

Ministry of Health

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Nurses (RN/RPN) – Province Wide - COVID-19 mRNA Vaccination Order

Brief Description of the Procedure:

This order is made under section 5(1)(b) of the *Nursing Act, 1991*.

A Registered Nurse (RN) or Registered Practical Nurse (RPN) may initiate a COVID-19 mRNA Vaccination of vaccine recipients for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus (the “Procedure”) on the terms and conditions set out in this order.

Authorization:

The RN/RPN may initiate the Procedure:

- (a) In respect of only those persons described by the provincial criteria for screening and prioritization for vaccination as identified by the Ontario Ministry of Health.
- (b) In accordance with all procedures and processes of the applicable public hospital, long-term care home or public health unit on whose behalf the RN/RPN is conducting the Procedure.
- (c) If the RN/RPN is knowledgeable regarding the manner for obtaining consent for the Procedure, completes any reporting, data collection and documentation requirements (including those set out below), and is knowledgeable about the management of anaphylaxis events in respect of the Procedure, including being familiar with where an emergency and anaphylaxis kit is kept.

(d) If the RN/RPN has reviewed this document and has self-assessed to have the appropriate knowledge, skill and judgement to conduct the Procedure, including having completed any required education.

(e) In accordance with the **Medications Table** attached.

Documentation:

Documentation of the implementation of the order and the fact that consent for vaccination was obtained must be recorded in the provincial documentation and registration system.

Documentation must include the name of the order, date of implementation and name and electronic signature including credentials of the implementer.

Ordering Physician:

Name: _____

Title: **Chief Medical Officer of Health**

Date: **February 5, 2021**

Medications Table

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
tozinameran	<p>Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine)</p> <p>Route: intramuscularly (IM)</p> <p>Site: deltoid muscle.</p> <p>Dose: 0.3 mL after reconstitution</p> <p>Number of Doses: 2</p> <p>Schedule:</p> <ul style="list-style-type: none"> • Minimum interval: 19 days <p>Recommended interval: 21-28 days (must be given before 42 days)</p>	<p>The following applies for both the first and second dose administrations.</p> <p>Vaccine Recipients presenting to be vaccinated and meeting the criteria of the targeted vaccination group must:</p> <ul style="list-style-type: none"> • Pass the COVID-19 Screening Criteria • Be 16 years of age and older <p>AND</p> <ul style="list-style-type: none"> • Provide Informed Consent <p>AND</p>	<p>Do not administer the vaccine if:</p> <ul style="list-style-type: none"> • Particulates or discoloration are present upon visual inspection of the vial <p>Do not administer the vaccine if the Vaccine Recipient has any of the following:</p> <ul style="list-style-type: none"> • Administration of another vaccine in the last 14 days • Severe allergic reaction to a previous dose of an mRNA vaccine, to the active substance or to any of the following excipients: <ul style="list-style-type: none"> - ALC-0315 = (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diy)bis(2-hexyldecanoate 	<p>Individuals with the following conditions, or receiving the following therapies, may be directed to consult with their health care provider who is most familiar with their medical history prior to vaccination:</p> <ul style="list-style-type: none"> • Autoimmune disease, immunocompromised or receiving immunosuppressant therapy • Pregnant

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
tozinameran (cont.)	<p>Reconstitution of thawed suspension with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP using a 21 gauge or narrower needle using aseptic technique.</p> <p>The diluted product must be used within 6 hours of being reconstituted.</p>	<ul style="list-style-type: none"> Indicate no contraindications based on the list of known contraindications during the consent process for vaccination 	<ul style="list-style-type: none"> ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide 1,2-distearoyl-sn-glycero-3-phosphocholine Cholesterol Dibasic sodium phosphate dihydrate Monobasic potassium phosphate Potassium chloride Sodium chloride Sucrose Temperature of greater than or equal to 38 degrees Celsius 	<p>For individuals who have a bleeding disorder, bruise easily or use a blood-thinning medication, IM administration may be safer when given with a small gauge needle (23 gauge or smaller) and when firm pressure is applied to the injection site for 5 to 10 minutes.</p>

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
mRNA-1273 SARS-CoV-2	<p>Moderna COVID-19 Vaccine</p> <p>Route: IM</p> <p>Site: deltoid muscle.</p> <p>Dose: 0.5 mL</p> <p>Number of Doses: 2</p> <p>Schedule:</p> <ul style="list-style-type: none"> • Minimum interval: 21 days • Recommended interval: 28 days <p>Intact vials can remain at room temperature for up to 12 hours. After puncture they must be discarded after 6 hours.</p>	<p>The following applies for both the first and second dose administrations.</p> <p>Vaccine Recipients presenting to be vaccinated and meeting the criteria of the targeted vaccination group must:</p> <ul style="list-style-type: none"> • Pass the COVID-19 Screening Criteria • Be 18 years of age and older <p>AND</p> <ul style="list-style-type: none"> • Provide Informed Consent <p>AND</p>	<p>Do not administer the vaccine if:</p> <ul style="list-style-type: none"> • Particulates or discoloration are present upon visual inspection of the vial <p>Do not administer the vaccine if the Vaccine Recipient has any of the following:</p> <ul style="list-style-type: none"> • Administration of another vaccine in the last 14 days • Severe allergic reaction to a previous dose of an mRNA vaccine, to the active substance or to any of the following excipients: <ul style="list-style-type: none"> - 1, 2-distearoyl-sn-glycero-3-phosphocholine (DSPC) - Acetic acid - Cholesterol - Lipid SM-102 	<p>Individuals with the following conditions, or receiving the following therapies, may be directed to consult with their health care provider who is most familiar with their medical history prior to vaccination:</p> <ul style="list-style-type: none"> • Autoimmune disease, immunocompromised or receiving immunosuppressant therapy • Pregnant

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
mRNA-1273 SARS-CoV-2 (cont.)	Once a dose is withdrawn from the vial, it should be administered immediately.	<ul style="list-style-type: none"> • Indicate no contraindications based on the list of known contraindications during the consent process for vaccination 	<ul style="list-style-type: none"> - PEG2000 DMG 1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol - Sodium acetate - Sucrose Tromethamine - Tromethamine hydrochloride • Temperature of greater than or equal to 38 degrees Celsius 	For individuals who have a bleeding disorder, bruise easily or use a blood-thinning medication IM administration may be safer when given with a small gauge needle (23 gauge or smaller) and when firm pressure is applied to the injection site for 5 to 10 minutes.

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
Alpha and beta-adrenergic agonist	<p>Epinephrine HCL 1:1,000 (1 mg/mL) IM STAT.</p> <p>Route: IM</p> <p>Site: mid-anterolateral thigh</p> <p>Dose: In individuals older than 12 years: 0.5 mL</p> <p>Dose may be repeated twice, administered 3 to 5 minutes apart</p>	<p>Vaccine Recipient observed or indicates Anaphylaxis or acute hypersensitivity reaction to administration of vaccine</p>		<ul style="list-style-type: none"> • Epinephrine dosing may be repeated twice, administered 3 to 5 minutes apart • Call for assistance as per the clinic's escalation protocol including calling 911 • Transfer patient to an Emergency Department immediately

Drug	Name & Dosage Range	Indications	Absolute Contraindications	Special Considerations
Antihistamines	{RUPALL} rupatadine 10 mg PO {CLARITIN} loratadine 10 mg PO {BEXTEN} bilastine 20 mg PO	Vaccine Recipient observed or reporting hives	Do not administer if Vaccine Recipient has: <ul style="list-style-type: none"> • A history of hypersensitivity to {RUPALL} rupatadine and/or {CLARITIN} loratadine and/or {BEXTEN} bilastine * Avoid use in persons with history of QT prolongation and/or torsade de pointes, including congenital long QT syndromes, history of cardiac arrhythmias or use of other QTc-prolonging drugs *Avoid use of rupatadine with known CYP3A4 inhibitors e.g., ketoconazole or erythromycin	May cause somnolence, impaired physical or mental abilities. Use in caution when performing tasks that require mental alertness.

Required Education:

The RN/RPN will complete any required education and will be evaluated by a clinical supervisor to ensure competency.

Implementation:

Pfizer-BioNTech:

- 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.
- Vials may be thawed in the refrigerator (2 degrees Celsius to 8 degrees Celsius) or at room temperature (up to 25 degrees Celsius)
- Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.
- The contents of the vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP to form the Pfizer-BioNTech COVID-19 Vaccine.
- After dilution, the vial contains 5 doses of 0.3 mL.
- After dilution, the vaccine will be an off-white suspension. Inspect vials to confirm there are no particulates and no discoloration is observed.
- Strict adherence to aseptic techniques must be followed.
- Never shake the vaccine vial
- Vaccine vials must be used within 6 hours of dilution and stored at a temperature between 2 degrees Celsius and 25 degrees Celsius.
- Do not mix Pfizer-BioNTech COVID-19 Vaccine with other vaccines or products in the same syringe.
- Individuals who have received one dose of the Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of the Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Moderna COVID-19 Vaccine:

- Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates.

- Inspect Moderna COVID-19 Vaccine vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Never shake the vaccine vial.
- Moderna COVID-19 Vaccine is preservative free. Once a dose is withdrawn from the vial, it should be administered immediately.
- Once the vial has been entered (needle-punctured), it should be discarded after 6 hours.
- Do not mix Moderna COVID-19 Vaccine with other vaccines or products in the same syringe.
- Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

For both vaccines:

- Individuals may not be protected until at least 7 days after their second dose of the vaccine.
- Adverse reactions from clinical studies include but may not be limited to:

Arthralgia, myalgia	Very common
Headache	Very common
Injection site pain, fatigue, chills, pyrexia	Very common
Redness at injection site, injection site swelling	Common
Nausea	Common
Malaise	Uncommon
Lymphadenopathy	Uncommon
Anaphylaxis	Rare