised populations and the increased risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines (NACI, 2021).

Ontario is following [NACI recommendations](#) for completion of a series started with the AstraZeneca COVID-19 vaccine. NACI states that while either an AstraZeneca COVID-19 vaccine or an mRNA COVID-19 vaccine product may be offered for the second dose in a vaccine series started with an AstraZeneca COVID-19 vaccine, **an mRNA COVID-19 product is preferred as a second dose**, due to emerging evidence, including the possibility of better immune response, and the safety of a “mixed” (heterologous) COVID-19 vaccine schedule.

- In Ontario, viral vector COVID-19 vaccines for second doses are currently only available to individuals with a [contraindication](#) to the mRNA COVID-19 vaccines as identified by an allergist/immunologist or specialist.
- Regardless of which product is offered, a complete two-dose series is important for protection; the previous dose should be counted, and the series does not need to be restarted.

- NACI recommends that a booster dose of an mRNA COVID-19 vaccine may be offered at least 6 months after completion of a primary COVID-19 vaccine series to adults who received two doses of the AstraZeneca vaccine. For guidance on individuals that may require a third dose of a COVID-19 vaccine, please consult the [COVID-19 Vaccine Third Dose Recommendations](#).
- A supplemental document has been developed for patients who received a first dose of the AstraZeneca/COVISHIELD COVID-19 vaccine: [COVID-19 Vaccine Information for Individuals who received a first dose of the AstraZeneca/COVISHIELD COVID-19 vaccine](#). Consent for the second dose will be informed through understanding the benefits and risks of the choices, supported by discussion with a health care provider.

Contraindications

AstraZeneca COVID-19 vaccine is contraindicated in individuals who have experienced major venous and/or arterial thrombosis with thrombocytopenia following vaccination with any vaccine.

The AstraZeneca COVID-19 vaccine is contraindicated in individuals who have experienced a previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia or who have experienced heparin-induced thrombocytopenia (HIT). Individuals who think they have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should not receive the vaccine.

The above recommendations were provided by the province's Vaccine Clinical Advisory Group (VCAG).

As per [NACI](#), the AstraZeneca COVID-19 vaccine is contraindicated in individuals who have previously experienced episodes of capillary leak syndrome (CLS) ([AstraZeneca](#) COVID-19 vaccine).

Warnings & Precautions

Thrombosis (blood clots) and thrombocytopenia (low platelets) following vaccination with viral vector COVID-19 vaccines: Vaccine Induced Immune Thrombotic Thrombocytopenia (VITT)

Very rare reports of serious thrombosis (blood clots), including cerebral sinus vein thrombosis (CSVT), splanchnic vein thrombosis and arterial thrombosis, associated with thrombocytopenia (low platelets), and in some cases bleeding, have been reported following vaccination with the AstraZeneca COVID-19 vaccine ([Health Canada, AstraZeneca COVID-19 vaccine](#)).

- In Canada, the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) use case definitions of Thrombosis with Thrombocytopenia Syndrome (TTS) to describe these events, which have also been referred to as **Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)** ([NACI](#)).
- Per the product monographs ([AstraZeneca COVID-19 vaccine](#)), whilst specific risk factors for thrombosis in combination with thrombocytopenia have not been identified, cases have occurred in patients with a previous history of thrombosis, as well as in patients with autoimmune disorders, including idiopathic thrombocytopenic purpura. The benefits and risks of vaccination should be considered in these patients.
- These events often occur between 4 and 28 days after receipt of the vaccine, and patients should monitor for symptoms for up to 42 days.
 - Early identification and appropriate treatment are critical.
 - Clots related to VITT can be very aggressive and can be challenging to treat with potential associated long-term morbidity. Ontario's Science Advisory Table has provided treatment and diagnosis guidance for [Emergency Department and Inpatient Settings](#) and [Outpatient Settings](#).
 - The reported case fatality rate of VITT varies between countries, and ranges between 20 and 50% ([NACI](#)). Case fatality rates may vary with increased awareness of the adverse event and appropriate early treatment ([NACI](#)).

Currently, the reported risk of VITT after the second dose of AstraZeneca COVID-19 vaccine is lower than after the first dose. With increased observation times, VITT rates have generally increased, including the risk estimate following the second dose. Risk estimates are continually updated as new data become available.

- The rate of VITT is estimated to be between 1 per 26,000 and 1 per 100,000 persons vaccinated with a first dose of an AstraZeneca COVID-19 vaccine ([NACI](#)). The rate of VITT in Canada after a first dose has been estimated to be approximately 1 per 55,000 doses administered ([Ontario Science Advisory Table](#)).

- At this time, data from the [United Kingdom \(UK\)](#) suggests that the rate of VITT following the first dose is 15.2 per million doses and 1.9 per million following the second dose (based on doses administered as up to Nov. 3, 2021).
- Anyone receiving the AstraZeneca COVID-19 vaccine should be informed of the risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) and advised to seek immediate medical attention if they develop symptoms of VITT ([NACI](#)).
- **Symptoms to be vigilant for include:** persistent and severe headache, seizures, or focal neurological symptoms including blurred or double vision (suggesting CSVT or arterial stroke); shortness of breath, chest, back, or abdominal pain (suggesting pulmonary embolism, acute coronary syndrome, abdominal vein thrombosis, or adrenal hemorrhage); unusual bleeding, bruising, petechiae, or blood blisters (suggesting thrombocytopenia or disseminated intravascular coagulation); or limb swelling, redness, pallor, or coldness (suggesting deep vein thrombosis or acute limb ischemia) ([Ontario Science Advisory Table](#)).
- Individuals diagnosed with thrombocytopenia within 3 weeks of vaccination with the AstraZeneca COVID-19 vaccine should be actively investigated for signs of thrombosis, and similarly individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.
- Healthcare providers should maintain vigilance for thrombosis and thrombocytopenia in vaccinated individuals and report any suspected [adverse events following immunization \(AEFI\)](#) to their local public health unit (as outlined in the section on “Adverse Events Following Immunization” previously).
- Since medical management of a post-vaccine thrombosis with thrombocytopenia may be different than medical management of other thromboses, if a patient presents with thrombosis with thrombocytopenia, healthcare professionals should consult with current guidance and hematologic specialists to diagnose and treat this post-vaccine event.
- Guidance for health care providers in diagnosing and treating VITT (Vaccine-induced thrombotic thrombocytopenia), are available from Ontario’s Science Advisory Table Science Brief for healthcare professionals in [Emergency Department and Inpatient settings](#) and [Outpatient settings](#).

Capillary Leak Syndrome

Capillary leak syndrome (CLS) has been observed very rarely after vaccination with AstraZeneca COVID-19 vaccine. A history of CLS has been reported in some cases. CLS is a rare, serious condition that causes fluid leakage from small blood vessels (capillaries) and is characterized by acute episodes of limb edema, hypotension, hemoconcentration and hypoalbuminemia leading to organ damage. Symptoms are often associated with feeling faint due to low blood pressure. Patients with an acute episode of CLS following vaccination require urgent medical attention and treatment. Intensive supportive therapy is usually warranted, as the condition can be life-threatening. Individuals with a known history of CLS should not be vaccinated with this vaccine, as per [NACI](#). Please see the product monograph for [AstraZeneca COVID-19 vaccine](#) for further details.

Allergies

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).

Vaccine components include the potential allergen polysorbate 80. Polysorbate 80 is found in products such as medical preparations (such as vitamin oils, tablets, and anticancer agents) or cosmetics.

Due to potential cross-reactivity with polysorbate, allergies to polyethylene glycol (PEG) must also be considered. Allergic reactions to PEG are rare. PEG is found in products such as prescription medications, bowel preparation products for colonoscopy, over the counter products (e.g., laxatives, cough syrups), cosmetics, dermal fillers, skin care products, products such as ultrasound gel, and contact lens care solution. PEG also can be found in foods or drinks but is not known to cause allergic reactions from foods or drinks.

Any component of the COVID-19 vaccine or its container could be a potential allergen. The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for people with a latex allergy. For a full list of vaccine components, please consult the product monograph for [AstraZeneca](#) COVID-19 vaccine.

Side Effects

The AstraZeneca COVID-19 vaccine, like medicines and other vaccines can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and on average resolved within a few days. Please see the product monograph for [AstraZeneca COVID-19 vaccine](#) for a complete list of reported side effects/adverse reactions.

Very common side effects	Occur in 10% or more of vaccine recipients	<ul style="list-style-type: none"> • Pain and tenderness at the injection site • Localized redness/erythema, warmth and pruritus (common after first dose) • Fatigue • Chills (common after first dose) • Headache • Muscle pain • Nausea (common after first dose) • Joint pain
Common side effects	Occur in 1 to less than 10% of vaccine recipients	<ul style="list-style-type: none"> • Localized swelling at the injection site • Induration • Vomiting (very common/common after first dose) • Fever/ Feverishness (feverishness very common after first dose)
Uncommon side effects	Occur in 0.1% to less than 1% of vaccine recipients	<ul style="list-style-type: none"> • Enlarged lymph nodes (Lymphadenopathy)

Source: [National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.](#)

See the Warnings and Precautions section above for information about the very rare cases of VITT and CLS that have been reported following vaccination with the AstraZeneca COVID-19 vaccine. Very rare events of demyelinating disorders, such as Guillain-Barré Syndrome (GBS), have been reported following vaccination with AstraZeneca COVID-19 Vaccine during post-authorization use. See the [product monographs](#) for further details on post-market adverse reactions ([AstraZeneca COVID-19 vaccine](#) and [COVISHIELD](#) vaccine).

Vaccine Preparation

Additional information on vaccine preparation can be found in the respective product monograph for [AstraZeneca COVID-19 vaccine](#).

- AstraZeneca COVID-19 vaccine must not be reconstituted, mixed with other medicinal products, or diluted.
- The unopened multi-dose vial can be stored in a refrigerator (+2°C to +8°C).
- Do not freeze.
- Store in original packaging 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°C 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

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).

- 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 0.5 mL is withdrawn into a syringe for injection to be administered intramuscularly, preferably in the deltoid muscle. Use a separate sterile needle and syringe for each individual.
- Each vial contains at least the number of doses stated. It is normal for residual liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose.
- Care should be taken to ensure a full 0.5 mL dose is observed.
 - 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 that proper sized syringes are chosen to ensure the correct volume is accurately drawn up
- Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.
- Visually inspect each dose in the dosing syringe prior to administration.

AstraZeneca COVID-19 vaccine
clear to slightly opaque, colourless to slightly brown, sterile, particle free, 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.
- Any non-viable/unused vaccine or waste material should be disposed of in accordance with local requirements. See Appendix G of the [COVID-19: Vaccine Storage and Handling Guidance](#) for details.

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 [COVID-19: Vaccine Storage and Handling Guidance](#) document.

Chapter 4: Janssen (Johnson & Johnson) COVID-19 Vaccine

Considerations for Administration

The Janssen COVID-19 vaccine is contraindicated in individuals who have experienced major venous and/or arterial thrombosis with thrombocytopenia following vaccination with any vaccine. Individuals with a history of capillary leak syndrome should not receive the Janssen COVID-19 vaccine, as per [NACI](#).

The Janssen COVID-19 vaccine is contraindicated in individuals who have experienced a previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia or who have experienced heparin-induced thrombocytopenia (HIT). Individuals who think they have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should not receive the vaccine. This recommendation comes from the province's Vaccine Clinical Advisory Group (VCAG) and [NACI](#).

Warnings & Precautions

As per [NACI](#), anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risks associated with viral vector vaccines including Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines (NACI, 2021) and be advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.

Rare cases of serious thrombosis (blood clots) and thrombocytopenia (low platelets): VITT (Vaccine-Induced Immune Thrombotic Thrombocytopenia)

A combination of thrombosis and thrombocytopenia (TTS), in some cases accompanied by bleeding, that resembles HIT (heparin-induced thrombocytopenia) have been observed very rarely following vaccination with Janssen COVID-19 Vaccine. This includes severe cases at unusual sites such as cerebral venous sinus thrombosis (CSVT) and splanchnic vein thrombosis, as well as arterial thrombosis, with thrombocytopenia.

- [Health Canada](#) has assessed the available data on the reported events and has determined that the benefits of the Janssen COVID-19 vaccine outweigh the risks of thrombosis and thrombocytopenia.
 - Following an evidence review and a risk-benefit analysis, NACI has provided specific [guidance for the use of Janssen COVID-19 vaccine](#).
 - Vaccine regulators in Canada and internationally will continue to closely monitor the safety of all COVID-19 vaccines.
- Healthcare providers administering the Janssen COVID-19 vaccine should inform clients to seek immediate medical attention for symptoms of thromboembolism and/or early signs of thrombocytopenia. Per [Health Canada](#) the majority of cases occurred within 3 weeks following vaccination, some cases had a fatal outcome, and no specific risk factors have been identified at this time.
- **Symptoms to monitor for include:** shortness of breath, chest pain, leg swelling or pain, persistent abdominal pain, skin bruising (other than at the site of vaccination) or petechiae (red or purple spots or blood blisters under skin); and neurological symptoms such as sudden onset of severe headaches, persistent or worsening headaches, blurred vision, double vision, confusion or seizures, difficulty speaking or moving a part of the body particularly those persisting or occurring approximately 4 days to 3-4 weeks after vaccination. ([Product Monograph](#), [Health Canada](#), [NACI](#), [Ontario Science Advisory Table](#))
- Healthcare providers should maintain vigilance for thrombosis and thrombocytopenia in vaccinated individuals and report any suspected [adverse events following immunization \(AEFI\)](#) to their local public health unit (as outlined in the section on “Adverse Events Following Immunization” previously).

Guidance for health care providers in diagnosing and treating VITT (Vaccine-induced thrombotic thrombocytopenia), previously named VIPIT (Vaccine-induced prothrombotic induced thrombocytopenia) are available from Ontario's Science Advisory Table Science Brief for both [Emergency Department/inpatient settings](#) as well as [outpatient settings](#)

Capillary leak syndrome (CLS)

A small number of reports of CLS have been reported following vaccination. CLS is a very rare, serious condition that causes fluid leakage from small blood vessels (capillaries), resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood and low blood levels of albumin (an important blood protein).

As of 21 June 2021, 3 cases of CLS in people who had received Janssen COVID-19 Vaccine had been reviewed by the EMA-PRAC among more than 18 million doses of Janssen COVID-19 Vaccine administered worldwide. One of those affected had a history of CLS and two subsequently died.

Individuals with a history of CLS should not be vaccinated with the AstraZeneca or Janssen COVID-19 vaccine.

Guillain-Barré syndrome (GBS)

There have been a small number of reports of people developing GBS after receiving a COVID-19 viral vector vaccine. GBS is a rare but potentially serious immune-mediated neurologic disorder that results in pain or numbness, muscle weakness, and paralysis in severe cases. Most people fully recover from GBS but some have residual deficits or symptoms and rarely, fatal cases can occur.

As of September 15, 2021, there were 201 preliminary cases of GBS reported in the US Vaccine Adverse Events Reporting System (VAERS) among more than 14.7 million doses of the Janssen vaccine administered (estimated rate of 1.37 cases per 100,000 doses).

In the US, reports of adverse events suggest an increased risk of GBS during the 42 days following vaccination with the Janssen COVID-19 vaccine.

See Side Effects section below for more information.

- Refer to [Vaccination Recommendations for Special Populations](#) for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

For more detailed recommendations on people with allergies, as well as breastfeeding or pregnant individuals, those with autoimmune conditions, or individuals who are immunocompromised due to disease or treatment, please consult the [Vaccination Recommendations for Special Populations](#) guidance document.

Allergies

Refer to [Vaccination Recommendations for Special Populations](#) for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Any component of the COVID-19 vaccine or its container could be a potential allergen. The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for people with a latex allergy. For a full list of vaccine components, please consult the [product monograph](#).

A component of the Janssen vaccine that may cause type 1 hypersensitivity reactions is polysorbate 80. Due to potential cross-reactivity, allergies to polyethylene glycol (PEG) must also be considered. Allergic reactions to Polysorbate 80 are rare. Polysorbate 80 is found in products such as medical preparations (e.g., vitamin oils, tablets, and anticancer agents) or cosmetics

Allergic reactions to PEG are rare. PEG is found in products such as prescription medications, bowel preparation products for colonoscopy, over the counter products (e.g., laxatives, cough syrups), cosmetics, dermal fillers, skin care products, products such as ultrasound gel, and contact lens care solution. PEG also can be found in foods or drinks but is not known to cause allergic reactions from foods or drinks.

Side effects

The Janssen COVID-19 vaccines, like medicines and other vaccines can cause side effects. 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 [Janssen COVID-19 vaccine](#) for a complete list of reported side effects/ adverse reactions.

Very common side effects	May affect more than 1 in 10 people	<ul style="list-style-type: none"> • Headache • Nausea • Muscle pain • Pain at injection site • Fatigue • Nausea and/or vomiting (after first dose)
Common	May affect 1 to less than 10 in 100 people	<ul style="list-style-type: none"> • Fever • Localized redness/swelling at injection site

Source: [National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials](#).

See the Warnings and Precautions section above for information about the very rare cases of VITT and CLS that have been reported following vaccination with the Janssen COVID-19 vaccine. Very rare events of demyelinating disorders, such as Guillain-Barré Syndrome (GBS), have been reported following vaccination with Janssen COVID-19 Vaccine during post-authorization use.

Point-of-care Guidance

- This is a single dose vaccine; maximum protection will be attained only after 2 weeks following administration of the vaccine.
- Do not mix the Janssen COVID-19 vaccine with other vaccines/products in the same syringe.
- See the [COVID-19 Vaccine Third Dose Guidance](#) for considerations on booster doses.

Vaccine Preparation & Administration

Additional information on vaccine preparation, including information on packaging types and expiry dates can be found in the [product monograph for Janssen COVID-19 vaccine](#).

- The Janssen COVID-19 vaccine must not be reconstituted, mixed with other medicinal products, or diluted.
- Janssen COVID-19 vaccine is a colourless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection.
 - The vaccine should be inspected visually for particulate matter and discoloration prior to administration.
 - The vial should be inspected visually for cracks or any abnormalities, such as evidence of tampering prior to administration.
 - **If the visual inspection fails, do not administer the vaccine.**
- Before administering a dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. **Do not shake.**
- Use a sterile needle and sterile syringe to extract a single dose of 0.5 mL from the multi-dose vial and administer by intramuscular injection only.
 - The preferred site is the deltoid muscle of the upper arm.
 - It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up.
 - Refer to the [Canadian Immunization guide](#) for assistance in selecting appropriate needle length and gauge

- Safety engineered needles must be used as required under O. Reg 474/07 made under the *Occupational Health and Safety Act*.
- Do not administer this vaccine intravenously or subcutaneously.
- 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.
 - Discard any remaining vaccine in the multi-dose vial after 5 doses have been extracted.
 - Where a full dose cannot be extracted, the remaining volume should be discarded.
- Visually inspect each dose in the dosing syringe prior to administration.
 - 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.**
- Strict adherence to aseptic techniques must be followed.
- After the first puncturing of the vial, the vial/filled syringe can be held at 2°C to 8°C for up to 6 hours or at room temperature (maximally 25°C) for up to 3 hours. Discard if vaccine is not used within this time.

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 [Janssen COVID-19 Vaccine Product Monograph](#)

Chapter 5: Pediatric Pfizer-BioNTech COVID-19 Vaccine (orange cap)

Considerations for Administration

As a precautionary measure, [NACI](#) has recommended that individuals who have experienced myocarditis or pericarditis following vaccination with a first dose of an mRNA COVID-19 vaccine defer their second dose in the vaccination series until more information is available. The National Advisory Committee on Immunization, Public Health Ontario and The Ministry of Health continue to follow this closely and will update this recommendation as more evidence becomes available. See Warnings and Precautions below for more details.

For children with a previous history of MIS-C unrelated to any previous COVID-19 vaccination, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.

Children 5 to 11 years (or turning 5 in 2021) of age should receive the 10 mcg dose of the Pfizer-BioNTech vaccine, whereas adolescents 12 years of age and older should continue to receive the 30 mcg dose of the Pfizer-BioNTech vaccine.

Children who receive the 10 mcg Pfizer-BioNTech COVID-19 vaccine for their first dose and who have turned 12 years of age by the time the second dose is due may receive the 30 mcg Pfizer-BioNTech COVID-19 vaccine that is authorized for individuals ages 12 and older to complete their primary series. If the second dose of 10 mcg is given, the dose should still be considered valid and the series complete.

Children who are 11 years of age and received the 30 mcg dose of the Pfizer-BioNTech vaccine as their first dose under Ontario's extended eligibility (2009 birth year) are recommended to complete the vaccine series with the product authorized for their age at the time of the second dose (i.e. 10 mcg if 11 years, 30 mcg if 12 years). If the dose given for the second dose differs from that authorized for age, among children who are aged 11 and 12 years, the dose should still be considered valid and the series complete.

Unlike adolescent and adult populations, COVID-19 vaccines for children 5-11 years old should not routinely be given concomitantly (i.e. same day) with other vaccines (live or inactivated) at this time ([NACI](#)). In the absence of evidence, it would be prudent to wait for a period of at least 14 days BEFORE or AFTER the administration of another vaccine before administering a COVID-19 vaccine to prevent erroneous attribution of an AEFI to one particular vaccine or the other. However, this

suggested minimum waiting period between vaccines is precautionary and therefore concomitant administration or a shortened interval between COVID-19 vaccines and other vaccines may be warranted on an individual basis in some circumstances. These circumstances may include:

- when there is a risk of the individual being unable to complete an immunization series due to limited access to health services or being unlikely to return at a later date;
- when an individual may not return to receive a seasonal influenza vaccine;
- when another vaccine is required for post-exposure prophylaxis;
- when individuals require accelerated vaccination schedules prior to immunosuppressive therapy or transplant; and
- at the clinical discretion of the healthcare provider

Warnings & Precautions

Myocarditis and Pericarditis

Rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) have been reported following vaccination with mRNA COVID-19 vaccines in Canada and internationally among individuals aged 12 years and older who received the 30mcg formulation of the Pfizer-BioNTech COVID-19 vaccine or 100mcg formulation of the Moderna Spikevax COVID-19 vaccine.

Symptoms of myocarditis/pericarditis can include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. Symptoms can be accompanied by abnormal test results (e.g., electrocardiogram, serum troponins, echocardiogram). Available data indicate that the majority of individuals affected have responded well to conservative therapy and tend to recover quickly.

Cases of myocarditis/pericarditis following COVID-19 mRNA vaccination occur more commonly in adolescents and young adults (12 to 30 years of age), more often after the second dose, more often in males than females, and usually within a week of vaccination. Emerging Canadian safety surveillance data suggest an extended interval between first and second dose of an mRNA COVID-19 vaccine may reduce the risk of myocarditis/pericarditis. [Data from the US](#) suggests the risk of myocarditis/pericarditis may be higher in older adolescents ages 16-17 compared to younger adolescents ages 12-15.

Classic myocarditis (pre-COVID-19) tends to have a similar epidemiologic profile to myocarditis following mRNA COVID-19 vaccines as it occurs more commonly in adolescents and young adult males. Classic myocarditis is less common in younger children in the 5 to 11 year age range. It is unknown if and/or to what extent myocarditis/pericarditis will occur after lower doses of mRNA vaccinations in 5 to 11 year old children. Myocarditis can also occur as a complication of SARS-CoV-2 infection, including [very rarely] in children.

- Anyone receiving an authorized mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop symptoms including chest pain, shortness of breath, palpitations (pounding or heart racing), or feeling of rapid or abnormal heart rhythm ([NACI](#)).
- As a precautionary measure, [NACI](#) has recommended that individuals who have experienced myocarditis or pericarditis following vaccination with a first dose of an mRNA COVID-19 vaccine defer their second dose in the vaccination series until more information is available. Children who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If they are no longer followed clinically for cardiac issues, they may receive the vaccine. [NACI](#), Public Health Ontario and the Ministry of Health Ontario will continue to monitor the evidence and update recommendations as needed.

Very rare cases of MIS-C/A have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals ages 12 years and older. However, on October 29, 2021, the European Medical Association Pharmacovigilance Risk Assessment Committee (EMA-PRAC) issued a statement that there is currently insufficient evidence on a possible link between mRNA COVID-19 vaccines and very rare cases of MIS-C/A.

NACI continues to strongly recommend that a complete series with an mRNA COVID-19 vaccines be offered to all eligible individuals in Canada, including those 5 years of age and older. Vaccines are safe, effective and continue to be the best way to protect young adults, their families and our community from COVID-19.

The benefits of vaccination with COVID-19 vaccines continue to outweigh the risks of COVID-19 illness and related, possibly severe consequences for all age groups.

mRNA COVID-19 vaccines also continue to be recommended internationally. This situation is being monitored closely in Canada and internationally.

- For more information consult Public Health Ontario's [Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines](#) resource.

- [Interim clinical guidance and an algorithm](#) for the identification and management of myocarditis and pericarditis following mRNA COVID-19 vaccination in children is available from the Hospital for Sick Children.
- A clinical framework is also available from the Canadian Journal of Cardiology [Myocarditis and Pericarditis following COVID-19 mRNA Vaccination: Practice Considerations for Care Providers](#)

Precautions During Vaccination Should Be Taken For:

Allergies

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).

Vaccine components include the potential allergen of **polysorbate 80** and/or **tromethamine (trometamol or Tris)**. However, these ingredients rarely cause allergic reactions. Polysorbate 80 is found in medical preparations (such as vitamin oils, tablets, and anticancer agents) and cosmetics. Tromethamine (trometamol or Tris) is a component in contrast media, oral and injectable medications. Due to potential cross-reactivity with polysorbate, Polyethylene Glycol (PEG) allergies must also be considered. Allergic reactions to polysorbates are rare. Allergic reactions to PEG are rare. PEG is found in products such as prescription medications, bowel preparation products for colonoscopy, over-the-counter products (e.g. laxatives, cough syrups), cosmetics, dermal fillers, skin care products, products such as ultrasound gel, and contact lens care solution. PEG also can be found in foods or drinks but is not known to cause allergic reactions from foods or drinks.

Any component of the COVID-19 vaccine or its container could be a potential allergen. The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for people with a latex allergy. For a full list of vaccine components, please consult the [product monograph](#).

People who experienced a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine may receive future doses of the same or another mRNA COVID-19 vaccine after consulting with an allergist/immunologist or another appropriate physician. See [NACI's recommendations on the use of COVID-19 vaccines](#) for more information.

Side effects

The pediatric Pfizer-BioNTech COVID-19 vaccine, like medicines and other vaccines, may cause side effects. In clinical trials, most of the side effects experienced were mild to moderate, and usually resolved within a few days. Please see the [product monograph](#) for a complete list of reported side effects.

Very common side effects	May affect more than 1 in 10 people	<ul style="list-style-type: none"> • Pain, swelling and redness at injection site • Fatigue • Headache • Muscle pain
Common	May affect 1 to less than 10 in 100 people	<ul style="list-style-type: none"> • Chills • Fever • Vomiting • Diarrhea • Joint pain

Source: [National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.](#)

See the Warnings and Precautions section above for information about the rare cases of myocarditis and pericarditis that have been reported following vaccination in individuals 12 years and older with mRNA COVID-19 vaccines. See the [product monograph](#) for further details on post-market adverse reactions.

Vaccine Preparation & Administration

Detailed information on vaccine preparation and transport can be found in the [product monograph](#) and the [COVID-19: Vaccine Storage and Handling Guidance](#).

- The Pfizer-BioNTech COVID-19 vaccine multiple dose vial contains a frozen suspension that does not contain preservative and **must be thawed and diluted prior to administration**. See the Preparation for Immunization Clinics section of the [COVID-19: Vaccine Storage and Handling Guidance](#) and [product monograph](#) for detailed thawing instructions

Vial Verification

Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an orange plastic cap and a label with an orange border and states “Age 5y to < 12y.”

Thawing Prior to Dilution

Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:

- Allowing vial(s) to thaw in the refrigerator (2°C to 8°C). A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.
- Allowing vial(s) to sit at room temperature [up to 25°C] for 30 minutes.
- Vials may be stored at room temperature [up to 25°C] for 12 hours prior to use.

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial with an orange cap and a label with an orange border contains a volume of 1.3 mL and is supplied as a frozen suspension that does not contain preservative.
- Each vial must be thawed before dilution.
- Vials may be thawed in the refrigerator (2°C to 8°C) or at room temperature up to 25°C.
- Before dilution, mix by inverting vaccine vial gently 10 times.
- **Do not shake.**
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

Dilution

- Each vial **MUST BE DILUTED** before administering the vaccine
- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use **ONLY** sterile 0.9% Sodium Chloride Injection, USP as the diluent. **Do not use bacteriostatic 0.9% Sodium Chloride injection or any other diluent.**
- Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.
- Do not add more than 1.3 mL of diluent
- Before removing the needle from the vial, withdraw 1.3 mL air into the empty diluent syringe to equalize vial pressure .
- After dilution, 1 vial contains 10 doses of 0.2 mL.
- Gently invert the vial containing the PfizerBioNTech COVID-19 Vaccine 10 times to mix.

- **Do not shake.**
- To minimize the risk of contamination never use the same diluent vial more than once. Make sure to discard any remaining saline in the diluent vial in a sharps container ([Pfizer-BioNTech COVID-19 Vaccine Resources](#)). In Ontario Pfizer-BioNTech vaccine is shipped with a diluent to vaccine ratio that supports single use of diluent.
- Inspect the vaccine in the vial.
- The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
- Record the time and date of first vial puncture on the vial label.
- Store between 2°C to 25°C.
- Discard any unused vaccine 12 hours after dilution.
- During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
- Thawed and diluted vials can be handled in room light conditions.

Withdrawal of Individual 0.2 mL Doses

- The vaccine is authorized as a 10-dose vial.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw **0.2mL** of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.2 mL of vaccine.
- For guidance on what to do when there is leftover solution in the vial or if more than 10 doses can be obtained from a vial, please see the [COVID-19: Vaccine Storage and Handling Guidance](#) document
- Administer immediately.

Administration

- It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up.
- Refer to the [Canadian Immunization Guide, Table 3: Needle selection guidelines](#) for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.
- Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension.
- During the visual inspection:
 - verify the final dosing volume of **0.2 mL**, and

- there are no particulates and that no discoloration is observed.
- **Do not administer if vaccine is discolored or contains particulate matter.**
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw each 0.2 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection. Pierce the stopper preferably at a different site each time.
- Administer Pfizer-BioNTech COVID-19 vaccine immediately, and no later than 12 hours after dilution
- Administer Pfizer-BioNTech COVID-19 vaccine intramuscularly in the deltoid muscle.
 - Do not inject the vaccine intravascularly, subcutaneously or intradermally.
- Any non-viable/unused vaccine or waste material should be disposed of in accordance with local requirements. See Appendix G of the [COVID-19: Vaccine Storage and Handling Guidance](#) for details.

Vaccination Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of 2 doses (0.2 mL each). The second dose should be given at a recommended dose interval of 8 weeks for mRNA vaccines, as recommended by [NACI](#). There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness (NACI).

Additional information on vaccine preparation, including information on packaging types and expiry dates can be found in the product monograph for [Pediatric Pfizer-BioNTech COVID-19 vaccine](#).

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 [COVID-19: Vaccine Storage and Handling Guidance](#)

Appendix A: 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). All clinic staff and management must also ensure they are working in accordance with the [*Occupational Health and Safety Act*](#) and its regulations.