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- Refer to SIM, Chapter 5, *Immunization Schedules,* Section 2.1, *Minimum Intervals for Specific Vaccine Series*.
- Product monographs are available in Health Canada's Drug Product Database.
- For post-exposure immunoprophylaxis, refer to the Saskatchewan Communicable Disease Control manual.

1.0 ACTIVE IMMUNIZING AGENTS

- **Herpes Zoster Vaccine**
  - Shingrix™ **(RZV)**
- **Human Papillomavirus Vaccine**
  - CERVARIX™ **(HPV-2**)
  - GARDASIL®9 **(HPV-9)**
- **Influenza Vaccine** (Non Publicly Funded)
  - FLUAD Pediatric and FLUAD
  - FLUMIST QUADRIVALENT
  - SUPEMTAK
- **Influenza Vaccine**
  - AFLURIA TETRA
  - FLULAVAL TETRA
  - FLUZONE® QUADRIVALENT
  - FLUZONE® HIGH DOSE QUADRIVALENT
- **Japanese Encephalitis Vaccine (JE)**
  - IXIARO™
- **Measles-Mumps-Rubella Vaccine (MMR)**
  - MMRII™
  - PRIORIX™
- **Measles-Mumps-Rubella-Varicella Vaccine (MMRV)**
  - PRIORIX-Tetra™
  - ProQuad™
- **Meningococcal Conjugate C Vaccine** (**Men-C-C**)
  - MENJUGATE™ Liquid
  - Neis Vac-C®
- **Meningococcal Conjugate ACYW-135 Vaccine** (**Men-C-ACYW-135**)
  - Menactra®
  - MenQuadfi™
  - Menveo™
  - NIMENRIX™
- **Multicomponent Meningococcal B Vaccine**
  - BEXSERO® **(MenB 4C)**
  - Trumenba™ **(MenB bivalent)**
- **Pneumococcal Conjugate Vaccine**
  - SYNFLORIX™ **(Pneu-C-10)**
  - Prevnar® 13® **(Pneu-C-13)**
  - VAXNEUVANCE® **(Pneu-C-15)**
  - PREVNAR 20 ™ **(Pneu-C-20)**
  - Age-based Risk Factor Eligibility for Pneu-C-20 Immunization (as noted in Panorama)
  - Pneu-C-20 Immunization Flow Chart for Individuals Through 64 Years of Age
  - Pneu-C-20 Immunization Flow Chart for Individuals 65 Years and Older
  - CAPVAXIVE® **(Pneu-C-21)**
- **Pneumococcal Polysaccharide Vaccine (Pneu-P-23**)
  - PNEUMOVAX® 23
- **Poliomyelitis Vaccine (Inactivated) (IPV)**
  - IMOVAX® Polio

- **Rabies Vaccine (Rab) (Post-exposure prophylaxis)**
  - IMOVAX® Rabies
  - RabAvert®
- **Respiratory Syncytial Virus Vaccine (RSV)**
  - ABRYSVO
  - AREXVY
  - mRESVIA
- **Rotavirus Vaccine**
  - Rotarix™ **(Rot-1)**
  - RotaTeq® **(Rot-5)**
- **Smallpox and Mpox Vaccine (SMV)**
  - IMVAMUNE
- **Tetanus-Diphtheria Vaccine (Td)**
  - Td Adsorbed™
- **Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)**
  - ADACEL®
  - BOOSTRIX™
- **Tetanus-Diphtheria-acellular Pertussis-Inactivated Poliomyelitis Vaccine (Tdap-IPV)**
  - ADACEL®-Polio
  - BOOSTRIX®-Polio™
- **Typhoid Vaccine (Typh-I) (Salmonella Typhi Vi Capsular Polysaccharide)**
  - Typhim Vi®
- **Typhoid Vaccine (Typh-O) (Live Oral Attenuated Ty 21a)**
  - Vivotif®
- **Varicella Vaccine (Var)**
  - VARILRIX®
  - Varivax III™
- **Yellow Fever Vaccine (YF)**
  - YF-Vax™

2.0 DIAGNOSTIC, PASSIVE IMMUNIZING AND ANTITOXIN AGENTS

- **Purified (tuberculosis) Protein Derivative (PPD) (Mantoux)**
  - Tubersol®
- **Botulism Immune Globulin**
  - BabyBIG
- **Hepatitis B Immune Globulin (HBIg)**
  - HepaGam B ™
  - HyperHEP B™
- **Immune Globulin (Ig - Intramuscular)**
  - GamaSTAN™
- **Rabies Immune Globulin (RabIg)**
  - HYPERRAB™
  - KamRAB™
- **Tetanus Immune Globulin (TIg)**
  - HYPERTET™

- **Varicella zoster Immune Globulin (VarIg)**
  - VariZIG™
- **Botulism Antitoxin (BAT)**
  - Botulism Antitoxin
- **Diphtheria Antitoxin (DAT)**
  - Diphtheria Antitoxin

THIS CHAPTER MEETS THE FOLLOWING IMMUNIZATION COMPETENCIES FOR HEALTH PROFESSIONALS (PHAC, 2008): http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf

#4: The Types of Immunizing Agents and Their Composition

- Competency: Applies the knowledge of the components and properties of immunizing agents as needed for safe and effective practice.

#8: Administration of Immunizing Agents

- Competency: Prepares and administers immunization agents correctly.

#11: Populations Requiring Special Considerations

- **Competency**: Recognizes and responds to the unique immunization needs of certain population groups

Chikungunya

[Non-publicly funded]

IXCHIQ

Product monograph: https://valneva.com/products/

Cholera (Chol-O)
[Non-publicly funded]

VAXCHORA®
Product monograph.

Cholera - E. coli (Chol-Ecol-O)

[Non-publicly funded]

DUKORAL®

(Product monograph available at https://valneva.com/products/valnevas-products/)

2024-25 COVID-19 Vaccine Q &A for Immunizers

1) **How many COVID-19 vaccine doses are recommended for immune competent or immunocompromised individuals?**
   Response: Refer to the 2024-25 COVID-19 Immunization Schedules for current recommendations.
2) **For previously immunized clients, what is the minimum interval recommended between their last COVID-19 vaccine dose before getting a 2024-25 COVID-19 vaccine dose?**
   Response:
   A. Refer to the 2024-25 COVID-19 Immunization Schedules for current recommendations.
   B. Long-term care facility, personal care home, or senior congregate living (i.e., assisted living facility) residents **can be** immunized less than 8 weeks after their last COVID-19 vaccine dose.
3) **Should previously immunized individuals wait before getting a COVID-19 vaccine dose after recovering from a COVID-19 infection?**
   Response:
   A. Previously immunized individuals with any immune competency status **may consider** delaying COVID-19 immunization by 3 months from recent symptom onset or positive test. They may be immunized sooner (i.e., feeling better) if they choose.
   B. Long-term care facility, personal care home, or senior congregate living (i.e., assisted living facility) residents **can be** immunized less than 3 months after infection.
4) **What are the recommended intervals between doses if an individual has a COVID-19 infection while receiving a primary series?**
   Response:
   A. At least 8 weeks following illness for non-immunocompromised individuals.
   B. At least 4 to 8 weeks following illness for moderately to severely immunocompromised individuals.
5) **Is there a preferred COVID-19 vaccine brand to be offered to immunocompromised or immune competent individuals of any age?**
   Response: No.
6) **What are the recommended COVID-19 vaccine dosages and schedules for children?**
   Response: Refer to the 2024-25 COVID-19 Immunization Schedules.
7) **Can COVID-19 vaccines be given concomitantly with non-COVID-19 vaccines?**
   Response: Yes, and no intervals are required before or after COVID-19 vaccine administration.
8) **Is there a preferred COVID-19 vaccine brand that should be offered to those 12 years to 29 years to decrease the possible risk of myocarditis or pericarditis?**
   Response: No.
9) **Who is recommended to get an additional COVID-19 dose until June 14, 2025?**
   Response: Adults 80 years of age and older; adult residents of long-term care facilities, personal care homes and other congregate living settings for seniors; individuals 6 months of age and older who are moderately to severely immunocompromised due to an underlying condition or treatment. Previously vaccinated adults 65 to 79 years old who are at increased risk of severe Covid 19 disease may also receive an additional dose.
10) **What is the end date of the 2024-25 COVID-19 campaign?**
    Response: June 14, 2025.
11) **Are there exceptions for immunization after June 14, 2025?**
    Response: The Saskatchewan Cancer Agency and the Saskatchewan Transplant Program approve that their adult transplant patients remain eligible to receive 2024-25 COVID-19 vaccine doses after June 14, 2025, from Public Health, until 2025-26 COVID-19 vaccines are available.

2024-25 COVID-19 Immunization Schedules

- Refer to 2024-25 COVID-19 Vaccine Q &A for Immunizers for additional interval recommendations (e.g., long-term care facility, personal care home, or senior congregate living (i.e., assisted living facility) residents.
- Refer Canadian Immunization Guide For a list of immunocompromising conditions: canada.ca/CIG - COVID19 Immunocompromised*

Table 1: Schedules for individuals presenting at 12 years and older who are NOT immunocompromised

Vaccination History (non-2024-25 vaccine)	2024-25 COVID-19 vaccine dosage	Dose required	Interval between last non-2024-25 vaccine & 2024-25 vaccine
0 doses	Moderna = 0.5 ml (50 mcg) Pfizer = 0.3 ml (30 mcg)	1	N/A
1 or more doses	Moderna = 0.5 ml (50 mcg) Pfizer = 0.3 ml (30 mcg)	1	≥ 8 weeks

Table 2: Schedules for individuals presenting at 12 years and older WHO ARE moderately to severely immunocompromised*

Vaccination History (non-2024-25 vaccine)	2024-25 COVID-19 vaccine dosage	Doses required	Interval between last non-2024-25 vaccine & 2024-25 vaccine	Interval between 2024-25 vaccine doses
0 doses	Moderna = 0.5 ml (50 mcg) Pfizer = 0.3 ml (30 mcg)	3	N/A	≥ 4-8 weeks
1 dose	Moderna = 0.5 ml (50 mcg) Pfizer = 0.3 ml (30 mcg)	2	≥ 8 weeks	≥ 4-8weeks
2 or more doses	Moderna = 0.5 ml (50 mcg) Pfizer = 0.3 ml (30 mcg)	1	≥ 8 weeks	N/A

Table 3: Schedules for children presenting at 5-11 years who are NOT immunocompromised

Vaccination History (non-2024-25 vaccine)	2024-25 COVID-19 vaccine dosage	Dose required	Interval between last non-2024-25 vaccine & 2024-25 vaccine
0	Moderna 0.25 ml (25 mcg)	1	N/A
1 or more doses		1	≥ 8 weeks

Table 4: Schedule for children presenting at 5 to 11 years WHO ARE moderately to severely immunocompromised*

Vaccination History (non-2024-25 vaccine)	2024-25 COVID-19 vaccine dosage	Doses required	Interval between last non-2024-25 vaccine & 2024-25 vaccine	Interval between 2024-25 vaccine doses
0 doses	Moderna 0.25 ml (25 mcg)	3	N/A	≥ 4-8 weeks
1 dose		2	≥ 8 weeks	≥ 4-8 weeks
2 or more doses		1	≥ 8 weeks	≥ 4-8 weeks

Table 5: Schedules for children presenting at age 6 months to 4 years who are NOT immunocompromised.

Vaccination History (non-2024-25 vaccine)	2024-25 COVID-19 vaccine dosage	Doses required	Interval between last non-2024-25 vaccine & 2024-25 vaccine	Interval between 2024-25 vaccine doses
0 doses	Moderna 0.25 ml (25 mcg)	2	N/A	≥ 4-8 weeks
1 dose Pfizer		2	≥ 8 weeks	≥4-8 weeks
2 doses Pfizer		1	≥ 8 weeks	N/A
1 dose Pfizer **and** 1 dose Moderna				
1 dose Moderna				
3 doses Pfizer		1	≥ 8 weeks	N/A
2 doses Moderna				
2 doses Pfizer **and** 1 dose Moderna				
1 dose Pfizer **and** 2 doses Moderna				

Table 6: Schedules for children presenting at age 6 months to 4 years WHO ARE moderately to severely immunocompromised*

Vaccination History (non-2024-25 vaccine)	2024-25 COVID-19 vaccine dosage	Doses required	Interval between last non-2024-25 vaccine & 2024-25 vaccine	Interval between 2024-25 vaccine doses
0 doses	Moderna 0.25 ml (25 mcg)	3	N/A	≥ 4-8 weeks
1 dose Pfizer		2	≥ 8 weeks	≥ 4-8 weeks
1 dose Moderna		2	≥ 8 weeks	≥ 4-8 weeks
2 doses Pfizer		1		
1 dose Pfizer **and** 1 dose Moderna		1		
2 doses Moderna		1	≥ 8 weeks	≥/A
3 doses Pfizer				
2 doses Pfizer **and** 1 dose Moderna				
1 dose Pfizer **and** 2 doses Moderna				
4 doses Pfizer		1	≥ 8 weeks	N/A
3 doses Moderna				
3 doses Pfizer **and** 1 dose Moderna				
2 doses of Pfizer **and** 2 doses of Moderna				
1 dose of Pfizer **and** 3 doses of Moderna				

2024-25 Moderna SPIKEVAX COVID-19 Vaccine 0.1 mg/ml for 6 months and older

Composition/Platform Vaccine Type	• mRNA vaccine containing Omicron KP.2 variant. • Does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials.
Route	• Intramuscular injection (IM) only. • Do not inject the vaccine intravascularly, subcutaneously or intradermally.
Schedule & Dosage	Refer to the 2024-25 COVID-19 Immunization Schedules.
Contraindications	• **Anaphylaxis to previous dose of mRNA or other COVID-19 vaccine.** • SPIKEVAX is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container. • For History of Severe Immediate Allergic Reactions to Previous COVID-19 Vaccine Dose, refer to the Ministry of Health's COVID-19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
Precautions	Refer to the COVID-19 Vaccine Contraindications and Precautions Background document found in the COVID-19 Immunization Manual regarding: • Recent COVID-19 Infection • Multisystem Inflammatory Syndrome in Adults (MIS-A) and Children (MIS-C) • History of Myocarditis and/or Pericarditis Following COVID-19 Vaccination • Immunocompromised individuals • Auto-immune conditions

Pregnancy & Lactation	• People who are pregnant or lactating are recommended to be immunized with COVID-19 vaccines.
	• The product monograph does note:
	  ○ The safety and efficacy of SPIKEVAX in pregnant individuals have not yet been established. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition, or post-natal development.
	  ○ Individuals who are vaccinated with SPIKEVAX during pregnancy are encouraged to report experienced adverse events by calling 1-866-MODERNA (1-866-663-3762).
	  ○ It is unknown if SPIKEVAX is excreted in human milk. A risk to the newborns/infants cannot be excluded. The developmental and health benefits of breastfeeding should be considered along with the breastfeeding parent's clinical need for immunization against COVID-19.

Possible Reactions	**Common or very commonly reported local and systemic adverse reactions lasting 2-3 days:** • Pain, warmth, redness and swelling at the injection site and/or limited movement of the immunized arm or leg. • Swollen and tender lymph nodes in the underarm (resolves in up to 7-10 days). • Headache, muscle aches, stiffness, joint pain, fever, chills, rash, fatigue, nausea, vomiting, loss of appetite. • A local delayed reaction (onset at least 7 days) known as 'COVID arm' is associated with mRNA COVID-19 vaccines and resolves on its own within 7-10 days. **Rare** • Anaphylaxis • Myocarditis (inflammation of the heart) and pericarditis (inflammation of the outer lining of the heart) have been reported with the administration of previous mRNA vaccines. Health Canada monitors for myocarditis and pericarditis following mRNA vaccine administration. • Non-severe allergic reactions (such as rash, itching, hives or swelling of the face), severe allergic reactions, erythema multiforme (red round patches on the skin) and/or facial paralysis / Bell's palsy have been reported with the administration of previous mRNA vaccines. Vaccinated individuals (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. • Prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication

<table>
<tr><td></td><td>to vaccination.
• Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.</td></tr>
<tr><td>Preparation & Administration</td><td>• Thaw vials before use: 2 hours in fridge or 45 minutes at room temperature.
• Swirl the vial gently after thawing and between each withdrawal. Do not shake.
• Thawed vials and filled syringes can be handled in room light conditions during preparation. Additional thawing instructions, refer to COVID-19 Immunization Manual COVID-19 Vaccine Storage & Handling & Cold Chain Break Procedures work standard.</td></tr>
<tr><td>Storage & Handling</td><td>• Store frozen between -50°C to -15°C up to expiry date. Do not store below -50°C.
• Store in original carton to protect from light. Do not refreeze thawed vials.
<table>
<tr><th>Storage Conditions</th><th>SPIKEVAX
Unpunctured vial</th><th>SPIKEVAX
Punctured Vial</th></tr>
<tr><td>Refrigerated conditions:
(2°C to 8°C)</td><td>50 days</td><td>Discard 24 hours after first dose has been withdrawn</td></tr>
<tr><td>Room temperature conditions:
(8°C to 25°C)</td><td>12 hours</td><td>Discard 12 hours after first dose has been withdrawn</td></tr>
</table>
• For additional storage and handling details, refer to the COVID-19 Immunization Manual:
○ Appendix A1- Moderna Spikevax™ COVID-19 Vaccine Storage & Handling Summary Table</td></tr>
<tr><td>Transportation</td><td>Refer to Transportation of Moderna COVID-19 Vaccine in a Frozen and Thawed State work standard found on the COVID-19 Immunization Manual website.</td></tr>
<tr><td>Ingredients</td><td>mRNA encoding SARS-CoV-2 KP.2 spike protein, 5’(m7G-5’-ppp-5’-Gm) cap, 100-nucleotide 3' poly(A) tail of the KP.2 strain, acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-Phosphocholine), SM-102 (Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy)hexyl) amino) octanoate), PEG2000-DMG (1,2-dimyristoyl-racglycero- 3-methoxypolyethylene glycol-2000), sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection.</td></tr>
</table>

- *Moderna SPIKEVAX™ Product Monograph* (2024-09-17). https://static.modernatx.com/pm/6cef78f8-8dad-4fc9-83d5-d2fbb7cff867/3fdb383d-75df-4fdc-9c55-60253d6942c8/3fdb383d-75df-4fdc-9c55-60253d6942c8_viewable_rendition__v.pdf
- *Guidance on the use of COVID-19 vaccines during the fall of 2024* (NACI 2024) https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-guidance-covid-19-vaccines-fall-2024.html
- *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html

2024-25 Pfizer BioNTech Comirnaty® COVID-19 Vaccine 12+ years

Composition/Platform Vaccine Type	• Each dose contains contains 30 mcg of a nucleoside modified messenger RNA (modRNA) encoding the viral spike (S) protein of SARS-CoV-2 Omicron variant lineage KP.2. • Does not contain any preservatives.
Route	• 0.3 mL Intramuscular injection (IM) only. • Do not inject the vaccine intravascularly, subcutaneously or intradermally.
Schedule & Dosage	• Refer to the 2024-25 COVID-19 Immunization Schedules.
Contraindications	• **Anaphylaxis to previous dose of mRNA or other COVID-19 vaccine.** • COMIRNATY is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container. • For History of Severe Immediate Allergic Reactions to Previous COVID-19 Vaccine Dose, refer to the Ministry of Health's COVID-19 Vaccine Contraindications and Precautions Background Document found in the COVID-19 Immunization Manual.
Precautions	Refer to the COVID-19 Vaccine Contraindications and Precautions Background document found in the COVID-19 Immunization Manual regarding: • Recent COVID-19 Infection • Multisystem Inflammatory Syndrome in Adults (MIS-A) and Children (MIS-C) • History of Myocarditis and/or Pericarditis Following COVID-19 Vaccination • Immunocompromised individuals • Auto-immune conditions
Pregnancy & Lactation	• People who are pregnant or lactating are recommended to be immunized with COVID-19 vaccines. • The product monograph does note: a. No data are available yet regarding the use of COMIRNATY during pregnancy or during lactation. b. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition, or post-natal development. c. It is unknown whether COMIRNATY is excreted in human milk. A risk to the newborns/infants cannot be excluded. d. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunization against COVID-19.
Possible reactions	**Common or very commonly reported local and systemic adverse reactions lasting 2-3 days:** • Pain, warmth, redness and swelling at the injection site and/or limited movement of the immunized arm or leg. • Swollen and tender lymph nodes in the underarm (resolves in up to 7-10 days). • Headache, muscle aches, stiffness, joint pain, fever, chills, rash, fatigue, nausea, vomiting, loss of appetite. • A local delayed reaction (onset at least 7 days) known as 'COVID arm' is associated with mRNA COVID-19 vaccines and resolves on its own within 7-10 days. **Rare** • Anaphylaxis • Myocarditis (inflammation of the heart) and pericarditis (inflammation of the outer lining of the heart) have been reported with the administration of previous mRNA vaccines. Health Canada monitors for myocarditis and pericarditis following mRNA vaccine administration. • Non-severe allergic reactions (such as rash, itching, hives or swelling of the face), severe allergic reactions, erythema multiforme (red round patches on the skin) and/or facial paralysis / Bell's palsy have been reported with the administration of previous mRNA vaccines. Vaccinated individuals (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. • Prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not

	be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. • Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.
Preparation & Administration	• Each vial must be thawed prior to administration. • For thawing instructions, refer to COVID-19 Immunization Manual COVID-19 Vaccine Storage & Handling & Cold Chain Break Procedures work standard. • Before use, mix by inverting vaccine vial gently 10 times. Do not shake. • Thawed vials and filled syringes can be handled in room light conditions during preparation.
Storage and Handling	• Store ultra-frozen at -90°C to -60°C for up to 18 months from the date of manufacture (printed on the vial). • **Do not store vials at -25°C to -15°C.** • Thawed vials can be stored between +2°C to +8°C for up to 10 weeks within the expiry date. • Store in original carton to minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. • **Do not refreeze after thawing.** • After first vial puncture, the vaccine must be used within 12 hours. • Thawed vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use. • For additional storage and handling details, refer to the Appendix A2 Pfizer Comirnaty COVID-19 Vaccine Storage and Handling Summary.
Transportation	• Refer to *Transportation of Pfizer COVID-19 Vaccine in Ultra-frozen and Thawed State* work standard found on the COVID-19 Immunization Manual website: https://www.ehealthsask.ca/services/Manuals/Pages/COVID-19.aspx.
Ingredients	mRNA encoding SARS-CoV-2 KP.2 spike protein, ALC-0315 = ((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, cholesterol, DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine, sodium chloride, sucrose, tromethamine, tromethamine hydrochloride, water for injection

- Pfizer Comirnaty™ Product Monograph (2024-10-25). https://webfiles.pfizer.com/file/fddae31e-ac0e-4bed-83b2-59e7c848d6d7?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6
- *Guidance on the use of COVID-19 vaccines during the fall of 2024* (NACI 2024) https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-guidance-covid-19-vaccines-fall-2024.html
- *Canadian Immunization Guide*: COVID-19 Vaccines: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

INFANRIX™-IPV/Hib

Product monograph: https://ca.gsk.com/en-ca/products/infanrix-ipvhib/
)

DOSE / PRIMARY SERIES [1, 2, 5]	**Dose 1**: 0.5 mL IM at 2 months old **Dose 2**: 0.5 mL IM at 4 months old **Dose 3**: 0.5 mL IM at 6 months old **Dose 4**: 0.5 mL IM at 18 months old [3]
REINFORCEMENT [4]	Tdap-IPV at age 4-6 years (school entry)
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV or Hib-containing vaccine or to any INFANRIX™-IPV/Hib vaccine component. • History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a tetanus-containing vaccine. • Individuals who have experienced other neurological complications following an earlier immunization against diphtheria and/or tetanus. • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine.
VACCINE COMPONENTS	Sterile suspension for injection/ not less than 25 limit of flocculation (Lf) [30 International Units (IU)] of diphtheria toxoid; 10 Lf (40 IU) of tetanus toxoid; 25 mc of pertussis toxoid; 25 mcg of filamentous haemagglutinin; 8 mcg of pertactin; 40 D-antigen units (DU) of type 1 poliovirus; 8 DU type 2 poliovirus; 32 DU type 3 poliovirus; 10 mcg of purified polyribosyl-ribitol-phosphate capsular polysaccharide of *Haemophilus Influenzae* type B covalently bound to 25 mcg of tetanus toxoid per 0.5 mL dose. **Clinically Relevant Nonmedicinal Ingredients:** lactose, sodium chloride, aluminum adjuvant (as aluminum salts), Medium 199 (as stabilizer including amino acids, mineral salts and vitamins) and water for injection, residual formaldehyde, polysorbate 80, potassium chloride, disodium phosphate, monopotassium phosphate, glycine and trace amounts of neomycin sulphate and polymyxin B sulphate. Thimerosal and latex-free. The vial is sealed with a butyl rubber stopper. The syringes are fitted with butyl rubber plunger stoppers and tip caps.
EXPECTED REACTIONS	**Local**: Redness, tenderness, and swelling. **Systemic**: Irritability, crying, fever, drowsiness, decreased activity and decreased appetite, vomiting and diarrhea.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

INFANRIX™-IPV/Hib

EFFECTIVENESS	Following administration of the 4th dose in the second year of life, more than 99.5% of infants had tetanus and diphtheria antibody titres of > 0.1 IU/mL. Following administration of the 4th dose in the second year of life, a booster response was seen in 98.6%, 97.6% and 97.9% of vaccinated infants against pertussis antigens. Following administration of the 4th dose in the second year of life, 100% of infants were seroprotected for the three polio serotypes. One month after the 4th dose was administered in the second year of life, a Hib titre of ≥ 0.15 mcg/mL was obtained in 99.7% of all infants, and in > 98.3% of infants, a Hib titre of 1 mcg/mL was reached.

[1] Minimum age is 6 weeks.

[2] If a child's immunization schedule is delayed, the child may require fewer doses of Hib vaccine. Refer to SIM, Chapter 5, *Immunization Schedules* Section 1.2, *Hib Schedule for Children Delayed by 1 Month or More* .

[3] If required, this dose can be given as early as 24 weeks following dose number 3. For protection against Hib, do not give the 4th dose before 12 months of age.

[4] The 5th dose is not necessary if the 4th dose was given after the 4th birthday.

[5] May be administered off label to HSCT and solid organ transplant patients (whose age is beyond the vaccine's licensed age range) to reduce the number of injections they require to meet the antigen requirements as noted in SIM chapter 7 Appendix 7.6, 7.9 or 7.10 immunization schedules.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

PENTACEL®
Product monograph available at https://pdf.hres.ca/dpd_pm/00069515.PDF)

DOSE / PRIMARY SERIES [1, 2, 5]	**Dose 1**: 0.5 mL IM at 2 months old **Dose 2**: 0.5 mL IM at 4 months old **Dose 3**: 0.5 mL IM at 6 months old **Dose 4**: 0.5 mL IM at 18 months old [3]
REINFORCEMENT [4]	Tdap-IPV at age 4-6 years (school entry)
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV or Hib--containing vaccine or to any PEDIACEL® vaccine component. • History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a tetanus-containing vaccine. • Individuals who have experienced other neurological complications following an earlier immunization against diphtheria and/or tetanus. • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine.
VACCINE COMPONENTS	Diphtheria toxoid, tetanus toxoid, acellular pertussis [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)], inactivated poliomyelitis vaccine [type 1 (Mahoney), type 2 (MEF1), type 3 (Saukett)], purified polyribosylribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to tetanus protein, water for injection, Tris (hydroxymethyl) aminomethane, sucrose. **Excipients**: aluminum phosphate (adjuvant), 2-phenoxyethanol, polysorbate 80. **Manufacturing process residuals**: formaldehyde, glutaraldehyde, bovine serum albumin, neomycin, polymyxin B, streptomycin sulfate. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Redness, tenderness, and swelling. **Systemic**: Irritability, crying, fevers greater than 38.3°C, drowsiness, decreased activity and decreased appetite, vomiting and diarrhea.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib) **PENTACEL®**	
EFFECTIVENESS	One month after the third and fourth doses, no clinically significant differences were observed between the antibody responses to each of the vaccine antigens in children receiving PEDIACEL®. After the third and fourth doses, at least 97.9% of the PEDIACEL® vaccinees achieved seroprotective levels against Hib disease (anti-PRP antibody ≥ 0.15 mcg/mL), diphtheria (diphtheria antitoxin ≥ 0.01 IU/mL), tetanus (tetanus antitoxin ≥ 0.01 EU/mL) and poliomyelitis types 1, 2, and 3 (poliovirus neutralizing antibody titre ≥ 1:8). Seroconversion rates (≥ 4-fold rise) were high for each of the pertussis antibodies after the primary series. A robust booster response was observed after the fourth dose.

[1] Minimum age is 6 weeks.

[2] If a child's immunization schedule is delayed, the child may require fewer doses of Hib vaccine. Refer to SIM, Chapter 5, *Immunization Schedules* Section 1.2, *Hib Schedule for Children Delayed by 1 Month or More* .

[3] If required, this dose can be given as early as 24 weeks following dose number 3. For protection against Hib, do not give the 4th dose before 12 months of age.

[4] The 5th dose is not necessary if the 4th dose was given after the 4th birthday.

[5] May be administered off label to HSCT and solid organ transplant patients (whose age is beyond the vaccine's licensed age range) to reduce the number of injections they require to meet the antigen requirements as noted in SIM chapter 7 Appendix 7.6, 7.9 or 7. 10 immunization schedules.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

PEDIACEL®

Product monograph at https://pdf.hres.ca/dpd_pm/00071965.PDF

DOSE / PRIMARY SERIES [1, 2, 5]	**Dose 1**: 0.5 mL IM at 2 months old **Dose 2**: 0.5 mL IM at 4 months old **Dose 3**: 0.5 mL IM at 6 months old **Dose 4**: 0.5 mL IM at 18 months old [3]
REINFORCEMENT [4]	Tdap-IPV at age 4-6 years (school entry)
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV or Hib--containing vaccine or to any PEDIACEL® vaccine component. • History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a tetanus-containing vaccine. • Individuals who have experienced other neurological complications following an earlier immunization against diphtheria and/or tetanus. • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine.
VACCINE COMPONENTS	Diphtheria toxoid, tetanus toxoid, acellular pertussis [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)], inactivated poliomyelitis vaccine [type 1 (Mahoney), type 2 (MEF1), type 3 (Saukett)] and purified polyribosylribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to tetanus protein. **Excipients**: aluminum phosphate (adjuvant), 2-phenoxyethanol, polysorbate 80. **Manufacturing process residuals**: bovine serum albumin, neomycin, polymyxin B and trace amounts of streptomycin, formaldehyde and glutaraldehyde. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Redness, tenderness, and swelling. **Systemic**: Irritability, crying, fevers greater than 38.3°C, drowsiness, decreased activity and decreased appetite, vomiting and diarrhea.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib) **PEDIACEL®**	
EFFECTIVENESS	One month after the third and fourth doses, no clinically significant differences were observed between the antibody responses to each of the vaccine antigens in children receiving PEDIACEL®. After the third and fourth doses, at least 97.9% of the PEDIACEL® vaccinees achieved seroprotective levels against Hib disease (anti-PRP antibody ≥ 0.15 mcg/mL), diphtheria (diphtheria antitoxin ≥ 0.01 IU/mL), tetanus (tetanus antitoxin ≥ 0.01 EU/mL) and poliomyelitis types 1, 2, and 3 (poliovirus neutralizing antibody titre ≥ 1:8). Seroconversion rates (≥ 4-fold rise) were high for each of the pertussis antibodies after the primary series. A robust booster response was observed after the fourth dose.

[1] Minimum age is 6 weeks.

[2] If a child's immunization schedule is delayed, the child may require fewer doses of Hib vaccine. Refer to SIM, Chapter 5, *Immunization Schedules* Section 1.2, *Hib Schedule for Children Delayed by 1 Month or More* .

[3] If required, this dose can be given as early as 24 weeks following dose number 3. For protection against Hib, do not give the 4th dose before 12 months of age.

[4] The 5th dose is not necessary if the 4th dose was given after the 4th birthday.

[5] May be administered off label to HSCT and solid organ transplant patients (whose age is beyond the vaccine's licensed age range) to reduce the number of injections they require to meet the antigen requirements as noted in SIM chapter 7 Appendix 7.6, 7.9 or 7. 10 immunization schedules.

Diphtheria-Tetanus-acellular Pertussis-Hepatitis B-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-HB-IPV-Hib)

[Non-publicly funded]

INFANRIX-hexa®
Product monograph: https://ca.gsk.com/en-ca/products/infanrix-hexa/

Refer to Appendix 5.1: DTaP-IPV-Hib and HB Vaccine Schedule for Children who have previously Received DTaP-HB-IPV-Hib (INFANRIX hexa®) Vaccine Doses for immunization directives.

Ebola Zaire Vaccine
[not publicly funded]

EVERBO®
(Merck) product monograph: https://www.merck.ca/en/wp-content/uploads/sites/20/2022/11/ERVEBO-PM_E.pdf

Haemophilus influenzae type b Conjugate Vaccine (Hib)

Act-HIB®

Product monograph: https://pdf.hres.ca/dpd_pm/00070195.PDF

INDICATIONS and DOSE / SERIES [1]	
1. As a component of DTaP-IPV-Hib 0.5 mL IM for children at 2, 4, 6, and 18 months of age [2]**.** **2. Children 2-59 months of age who are delayed by 1 month or more** [3] **3. People 5 years and older with the following medical conditions regardless of Hib immunization or Hib disease history:** [4] Anatomic or functional asplenia Including (sickle cell disease) [5, 7]; HIV [7]; immunosuppression related to disease [7] (e.g., congenital immunodeficiency states such as complement, properidin or factor D deficiency; malignant neoplasm including leukemia and lymphoma;) or therapy [7]; candidates or recipients of solid organ or islet cell transplants [7], or cochlear implants [7]. **4. Haematopoietic stem cell transplant (HSCT) recipient** [6]	
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of a Hib-containing vaccine or to any component of Act-HIB®.
VACCINE COMPONENTS	Purified Polyribosylribitol Phosphate Capsular Polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to 18-30 mcg of Tetanus Protein 10 mcg. **Excipients**: Tris (hydroxymethyl) aminomethane, sucrose, sodium chloride. Thimerosal free. The stoppers of the vials containing Act-HIB® and the diluent (0.4% saline) do not contain latex (natural rubber).
EXPECTED REACTIONS	**Local**: redness, tenderness, swelling, pain. **Systemic:** fever more than 38.3°C, fussiness, irritability, lethargy, loss of appetite.
EFFECTIVENESS	After 4 doses, 99% of children maintained high antibody levels at age 4- 5 years.

[1] Minimum age is 6 weeks old.
[2] The 18 month reinforcement dose may be given at 12 months if there is an 8 week interval following the previous dose.
[3] Refer to SIM, Chapter 5 *Immunization Schedules*, section 1.2 *Hib Schedule for Children Delayed by 1 Month or More*.
[4] Refer to SIM, Chapter 7, *Immunization of Special Populations* for more information on specific conditions.
[5] Give vaccine at least 14 days prior to elective splenectomy, or if impossible, 14 days or more days post-splenectomy. If there is concern that the client may not present later for immunization, give vaccine before discharge.
[6] Refer to SIM, Chapter 7, *Immunization of Special Populations*, Section 3.6 *Transplant Recipient - Haematopoietic Stem Cell Transplant.*
[7] At least 1 year after any previous dose.

Publicly Funded [3] *
Hepatitis A (HA) Vaccine Indications

- People born since Jan. 1/82 who live in the Athabasca Health Authority; off reserves in Northern SK (former Mamawetan Churchill River and Keewatin Yatthé health regions excluding Creighton, Air Ronge and La Ronge); or on reserves anywhere is SK, regardless of where they access immunization services.
- Men who have sex with men.
- Individuals that use or share illicit drug snorting, smoking or injection equipment.
- Sexual partners and household contacts 6 months and older of individuals who use illicit drugs.
- Post-exposure prophylaxis of case contacts 6 months and older with one dose as outlined in the Saskatchewan Communicable Disease Control Manual.[1]
- Non-immune individuals 6 months and older with bleeding disorders and others who receive repeated infusions of blood or blood products or plasma-derived replacement clotting factors.
- Individuals 6 months and older who have liver disease (e.g., alcoholism, hepatitis C, hepatitis B, cirrhosis) who are non-immune to HA.
- Liver transplant candidates or recipients 6 months and older.
- Haematopoietic stem cell transplant (HSCT) recipients 6 months and older.

HA vaccine recommended for but not provided free: [2]

- Travellers to countries with endemic hepatitis A.
- Food handlers.
- Residents in certain institutions, such as correctional facilities and those for developmentally challenged individuals.
- Residents in communities in rural or remote areas lacking adequate sanitation or a secure supply of potable water.

[1] If a client received 1 dose of a HA-containing vaccine more than 6 months previously, provide a second dose of HA vaccine.

[2] These individuals should be referred to a travel clinic, family physician, nurse practitioner or pharmacist to receive non-publicly funded vaccine.

[3] CIG Hepatitis A chapter https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-6-hepatitis-a-vaccine.html).

* Previously, HIV positive individuals were deemed eligible to receive HA vaccine based on this diagnosis. If such an individual had started a HA series, the series is to be completed.

Hepatitis A Vaccine (HA) (inactivated viral)

AVAXIM® / AVAXIM® - Pediatric

Product monograph available at: https://pdf.hres.ca/dpd_pm/00074466.PDF

INDICATIONS	**Refer to publicly funded HA vaccine indications**
DOSE [1] / SERIES NOTE: Either vaccine may be used for persons between 12 to 15 years of age.	**Children 6 months up to and including 15 years of age:** (In SK, AVAXIM Pediatric may be provided off-label to those 6-11 months). **Dose 1**: AVAXIM® - Pediatric 0.5 mL IM **Dose 2**: AVAXIM® - Pediatric 0.5 mL IM 6-36 months after dose
	Persons 12 years and older: **Dose 1**: AVAXIM® 0.5 mL IM **Dose 2**: AVAXIM® 0.5 mL IM 6-36 months after dose
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of an anaphylactic reaction to a previous dose of any HA vaccine or to any AVAXIM® vaccine components.
VACCINE COMPONENTS	Inactivated hepatitis A virus, (GBM strain, Phenoxyethanol-Ethanol (50% v/v solution) with 2 phenoxyethanol (2.5 µL) and ethanol anhydrous (2.5 µL); Formaldehyde (12.5 mcg); Aluminum hydroxide, hydrated (expressed as aluminum 0.3 mg); 1 x C Medium 199 Hanks (up to 0.5 mL). 1 x C Medium 199 Hanks (without phenol red) is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins and other components supplemented with polysorbate 80 and is reconstituted in water for injection. Hydrochloric acid and or sodium hydroxide can be used for pH adjustment; these components are only present in trace amounts. Neomycin is also present in trace amounts Latex and thimerosal free.
EXPECTED REACTIONS	Tend to be mild and transient. **Local:** Pain, swelling, redness at injection site. **Systemic:** Weakness, myalgia/arthralgia, headache, gastrointestinal symptoms and mild fever.
EFFECTIVENESS	In clinical studies involving over 1,000 volunteers, specific humoral antibodies against hepatitis A were elicited after the first injection and more than 90% of immunocompetent subjects were protected (titres above 20 mIU/mL) 14 days after vaccination. One month after the first injection, 100% of the subjects were protected. Immunity persisted for at least 36 months and was reinforced after a first booster dose.

[1] HA vaccines are interchangeable for any scheduled dose for children and adults, using the age-specific dosage for the particular product.

Hepatitis A Vaccine (HA) (inactivated viral)

HAVRIX® (for Havrix® 1440 and Havrix® 720 Junior)
Product monograph available at: https://pdf.hres.ca/dpd_pm/00073325.PDF

INDICATIONS	**Refer to publicly funded HA vaccine indications**
DOSE / SERIES [1] **NOTE: The product monograph recommends 1 dose as the primary immunization requirement for all ages; and 1 booster dose 6-12 months later to ensure long-term protections.** **SK recommended that 2 doses always be given to all clients as indicated.**	**Children 6 months up to and including 18 years of age:** (In SK, HAVRIX 720 may be provided off-label to those 6-11 months). **USE HAVRIX® pediatric presentation of 720 ELU per 0.5 mL** **Dose 1**: 0.5 mL IM **Dose 2**: 0.5 mL IM 6-12 months after dose 1
	Adults 19 years and older: (In SK, HAVRIX 1440 may be provided off-label to those 18 years old if another adult HA vaccine brand is unavailable). • **USE HAVRIX® adult presentation of 1440 ELU per 1 mL** **Dose 1**: 1 mL IM **Dose 2**: 1 mL IM 6-12 months after dose 1 [2]
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of an anaphylactic reaction to a previous dose of any HA vaccine, or to any HAVRIX® vaccine components.
VACCINE COMPONENTS	HAVRIX 1440 contains: 1440 ELISA units per 1 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain); HAVRIX 720 Junior contains: 720 ELISA units per 0.5 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain). The virus is adsorbed on aluminium (0.5 mg/1 mL adult dose, 0.25 mg/0.5 mL pediatric dose) in the form of aluminium hydroxide. Excipients: aluminium (as aluminium hydroxide), amino acids for injection, disodium phosphate, monopotassium phosphate, polysorbate 20, potassium chloride, sodium chloride, water for injection. Residue from the manufacturing process: neomycin sulphate (less than 10 ng for HAVRIX 720 Junior; less than 20 ng for HAVRIX 1440). Thimerosal and latex free.
EXPECTED REACTIONS	Tend to be mild and transient. **Local:** Soreness, swelling and redness at injection site. **Systemic:** Headache, fatigue, fever, malaise, and gastrointestinal symptoms.
EFFECTIVENESS	Protective serum antibody levels in 95-100% of people within 4 weeks of immunization.

[1] HA vaccines are interchangeable for any scheduled dose for children and adults, using the age-specific dosage for the particular product.

[2] In SK, all eligible adult recipients must receive 1440 ELU for each publicly funded dose, even though studies show that 720 ELISA units may provide an effective 2nd HA dose in adults.

Hepatitis A Vaccine (HA) (purified inactivated viral)

VAQTA®

Product monograph available at https://pdf.hres.ca/dpd_pm/00019913.PDF

INDICATIONS	**Refer to publicly funded HA vaccine indications**
DOSE / SERIES [1]	**Eligible children 6 months up to and including 17 years**: (In SK, VAQTA Pediatric may be provided off-label to those 6-11 months). • **USE VAQTA® pediatric presentation of 25U per 0.5 mL** **Dose 1**: 0.5 mL IM **Dose 2**: 0.5 mL IM 6-12 months after dose 1
	Eligible adults 18 years and older: • **USE VAQTA® adult presentation of 50U per 1 mL** **Dose 1**: 1 mL IM **Dose 2**: 1 mL IM 6-12 months after dose 1
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of an anaphylactic reaction to a previous dose of any HA vaccine, to any VAQTA® vaccine components, or to latex (vials).
VACCINE COMPONENTS	Hepatitis A virus protein, aluminum (as amorphous aluminum hydroxyphosphate sulfate), sodium borate, sodium chloride, water for injection. **Manufacturing process residuals:** Within the limits of current assay variability, the 50 unit (1 mL) dose of VAQTA® contains less than 0.1 mcg (less than 100 ng) of non-viral protein, less than 4 x 10-6 mcg (less than 0.004 ng) of DNA, less than 10-4 mcg (less than 0.1 ng) of bovine albumin, less than 0.8 mcg (less than 800 ng) of formaldehyde and a trace of neomycin [≤ 0.002 mcg (≤ 2 ng)]. Other process chemical residuals are less than 10 parts per billion (ppb). VAQTA® meets the World Health Organization requirement for biological substances including those for final vaccine residual bovine serum albumin. The vial stopper contains latex.
EXPECTED REACTIONS	**Local:** Soreness, swelling and redness at injection site. **Systemic:** Headache, fatigue, fever, malaise, and gastrointestinal symptoms.
EFFECTIVENESS	Protective serum antibody levels in 95-100% of people within 4 weeks of immunization.

[1] HA vaccines are interchangeable for any scheduled dose for children and adults, using the age-specific dosage for the particular product.

Hepatitis A and B Vaccine (combined) (HAHB)

[Not publicly funded]

TWINRIX® and TWINRIX® Junior

Product monograph available at https://ca.gsk.com/en-ca/products/twinrix/

Adult presents with history of:	HA completion [1]	HB completion [2]
1 dose HAHB 1.0 ml	2 doses of HA adult	2 doses of HB 1.0 ml
2 doses HAHB 1.0 ml	1 dose of HA adult	1 dose of HB 1.0 ml
Child or adolescent presents with history of:	**HA completion [1]**	**HB completion [2]**
1 dose of HAHB 0.5 ml	2 doses of HA pediatric	2 doses of 0.5 ml HB
1 dose of HAHB 1.0 ml	1 dose of HA pediatric	**6 mo. – 10 years:** 2 doses of HB 0.5 ml **11 – 15 years**: 1 dose of HB 1.0 ml **16 – 19 years**: 2 doses of HB 0.5 ml
2 doses of HAHB 0.5 ml	1 dose of HA pediatric	1 dose of HB 0.5 ml
2 doses of HAHB 1.0 ml [3]	Complete	Complete

[1] See SIM chapter 10 biologics page Hepatitis A for appropriate dosing and scheduling for age.
[2] See SIM chapter 10 biologics page Hepatitis B for appropriate dosing and scheduling for age.
[3] Two doses of HAHB adult 1.0 mL given 24 weeks apart for age 6 months up to including age 15 years is considered a complete series.

Publicly Funded Hepatitis B (HB) Vaccine Indications [1, 4]

- Those born since January 1, 1984.
- Grade 6 students.
- Children of immigrants to Canada from regions with HB prevalence of 2% and higher.
  - Refer to: HB Immunization Eligibility for Children of Families from Countries with Moderate or High (≥ 2%) HB Prevalence in this chapter.
- AHA/SHA/SCA/FNJ Healthcare workers (refer to SIM Chapter 7 section 6.2).
- Healthcare students as noted in SIM Ch. 7 section 6.3.
- Those who started a publicly funded series in another jurisdiction.
- Non-immune individuals with bleeding disorders and others who receive repeated infusions of blood or blood products or plasma-derived replacement clotting factors.
- Individuals with congenital immunodeficiencies. [3]
- Individuals who are HIV positive who are non-immune to HB[3].
- Individuals who have liver disease (e.g., alcoholism, hepatitis C, cirrhosis) who are non-immune to HB.
- Individuals with renal disease (predialysis, hemodialysis & peritoneal dialysis) who are non-immune to HB [3].
- Liver or kidney transplant candidates or recipients who are non-immune to HB [2].
- Haematopoietic stem cell transplant (HSCT) recipients [2].
- Household/sexual/close contacts of individuals who have an acute or chronic HB infection [6].
  - Includes children in a childcare setting in which there is an HB infected individual.
- Males and females with multiple sexual partners.
- Men who have sex with men
- Individuals that use or share illicit drug snorting, smoking or injection equipment.
- Sexual partners and household contacts of individuals who use illicit drugs.
- Group home residents
- Provincial correctional facility residents.
- Infant born to a HBsAg+ mother or high-risk mother whose HB status at delivery is unknown and STAT test results cannot be obtained within 12 hours after delivery [5, 7].
- Percutaneous (e.g., needle stick, bite) or mucosal exposure (e.g., sexual assault) [4, 6, 7].

HB vaccine recommended for but not provided free: [8]

- Travellers to countries with endemic hepatitis B.
- Non-healthcare workers who have an occupational risk of exposure.

[1] Most SK residents born since 1984 would have received routine HB vaccine in Grade 6. If records are unavailable and the client does not recall receiving HB series, proceed with HB vaccine as per indication.

[2] Refer SIM, Chapter 7, *Immunization of Special Populations* for specific medical conditions.

[3]. Refer SIM, Chapter 7, *Immunization of Special Populations,* Appendix 7.4: *High Dose Hepatitis B Immunization Algorithm.*

[4] Refer to *Guidelines for the Management of Exposures to Blood and Body Fluids* recommendations available at: http://www.ehealthsask.ca/services/manuals/Pages/hiv-guidelines.aspx

[5] Refer to SIM, *Chapter 7, Immunization of Special Populations, Section 4.2.1, Hepatitis B Infant Immunoprophylaxis Protocol.*

[6] Must present within 14 days of sexual assault.

[7] Post-vaccination testing should be performed no sooner than 1 month after completion of HB vaccine series.

[8] These individuals should be referred to a travel clinic, family physician, nurse practitioner or pharmacist to receive non-publicly funded vaccine.

HB Immunization Eligibility for Children of Families from Countries with Moderate or High (≥ 2%) HB Prevalence

- Children whose families originated or immigrated from countries **other than those listed below** are eligible to be immunized with publicly funded HB vaccine prior to Grade 6/11 years of age.
- Apply the Panorama risk factor 'Children of Immigrants – HB'.

Countries with low (< 2%) HB prevalence

Afghanistan	Colombia	Greenland	Montserrat	Serbia
Algeria	Costa Rica	Grenada	Montenegro	Slovakia
Andorra	Croatia	Grenadines	Morocco	Slovenia
Anguilla	Cuba	Guatemala	Nepal	Spain
Antigua & Barbuda	Curacao	Haiti	Netherlands	Sri Lanka
Argentina	Cyprus	Honduras	Netherlands Antilles	Saint Croix (USVI)
Armenia	Czechia	Hungary	New Zealand	Saint Kitts & Nevis
Aruba	Denmark	Iceland	Nicaragua	Saint John (USVI)
Australia	Dominica	Iran	North Macedonia	Saint Lucia
Austria	Dominican Republic	Ireland	Northern Ireland	Saint Thomas (USVI)
Azerbaijan	Ecuador	Israel	Norway	Saint Vincent
Bahamas	Egypt	Italy	Pakistan	Sweden
Bahrain	El Salvador	Japan	Palestine	Switzerland
Barbados	England	Jordan	Panama	Thailand
Belgium	Estonia	Kosovo	Paraguay	Trinidad & Tobago
Belize	Falkland Islands	Kuwait	Peru	Turks & Caicos
Bermuda	Fiji	Lebanon	Poland	Ukraine
Bhutan	Finland	Libya	Portugal	United Arab Emirates
Bolivia	France	Liechtenstein	Puerto Rico	United States
Brazil	French Guiana	Lithuania	Qatar	Uzbekistan
British Virgin Islands	French Polynesia	Luxemburg	Russia	Venezuela
Brunei	Georgia	Malta	San Marino	Zambia
Cayman Islands	Germany	Mexico	Saudi Arabia	
Chile	Greece	Monaco	Scotland	

Source: The CDA Foundation. Hepatitis B. Lafayette, CO: CDA Foundation, 2025. Available from https://cdafound.org/polaris/database-query/ (Accessed 2025-04-16).

HB Recommendations for Healthcare Workers & Students

Scenario 1: No documented completed age and interval appropriate HB series (incomplete series or no doses) AND no documented serology

1. **Do not do serology** prior to starting/resuming **or** during the HB series.
2. Provide and complete an appropriately spaced HB vaccines series (0, 1, 6 months).
   a. Refer individuals with risk factors noted in SIM Chapter 7 App. 7.4 (e.g., renal disease, immunocompromised) to Public Health for high dose HB series.
3. Test anti-HBs, HBsAg and Anti-HBc at least 4 weeks after the last dose.
4. Refer to Scenario 6 if anti-HBs is less than 10 IU/L.

Scenario 2: HB immunity from natural infection

A. Has documented serology results: HBsAg negative, anti-HBc positive and anti-HBs positive OR negative.
B. Document as immune. Future immunization or serology is not required, even upon potential HB exposure, **UNLESS** the individual becomes immunocompromised.

Scenario 3: HB immunity from immunization

1. Has documented completed and appropriately spaced HB series for age at immunization.
2. Has documented anti-HBs equal to/greater than 10 IU/L when done at least 4 weeks after last dose.
3. Document as immune. Further serology and immunization are not required, even upon potential HB exposure **UNLESS** they become immunocompromised (T-cells retain long-term memory and B-cells will activate upon HB exposure).

Scenario 4: Documentation of a completed age and interval appropriate HB series BUT no documented serology

1. Test for anti-HBs, HBsAg and Anti-HBc at least 4 weeks after the last dose.
2. Refer to Scenario 6 if anti-HBs is less than 10 IU/L.

Scenario 5: No documented completed age and interval appropriate HB series (incomplete or no doses) AND has documented anti-HBsAb equal to/greater than 10IU/L.

1. Provide and complete an appropriately spaced HB vaccines series (0, 1, 6 months)
   a. Refer individuals with risk factors noted in SIM Chapter 7 App. 7.4 (e.g., renal disease, immunocompromised) to Public Health for high dose HB series.
2. Test anti-HBs, HBsAg and Anti-HBc at least 4 weeks after the last dose in the series.
3. Refer to Scenario 6 if anti-HBs is less than 10 IU/L.

Scenario 6: Anti-HBs is less than 10 IU/mL when done at least 4 weeks after completing the first HB series

a. **If anti-HBs is detectable between 2 and 9.9 IU/L:**
   i. Provide 1 HB vaccine dose and retest anti-HBs at least 4 weeks later.
      - If anti-HBs is equal to/greater than 10 IU/L, they are immune.
      - If anti-HBs remains less than 10 IU/L, complete the second HB vaccine series and retest anti-HBs at least 4 weeks after the last dose.
      - Refer to Scenario 7 if Anti-HBs remains less than 10 IU/L.

b. **If anti-HBs is undetectable at less than 2 IU/L:**
   - Provide a second HB vaccine series (**do not** do any serology during the second HB series) and retest anti-HBs at least 4 weeks after the last dose.
   - Refer to Scenario 7 if anti-HBs remains less than 10 IU/L

Scenario 7: Anti-HBs remains less than 10 IU/L when done at least 4 weeks after completing the second HB series

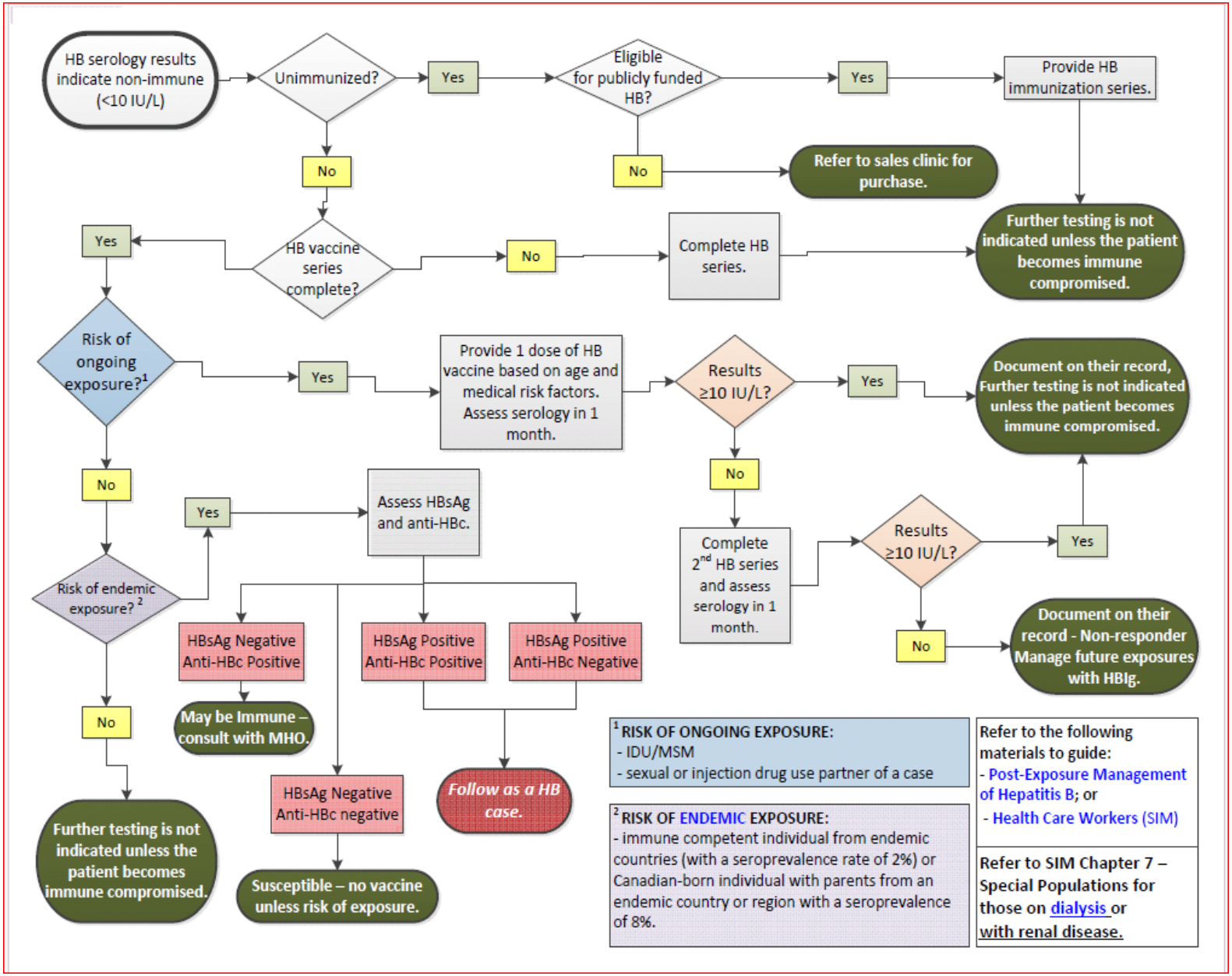
1. The individual is considered non-responder and susceptible to HB.
2. Document as a non-responder.
3. Provide HBIg after a HB exposure.
4. The individual's primary care provide should order HBsAg and total anti-HBc tests to determine their HBV infection status or immunologic issues.

References: https://www.immunize.org/ask-experts/?q=HB+series+completion; Hepatitis B Chapter, SK CDC Manual

Hepatitis B Re-Vaccination Assessment Algorithm

This algorithm provides guidance in determining if vaccination is required in individuals that were tested for Hepatitis B immunity for no specific reason and have been assessed as non-immune for Hepatitis B. This algorithm should be used in conjunction with the eligibility criteria in Chapter 10.

This algorithm does not supersede Chapter 7 – dialysis patients; Chapter 10 – health care workers; or Post-exposure management of Exposures to Hepatitis B as outlined in the CDC Manual or the Guidelines for Exposures to Blood and Body Fluids or testing for Hepatitis B due to clinical suspicion



Hepatitis B Series Completion Recommendations for Children 11-15 Years Old

If a student has an incomplete HAHB or HB series:

1. The PHN should recommend completion of the original HAHB series [1].
2. If parent wishes to complete HB only, follow these Saskatchewan Committee on Immunization's (SCOI) recommendations for the appropriate scenario [2].
3. Applies to students in Grade 6 who are younger than 11 years old.

#	Historical (Valid) Dose(s) & Vaccine(s) [3]	Dosing Recommendations / Comments
1	1) HAHB 0.5 ml at ≥ 6 months old	2) HB 0.5 ml min. 4 weeks later; then 3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
2	1) HAHB 0.5 ml at ≥ 6 months old 2) HAHB 0.5 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
3	1) HAHB 0.5 ml at ≥ 6 months old 2) HAHB 1 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HAHB & 3rd HB.
4	1) HAHB 0.5 ml at ≥ 6 months old 2) HB 0.5 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
5	1) HAHB 0.5 ml at ≥ 6 months old 2) HB 1 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
6	1) HAHB 1 ml at ≥ 6 months old	2) HB 1.0 ml ≥ 24 weeks (min. 16 weeks) later.
7	1) HAHB 1 ml at ≥ 6 months old 2) HB 0.5 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
8	1) HAHB 1 ml at ≥ 6 months old 2) HB 1 ml min. 4 weeks later but less than 16 weeks	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
9	1) HB 0.5 ml at any age 2) HAHB 0.5 ml at ≥ 6 months old, min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
10	1) HB 0.5 ml at any age 2) HAHB 1 ml at ≥ 6 months old, min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
11	1) HB 1 ml at any age 2) HAHB 0.5 ml at ≥ 6 months old, min. 4 weeks later but less than 16 weeks	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
12	1) HB 1 ml at any age 2) HAHB 1 ml at ≥ 6 months old, min. 24 weeks later	Considered complete (CIG HB Table 3).
13	1) HAHB 1 ml at ≥ 6 months old 2) HB 1 ml min. 24 weeks later	Considered complete (CIG HB Table 3).
14	1) HAHB 1 ml at ≥6 months old 2) HAHB 1 ml min. 24 weeks later	Considered complete (CIG HB Table 3).

[1] If completing with HAHB, document HB refusal. Document in the Comments section of the consent directives: "Parent intends to complete HAHB to complete series."

[2] Document consent grant.

[3] DTaP-HB-IPV-Hib doses are equivalent to HB 0.5 mL pediatric vaccine doses.

Hepatitis B Completion Scenarios (excluding children 11-15 years old)

- If a client was immunized by **Public Health in Saskatchewan**, SIM chapter 1, *Appendix 5.1 School Immunization Programs* **may be** consulted to determine the HB series the client was eligible for.
- If a client's documented immunization record does not show the HB-containing vaccine volumes **and** the client **was not immunized by Public Health in Saskatchewan** for previous doses in which a minimum 3-dose series has not been completed, it is recommended that:
  - 0.5 mL HB doses are administered to clients younger than 20 years of age at appropriate intervals to complete a 3-dose series.
  - 1 mL HB doses are administered to clients 20 years of age and older at appropriate intervals to complete a 3-dose series.
- **PHNs are to consult their regional MHO for case-by-case determination** before contacting the Ministry.

Scenario A: Client originally started on a 2-dose series when 11-15 years (or at 10 years old and in Grade 6):

#1 Q – A client between 16-19 years of age needs to complete the HB series. They received their first dose (1 mL) of a two dose series in Grade 6, when they were between 11-15 years of age. How should their series be completed?
#1 A – If the minimum interval of 4 weeks has passed since the first dose, and based on their age at this presentation, their schedule is complete when the get:

- A 2nd dose of 0.5 mL IM HB vaccine then;
- A 3rd dose of 0.5 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

#2 Q – A client aged ≥ 20 years needs to complete the HB series. They received their first dose (1 mL) of a two dose series in Grade 6, when they were between 11-15 years of age. How should their series be completed?
#2 A – If the minimum interval of 4 weeks has passed since the first dose, and based on their age at this presentation, their schedule is complete when the get:

- A 2nd dose of 1 mL IM HB vaccine then;
- A 3rd dose of 1 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

Scenario B: Client originally started on a 3-dose series of 0.5 mL

#3 Q – A client received their first and/or second dose(s) of 0.5 mL between 0-19 years, and presents between ages 0-19. How should the series be completed?
#3 A – Complete the series with 0.5 mL IM for each outstanding dose.

- A 2nd dose of 0.5 mL IM HB vaccine 4 weeks later (if required) then;
- A 3rd dose of 0.5 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

#4 Q – If client received first and/or second dose of 0.5 mL dose between 0-19 years and presents ≥ age 20 years or older. How should their series be completed?
#4 A – Complete the series with 1 mL IM for each outstanding dose.

- A 2nd dose of 1 mL IM HB vaccine 4 weeks later (if required) then;
- A 3rd dose of 1 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

Hepatitis B Vaccine (HB) (recombinant viral)

ENGERIX®-B

Product monograph available at https://pdf.hres.ca/dpd_pm/00073321.PDF

INDICATIONS	Refer to publicly funded HB vaccine indications
DOSE / SERIES [1, 2, 3, 4] **NOTE: Accelerated and Rapid vaccination schedules noted in the product monograph should not be administered for publicly funded indications.**	**Children from birth up to and including 19 years old:** • **USE ENGERIX-B pediatric formulation 10 mcg per 0.5 mL** 0.5 ml IM (10 mcg) at 0, 1 and 6 months[5] or refer to minimum intervals in Ch. 5.
	2-dose regimen for adolescents 11 to 15 years of age (including Grade 6 students younger than 11 years old): • **USE ENGERIX-B adult formulation 20 mcg per 1 mL** **Dose 1**: 1 mL (20 mcg) IM **Dose 2**: 1 mL (20 mcg) IM 6 months after dose 1
	Eligible adults 20 years and older: • **USE ENGERIX-B adult formulation 20 mcg per 1 mL** 1 ml (20 mcg) IM at 0, 1 and 6 months
	Those with renal disease, HIV and Congenital Immunodeficiency Disorder [3] Refer to SIM, Chapter 7, *Appendix 7.4 High Dose Hepatitis B Immunization Algorithm*
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any hepatitis B vaccine or to any component of Engerix-B.
VACCINE COMPONENTS	Each 1.0 mL adolescent/adult dose of vaccine contains 20 mcg of hepatitis B surface antigen adsorbed onto 0.5 mg of Al3+ as aluminum hydroxide. Each 0.5 mL pediatric dose contains 10 mcg of hepatitis B surface antigen adsorbed onto 0.25 mg of Al3+ as aluminum hydroxide. Aluminium (as aluminium hydroxide), disodium phosphate dihydrate, sodium chloride, sodium dihydrogen phosphate dihydrate, and water for injection. Preservative, thimerosal and latex free. Rubber stoppers.
EXPECTED REACTIONS	**Local:** Soreness, swelling and redness at injection site. **Systemic:** Headache, fatigue, fever, nausea and malaise.
EFFECTIVENESS	50-99% response-varies with age and immunocompetence.

[1] Engerix®-B & RecombivaxHB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the particular product.

[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 2.1, *Minimum Intervals for Specific Vaccine Series* for minimum interval scheduling.

[3] Those with renal disease, HIV and Congenital Immunodeficiency Disorder require a specific HB vaccine dosage and series; refer to SIM, Chapter 7, *Appendix 7.4 High Dose Hepatitis B Immunization Algorithm*.

[4] High risk infants less than 2000 g require 4 dose series. Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 4.2.1, *Hepatitis B Infant Immunoprophylaxis Protocol.*

[5] Infant must be at least 24 weeks of age to receive 3rd dose.

- If a client was immunized by Public Health in Saskatchewan, SIM Chapter 1, Appendix 5.1 School Immunization Programs may be consulted to determine the HB series the client was eligible for.
- If a client's documented immunization record does not show the HB-containing vaccine volumes and the client was not immunized by Public Health in Saskatchewan for previous doses in which a minimum 3-dose series has not been completed, it is recommended that:
  - 0.5 mL HB doses are administered to clients younger than 20 years of age at appropriate intervals to complete a 3-dose series.
  - 1 mL HB doses are administered to clients 20 years of age and older at appropriate intervals to complete a 3-dose series.
  - PHNs are to consult their regional MHO for case-by-case determination before contacting the Ministry.

Hepatitis B Vaccine (recombinant)

RECOMBIVAX HB®

Product monograph available at: https://pdf.hres.ca/dpd_pm/00016542.PDF

INDICATIONS	Refer to publicly funded HB vaccine indications
DOSE / SERIES [1, 2, 3, 4]	**Eligible children from birth up to and including 19 years:** • **USE RECOMBIVAX® HB pediatric formulation 5 mcg per 0.5 mL** 0.5 ml IM (5 mcg) at 0, 1 and 6 months[5] or refer to minimum intervals in Ch. 5.
	2-dose regimen for adolescents 11 to 15 years of age (including Grade 6 students younger than 11 years old): • **USE RECOMBIVAX ® HB adult formulation 10 mcg per 1 mL** **Dose 1**: 1 mL (10 mcg) IM **Dose 2**: 1 mL (10 mcg) IM 6 months after dose 1
	Eligible adults 20 years and older: • **USE RECOMBIVAX ® HB adult formulation 10 mcg per 1 mL** 1 mL (10 mcg) IM at 0, 1 and 6 months
	Those with renal disease, HIV and Congenital Immunodeficiency Disorder [3] Refer to SIM, Chapter 7, *Appendix 7.4 High Dose Hepatitis B Immunization Algorithm*
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any hepatitis B vaccine or to any component of RECOMBIVAX® HB.
PRECAUTION	Use caution when vaccinating latex-sensitive individuals since the vial stopper contains dry natural latex rubber that may cause allergic reactions.
VACCINE COMPONENTS	Hepatitis B surface antigen. **Excipients:** Aluminum (as amorphous aluminum hydroxyphosphate), sodium chloride, sodium borate, water for injection. **Manufacturing Process Residuals**: Each dose contains less than 1% yeast protein. The vaccine also contains < 15 mcg/mL formaldehyde as all preparations have been treated with formaldehyde prior to adsorption onto amorphous aluminum hydroxyphosphate. Thimerosal free.
EXPECTED REACTIONS	**Local:** Soreness, swelling and redness at injection site. **Systemic**: Headache, fatigue, fever, nausea and malaise.
EFFECTIVENESS	50-99% response-varies with age and immunocompetence.

[1] Engerix®-B & RECOMBIVAX HB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the particular product.

[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 2.1, *Minimum Intervals for Specific Vaccine Series* for minimum interval scheduling.

[3] Those with renal disease, HIV and Congenital Immunodeficiency Disorder require a specific HB vaccine dosage and series; refer to SIM, Chapter 7, *Appendix 7.4 High Dose Hepatitis B Immunization Algorithm*.

[4] High risk infants less than 2000 g require 4 dose series. Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 4.2.1, *Hepatitis B Infant Immunoprophylaxis Protocol.*

[5] Infant must be at least 24 weeks of age to receive 3rd dose.

- If a client was immunized by **Public Health in Saskatchewan**, SIM Chapter 1, *Appendix 5.1 School Immunization Programs* **may be** consulted to determine the HB series the client was eligible for.
- If a client's documented immunization record does not show the HB-containing vaccine volumes **and** the client **was not immunized by Public Health in Saskatchewan** for previous doses in which a minimum 3-dose series has not been completed, it is recommended that:
  - 0.5 mL HB doses are administered to clients younger than 20 years of age at appropriate intervals to complete a 3-dose series.
  - 1 mL HB doses are administered to clients 20 years of age and older at appropriate intervals to complete a 3-dose series.
  - **PHNs are to consult their regional MHO for case-by-case determination** before contacting the Ministry.

Hepatitis B Vaccine
(3-antigen Hepatitis B Vaccine (recombinant)) [Non-publicly funded]

PREHEVBRIO™
(VBI Vaccines 2023 product monograph available at (https://pdf.hres.ca/dpd_pm/00069966.PDF)

Herpes Zoster Vaccine (RZV)

(non-live recombinant, AS01$_B$ adjuvanted)

Shingrix™

Product monograph: https://pdf.hres.ca/dpd_pm/00077982.PDF

Eligibility as of June 2, 2025	• Solid organ transplant candidates and recipients 18 years and older. • Autologous, CAR-T therapy and allogeneic hematopoietic stem cell recipients 18 years and older.
Dosage & route	0.5 mL IM Administer the entire volume of the reconstituted product.
Series	**Dose 1**: Day 0 **Dose 2**: 6 months later (min. 4 weeks acceptable for SOT candidates /recipients **AND** all HSCT recipients)
Adult SOT candidate recommendations	• **The RZV series should be completed at least 2 weeks prior to transplant**. • **SOT candidates who are VZV seropositive AND who have not had *Herpes zoster* infection within 1 year:** o Includes SOT candidates previously immunized with LZV (Zostavax®). o A 1-year interval is currently recommended: ▪ between LZV and RZV; and ▪ *Herpes zoster* infection and immunization with RZV. • **If the SOT candidate is VZV seronegative:** o Do not give RZV AND follow varicella immunization recommendations in SIM Appendix 7.9. ▪ An 8-week spacing interval is required between the last dose in the varicella series and the first RZV dose.
Adult SOT recipient recommendations	• **SOT recipient immunizations may commence once they are on baseline immunosuppression, usually 6-12 months after transplant, AND as determined appropriate by the individual's attending transplant physician.** o Includes SOT recipients previously immunized with LZV (Zostavax®). o A 1-year interval is currently recommended: ▪ between LZV and RZV; and ▪ *Herpes zoster* infection and immunization with RZV • The Saskatchewan Transplant Program has confirmed **that a patient clearance letter is not required to begin or resume immunizations** for SOT recipients.
Adult autologous HSCT and CAR-T therapy recipient recommendations	• **Autologous HSCT and CAR-T therapy recipients who are VZV seropositive AND who have not had *Herpes zoster* infection within the past 6 months AND are at least 6 months post-transplant.** • **If the autologous HSCT and CAR-T therapy recipient is VZV seronegative:** o Do not give RZV **AND** follow varicella immunization recommendations in SIM Appendix 7.6. o Commence the RZV series starting 36 months post-transplant.
Adult allogeneic HSCT recipient recommendations	• **Allogeneic HSCT recipients who are VZV seropositive AND who have not had *Herpes zoster* infection within the past 6 months AND are at least 2 years post-transplant AND are at least 12 months off immunosuppression AND have no flare of GVHD**. • **If the allogeneic HSCT recipient is VZV seronegative:** o Do not give RZV **AND** follow varicella immunization recommendations in SIM Appendix 7.6. o Commence the RZV series starting 36 months post-transplant

Herpes Zoster Vaccine (RZV) (non-live recombinant, $AS01_B$ adjuvanted)
Shingrix™ Product monograph: https://pdf.hres.ca/dpd_pm/00077982.PDF

Contraindications	• Persons with active HZ should not be immunized with RZV. • Known hypersensitivity to the active substance or to any component of the vaccine. • Anaphylaxis to a previous dose of the vaccine.
Possible reactions	**Local:** pain, redness, swelling, tenderness at injection site. **Systemic**: myalgia, fatigue, headache, shivering, fever, nausea, vomiting, diarrhea, and/or abdominal pain. **Post-market reported reactions**: hypersensitivity reactions including rash, urticaria, angioedema. Very rare cases of Guillain-Barré syndrome have been reported and data is inconclusive to prove causation.
Vaccine components	Each dose contains 50 mcg Varicella Zoster Virus (VZV) glycoprotein E (gE). Non-medicinal ingredients: Cholesterol, dioleoyl phosphatidylcholine, dipotassium phosphate, disodium phosphate anhydrous, polysorbate 80, potassium dihydrogen phosphate, Quillaja saponaria Molina, fraction 21 (QS-21), 3-O-desacyl-4'-monophosphoryl lipid A (MPL), sodium chloride, sodium dihydrogen phosphate dihydrate, sucrose, water for injection

Human Papillomavirus Vaccine

[Non-publicly funded]

CERVARIX® (HPV-2)

Product monograph available at: https://pdf.hres.ca/dpd_pm/00073320.PDF

Human Papillomavirus 9-valent Vaccine (recombinant)

GARDASIL®9 (HPV-9)

Product monograph available at: https://pdf.hres.ca/dpd_pm/00078187.PDF

PUBLICLY FUNDED INDICATIONS	• Grade 6 students
	• As of April 1, 2025: All individuals eligible to start series through 26 years old.
	• Immunocompromised individuals aged 9 up to and including 26 years old.
	NOTE: Individuals who are eligible to receive publicly funded HPV-9 vaccine must start their series prior to age 27:
	  • If their first dose is given prior to age of 27, then subsequent publicly funded doses can be given to complete series after this age.
	  • If series is not started before 27th birthday, they are ineligible to start a publicly funded series.

SERIES
 	
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Note: immune compromised individuals must always receive a 3-dose HPV series.
	• **2-dose schedule**: 0.5 mL IM at 0 and 6 months for those 9 to 14 years of age
	  ➢ Persons who received their first HPV dose before their 15th birthday **must** complete the 3-dose schedule if they present for their second dose after their 15th birthday.
	• **3-dose schedule**: 0.5 mL IM at 0, 2, and 6 months for eligible immune competent persons ≥15 years of age up to and including 26 years of age (ineligible at 27th birthday).
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	• **3-dose schedule**: 0.5 mL IM at 0, 2, and 6 months individuals aged 9 up to and including 26 years of age with the following risk factors (ineligible at 27th birthday). **NOTE: Birth cohort eligibility (as described above under Publicly Funded Indications) does not apply to these risk factors; age at presentation applies.**
	  ➢ Immunocompromised – Acquired complement deficiency
	  ➢ Immunocompromised – Congenital immunodeficiency
	  ➢ Immunocompromised – HIV
	  ➢ Immunocompromised – Related to Disease
	  ➢ Immunocompromised – Treatment – Additional Information

REINFORCEMENT	Currently no recommendations.
NOTE	GARDASIL®9 should be used to complete an HPV series that was initiated with HPV-u, HPV-2 or HPV-4. Clients should be informed that a complete series of GARDASIL®9 is recommended to ensure protection against the five additional HPV types in the vaccine; however, additional doses of GARDASIL®9 beyond a complete HPV series for healthy or immune compromised individuals **are not part of the publicly-funded program**.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of a HPV vaccine, or to any component of GARDASIL®9.

Human Papillomavirus 9-valent Vaccine (recombinant)

GARDASIL®9 (HPV-9)

VACCINE COMPONENTS	Each 0.5-mL dose contains approximately 30 mcg of HPV Type 6 L1 protein, 40 mcg of HPV Type 11 L1 protein, 60 mcg of HPV Type 16 L1 protein, 40 mcg of HPV Type 18 L1 protein, 20 mcg of HPV Type 31 L1 protein, 20 mcg of HPV Type 33 L1 protein, 20 mcg of HPV Type 45 L1 protein, 20 mcg of HPV Type 52 L1 protein, and 20 mcg of HPV Type 58 L1 protein, approximately 500 mcg of aluminum (as Amorphous Aluminum Hydroxyphosphate Sulfate adjuvant), 0.78 mg of L-histidine, 50 mcg of polysorbate 80, 35 mcg of sodium borate, 9.56 mg of sodium chloride, and water for injection. Latex, antibiotic and preservative free.
EXPECTED REACTIONS	**Local:** Mild to moderate pain, swelling, erythema and pruritus at injection site. **Systemic:** Headache, tiredness, fever, nausea, dizziness. **Reported post-market**: vomiting, swollen glands (neck, armpit, or groin), Guillain-Barré syndrome, joint pain, aching muscles, unusual tiredness, weakness, or confusion, chills, stomachache, muscle weakness, leg pain, shortness of breath, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection.
EFFECTIVENESS	Please refer to the product monograph for data for females and males in specific age categories.
OTHER CONSIDERATIONS	• Immunization with HPV vaccine does not remove the need for screening for cervical, vulvar, vaginal, anal, and certain head and neck cancers, such as oral, throat and back of mouth cancers as recommended by a health care professional; women should still get routine cervical cancer screening. • It is not known whether GARDASIL®9 is excreted in human milk. • There are no adequate and well-controlled studies in pregnant individuals. Because animal reproduction studies are not always predictive of human response, pregnancy should be avoided during the vaccination regimen for GARDASIL®9. **Pregnancy is NOT a contraindication for HPV-9 immunization**, however, individuals who become pregnant before completion of the vaccine series **may choose to defer** their vaccination schedule until after childbirth. Pregnant individuals exposed to GARDASIL® are encouraged to report their exposure or suspected adverse reactions by contacting Merck Canada Inc., at 1-800-567-2594.

Influenza Vaccines [Non-Publicly Funded]

FLUAD® Pediatric and FLUAD®, and FLUCELVAX® QUAD
Seqirus product monographs available at https://www.cslseqirus.ca/products

FLUMIST® QUADRAVALENT
AstraZeneca product monograph available at https://www.astrazeneca.ca/en/our-medicines.html

Supemtek®
Sanofi Pasteur product monograph available at https://www.sanofi.ca/en/products-and-resources/vaccines

Influenza Vaccine (Inf) 2024-25
(inactivated split virion)

AFLURIA® TETRA
https://www.cslseqirus.ca/-/media/seqirus-canada/docs-en/afluria-tetra_en-clean-pm_asu-2024-2025_watermark.pdf

INDICATION	**DOSE / SERIES (Min. 5 years old)**		
Prevention of seasonal influenza **in those 5 years and older**	**Age group**	**Dosage**	**No. of Doses**
	5-8 years	**0.5 mL**	**1 or 2** [1]
	9 years and older	**0.5 mL**	**1**
CONTRA-INDICATIONS	1. AFLURIA® TETRA is contraindicated in individuals with known severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine, or to a previous dose of any influenza vaccine. 2. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. 3. Children younger than 5 years old.		
PRECAUTIONS	Severe oculo-respiratory syndrome (ORS) after a previous dose of influenza vaccine.		
VACCINE COMPONENTS	Each 0.5 mL dose of vaccine contains 15 micrograms haemagglutinin of each of the following four influenza virus strains: A/Victoria/4897/2022 (H1N1)pdm09-like virus (A/Victoria/4897/2022 IVR-238); A/Thailand/8/2022 (H3N2)-like virus (A/Thailand/8/2022 IVR-237); B/Austria/1359417/2021-like virus (B/Austria/1359417/2021 BVR-26); B/Phuket/3073/2013-like virus (B/Phuket/3073/2013 BVR-1B). Non-medicinal ingredient: calcium chloride, dibasic sodium phosphate (anhydrous), monobasic potassium phosphate, monobasic sodium phosphate, potassium chloride, sodium chloride, thimerosal* and water for injection. Each dose may also contain sodium taurodeoxycholate, ovalbumin (egg proteins) and trace amounts of beta-propiolactone, neomycin sulfate, polymyxin B sulfate, hydrocortisone and sucrose. *Multi-dose vials contain thimerosal. Latex-free.		
EXPECTED REACTIONS	In adults 18 to < 65 years, the most commonly reported injection-site adverse reaction observed in clinical studies with AFLURIA® TETRA was pain (≥ 40%). The most common systemic adverse events observed were myalgia and headache (≥ 20%). In adults ≥ 65 years of age, the most commonly reported injection-site adverse reaction observed in clinical studies with AFLURIA® TETRA was pain (≥ 20%). The most common systemic adverse event observed was myalgia (≥ 10%). In children 5 to < 18 years of age, the most commonly reported injection-site adverse reactions observed in clinical studies with AFLURIA® TETRA were pain (51.4%), redness (17.1%), and swelling (13.8%). The most common systemic adverse events were headache (15.5%) and myalgia (13.1%).		
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.		
STORAGE & HANDLING	Discard multi-dose vials 28 days after first entry. Protect from light. Do not freeze.		
EFFECTIVENESS	Refer to product monograph as data depends on age and studies design.		

[1] Children under 9 years of age who have not previously received seasonal influenza vaccine require 2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required.

Influenza Vaccine (Inf)
(inactivated split virion)

FLULAVAL TETRA®

GSKproduct monograph https://ca.gsk.com/en-ca/products/flulaval-tetra/

INDICATION	**DOSE / SERIES (Min. 6 months old)**		
Prevention of seasonal influenza	**Age group**	**Dosage**	**No. of Doses**
	6 months-8 years	**0.5 mL**	**1 or 2** [1]
	9 years and older	**0.5 mL**	**1**
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine. 2. History of anaphylactic reaction to any component of any influenza vaccine. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. 4. Infants less than 6 months of age.		
PRECAUTIONS	Severe oculo-respiratory syndrome (ORS) after a previous dose of influenza vaccine.		
VACCINE COMPONENTS	Each 0.5 mL dose of vaccine contains 15 micrograms haemagglutinin of each of the four influenza virus strains recommended annually by the WHO. The vaccine is formulated with phosphate buffered saline composed of sodium chloride, potassium chloride, disodium hydrogen phosphate heptahydrate, potassium dihydrogen phosphate and water for injection. Each 0.5 mL dose contains, α-tocopheryl hydrogen succinate (267 μg), and polysorbate 80 (683 μg). Each 0.5 mL dose may also contain residual amounts of egg proteins (ovalbumin ≤0.3μg), sodium deoxycholate, ethanol, formaldehyde and sucrose from the manufacturing process. The multidose vial presentation contains thimerosal, a mercury derivative, added as a preservative. Each 0.5 mL dose contains 50 mcg thimerosal. The single-dose prefilled syringe presentation does not contain thimerosal or any other preservative. Antibiotics are not used in the manufacture of this vaccine.		
EXPECTED REACTIONS	In adults, the most common (≥10%) solicited local reaction was pain (60%); the most common solicited systemic adverse events were myalgia (26%), headache (22%), fatigue (22%), and arthralgia (15%). In children 3 to 17 years of age, the most common (≥10%) solicited local reaction was pain (65%). In children 3 to 4 years of age, the most common (≥10%) solicited systemic adverse events were irritability (26%), drowsiness (21%), and loss of appetite (17%). In children 5 to 17 years of age, the most common (≥10%) systemic adverse events were muscle aches (29%), fatigue (22%), headache (22%), arthralgia (13%), and gastrointestinal symptoms (10%). In children 6 to 35 months of age, injection site pain was the most common (≥10%) solicited local reaction (40%). The most common solicited systemic adverse events were irritability (49%), drowsiness (37%), and loss of appetite (29%).		
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.		
SPECIAL CONSIDERATIONS	Discard multi-dose vials 28 days after first entry. Protect from light. Do not freeze.		
EFFECTIVENESS	Refer to product monograph as data depends on age and studies design.		

[1] Children under 9 years of age who have not previously received seasonal influenza vaccine require 2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required.

Influenza Vaccine (Inf)
(inactivated quadrivalent split virion)

FLUZONE® Quadrivalent

Sanofi Pasteur product monograph:
https://www.sanofi.com/assets/countries/canada/docs/products/vaccines/fluzone-qiv-en.pdf

INDICATION	**DOSE / SERIES (Min. 6 months old)**		
Prevention of seasonal influenza	Age group	Dosage	No. of Doses
	6 months-8 years	0.5 mL	1 or 2 [1]
	9 years and older	0.5 mL	1
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine. 2. History of anaphylactic reaction to any component of any influenza vaccine. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. 4. Infants less than 6 months of age.		
PRECAUTIONS	Severe oculo-respiratory syndrome (ORS) after previous receipt of an influenza vaccine.		

VACCINE COMPONENTS	FLUZONE® Quadrivalent 0.5 mL dose contains 15 mcg HA of each of the four influenza strains recommended annually by the WHO. Each 0.5 mL dose: ≤100 mcg formaldehyde, up to 0.5 mL sodium phosphate buffered, isotonic sodium chloride solution and ≤250 mcg Triton® X-100. 0.01% w/v thimerosal in multidose presentation only (25 mcg mercury/0.5 mL dose). Latex, antibiotic and gelatin free.
EXPECTED REACTIONS	**Very common (≥10%)**: pain at the injection site, myalgia, headache, myalgia and malaise. **Common (≥1% to <10%)**: shivering; redness, swelling, induration and ecchymosis at the injection site, fever. **Children 6 months-35 month** of age also experienced irritability, abnormal crying, drowsiness, loss of appetite and vomiting.
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.
SPECIAL CONSIDERATIONS	Protect vials from light. A multidose vial of FLUZONE® Quadrivalent which has been entered and stored at 2° to 8° C may be used up to the expiry date indicated on the vial label. Do not freeze.
EFFECTIVENESS	Refer to product monograph as data depends on age and studies design.

[1] Children under 9 years of age who have not previously received seasonal influenza vaccine require 2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required.

Influenza High Dose Vaccine (InfHD QIV)
(inactivated trivalent split virion)

FLUZONE® High Dose Quadrivalent

Sanofi Pasteur product monograph:
https://www.sanofi.com/assets/countries/canada/docs/products/vaccines/fluzone-qiv-hd-en.pdf

INDICATION	Prevention of seasonal influenza in those ≥ 65 years old
DOSE / SERIES	0.7 mL IM annually.
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine 2. History of anaphylactic reaction to any component of any influenza vaccine. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified.
PRECAUTIONS	Severe oculo-respiratory syndrome (ORS) after previous receipt of an influenza vaccine.
VACCINE COMPONENTS	FLUZONE® High Dose contains: 60 mcg HA of each influenza strain recommended annually by the WHO. Each dose: ≤ 350 mcg octylphenol ethoxylate (Triton® X-100), ≤ 200 mcg/mL formaldehyde and up to 0.7 mL sodium phosphate buffered, isotonic sodium chloride solution. Each dose may contain traces of ovalbumin. Latex, antibiotic and thimerosal free.
EXPECTED REACTIONS	The most common reactions occurring after FLUZONE® High-Dose Quadrivalent administration were injection site pain (41%), myalgia (23%), headache (14%) and malaise (13%). Onset usually occurred within the first 3 days after vaccination. The majority of solicited reactions resolved within three days of vaccination.
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.
SPECIAL CONSIDERATIONS	Protect vials from light. Do not freeze. Shake the prefilled syringe well to uniformly distribute the suspension before administering the dose.
EFFECTIVENESS	Immunogenicity of FLUZONE® High-Dose Quadrivalent was found to be non-inferior to FLUZONE® High-Dose. The pre-defined non-inferiority immunogenicity criteria for FLUZONE® High-Dose Quadrivalent were met for both GMTs and seroconversion rates for all four of the influenza strains common between the two vaccines. Additionally, FLUZONE® High-Dose Quadrivalent induced a higher immune response, as measured by GMTs and seroconversion rates, with respect to the additional B strain than the immune response induced by FLUZONE® High Dose that does not contain the corresponding B virus.

Japanese Encephalitis Vaccine

[Non-publicly funded]

IXIARO®

Product monograph available at: https://valneva.com/products/valnevas-products/

Measles-Mumps-Rubella Vaccine (MMR)

(live, attenuated)

M-M-R® II

(Merck Canada Inc. product monograph available at:https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/MMR_II-PM_E.pdf)

INDICATIONS [1] ▪ Series for those born **since** January 1, 1970 who are 12 months and older. According to CIG, 1 dose of rubella is considered sufficient for immunity in all ages. Refer to *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.* ▪ Recommended for post-exposure prophylaxis of measles contacts as outlined in the Saskatchewan Communicable Disease Control Manual. ▪ **Additional indications** as noted in SIM Chapter 5 *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.* • 1 dose for some adult travellers born before January 1, 1970. • Infants 6-11 months old who are travelling abroad may be offered 1 early publicly funded dose of MMR.	**DOSE / SERIES** **Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC minimum 4 weeks later ***MMR II may be given IM as per the product monograph, but SC recommended for practice consistency.***

REINFORCEMENT	Not indicated after 2 MMR doses.
PRECAUTIONS	• MMR should be given at the same time as other live vaccines. Otherwise there must be 4 or more weeks between administering live vaccines. • For immune compromised clients only: separate the administration of MMR and Var by 4 weeks. • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 weeks. • Family history of congenital immunodeficiency. Refer to SIM, Chapter 6, *Contraindication and Precautions.* • Physician or NP diagnosed thrombocytopenia within 6 weeks after first dose of a MMR-containing vaccine.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella-containing vaccine, to any component of MMRII. • **Immunocompromised individuals unless determined by their specialist.** Refer to SIM, Chapter 7, *Immunization of Special Populations,* under specific condition for information. • Pregnancy. Counsel female recipients to avoid pregnancy for 1 month following immunization. Inadvertent immunization during pregnancy is not considered a medical indication for therapeutic abortion. • People with active untreated tuberculosis. • Recent administration of an immune globulin preparation **(excluding RhoGam [RhIg])** or blood product. [1]
VACCINE COMPONENTS	Measles virus, Enders' Edmonston strain (live, attenuated); Mumps virus, Jeryl Lynn® (B level) strain (live, attenuated); and Rubella virus, Wistar RA 27/3 strain (live, attenuated). **Excipients**: sorbitol, hydrolyzed gelatin, medium 199 with Hank's salts, sodium phosphate monobasic, sodium phosphate dibasic (anhydrous), sucrose, sodium bicarbonate, minimum essential medium (Eagle), potassium phosphate dibasic (anhydrous), neomycin, monosodium L-glutamate monohydrate, potassium phosphate monobasic, phenol red, water for injection. **Manufacturing process residuals:** Recombinant human albumin, fetal bovine serum, may contain minute quantities of egg protein. Preservative, latex and thimerosal free.

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated)	
EXPECTED REACTIONS	**Local:** Tenderness, redness, swelling, induration, wheal and flare reaction, urticaria. **Systemic:** • A fever lasting up to 3 days may occur 6 to 23 days after immunization. Monitor your child and treat their fever **if** they are uncomfortable, refusing fluids and not sleeping. • Swelling of the jawline (salivary glands), cheeks and neck 7 to 12 days later. • A blotchy red rash 4 to 12 days later. • Joint or muscle aches and pain. • Nausea, vomiting, diarrhea or decreased appetite. • Headache, dizziness, fussiness, tiredness. • Lymph nodes swelling near the immunized limb. **Extremely rare** reactions may include: • A temporary drop in the number of blood cells (platelets) that prevent bleeding (thrombocytopenia) within 6 weeks of being immunized. In most people, this resolves within 3 months without serious complications. • Encephalitis (less than 1 in a million). The risk of encephalitis from measles disease is about 1 in 1,000, which is much higher than from this vaccine.
SPECIAL CONSIDERATION	Re: Immunization of immunocompromised clients - consult the appropriate physician (i.e., either the primary care physician most familiar with the client's current medical status or a medical specialist) and obtain a completed *MMR Immunization Referral Form* (Chapter 7, *Immunization of Special Populations,* Appendix 7.3) before immunization.
EFFECTIVENESS	After 1st dose, 85-95% protection to measles; 95.5% to mumps; 99.3% to rubella. After 2nd dose 100% protection to all antigens.

[1] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.51, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

Measles-Mumps-Rubella Vaccine (MMR)

(live, attenuated)

PRIORIX®

Product monograph available at: https://ca.gsk.com/en-ca/products/priorix/

INDICATIONS ▪ Series for those born **since** January 1, 1970 who are 12 months and older. According to CIG, 1 dose of rubella is considered sufficient for immunity in all ages. Refer to *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.* ▪ Recommended for post-exposure prophylaxis of measles contacts as outlined in the Saskatchewan Communicable Disease Control Manual. ▪ **Additional indications** as noted in SIM Chapter 5 *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.* • 1 dose for some adult travellers born before January 1, 1970. • Infants 6-11 months old who are travelling abroad may be offered 1 early publicly funded dose of MMR.	**DOSE / SERIES** **Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC minimum 4 weeks later
REINFORCEMENT	Not indicated after 2 MMR doses.
PRECAUTIONS	• MMR should be given at the same time as other live vaccines. Otherwise there must be 4 weeks between administering live vaccines. • For immune compromised clients only: separate the administration of MMR and Var by 4 weeks. • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 weeks. • Family history of congenital immunodeficiency. Refer to SIM, Chapter 6, *Contraindication and Precautions.* • Physician-diagnosed thrombocytopenia within 6 weeks after first dose of a MMR-containing vaccine.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella-containing vaccine, to any component of Priorix, or to latex when administering Priorix with the pre-filled syringe (latex is present in the pre-filled syringe of diluent for Priorix). • **Immunocompromised individuals unless determined by their specialist**. Refer to SIM, Chapter 7, *Immunization of Special Populations,* under specific condition for information. • Pregnancy. Counsel female recipients to avoid pregnancy for 1 month following immunization. Inadvertent immunization during pregnancy is not considered a medical indication for therapeutic abortion. • People with active untreated tuberculosis. • Recent administration of an immune globulin preparation **(excluding RhoGam [RhIg])** or blood product [1]
VACCINE COMPONENTS	Not less than: $10^{3.0}$ $CCID_{50}$ of the Schwarz measles; $10^{3.7}$ $CCID_{50}$ of the RIT 4385 mumps; and $10^{3.0}$ $CCID_{50}$ of the Wistar RA 27/3 rubella virus strains/ per 0.5 mL dose, and amino acids, lactose, mannitol and sorbitol. Residual: neomycin sulphate. Vaccine and diluent vial stoppers made of natural rubber. Thimerosal free. The vaccine may contain minute quantities of egg protein

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated)

EXPECTED REACTIONS	**Local:** Pain, redness, swelling, induration, wheal and flare reaction, urticaria. **Systemic:** • A fever lasting up to 3 days may occur 6 to 23 days after immunization. Monitor your child and treat their fever **if** they are uncomfortable, refusing fluids and not sleeping. • Pain, swelling and redness where the needle was given. • Swelling of the jawline (salivary glands), cheeks and neck 7 to 12 days later. • A blotchy red rash 4 to 12 days later. • Joint or muscle aches and pain. • Nausea, vomiting, diarrhea or decreased appetite. • Headache, dizziness, fussiness, tiredness. • Lymph nodes swelling near the immunized limb. **Extremely rare** reactions may include: • A temporary drop in the number of blood cells (platelets) that prevent bleeding (thrombocytopenia) within 6 weeks of being immunized. In most people, this resolves within 3 months without serious complications. • Encephalitis (less than 1 in a million). The risk of encephalitis from measles disease is about 1 in 1,000, which is much higher than from this vaccine.
SPECIAL CONSIDERATIONS	Re: Immunization of immunocompromised clients - consult the appropriate physician (i.e., either the primary care physician most familiar with the client's current medical status or a medical specialist) and obtain a completed *MMR Immunization Referral Form* (Chapter 7, *Immunization of Special Populations,* Appendix 7.3) before immunization.
EFFECTIVENESS	After 1st dose, 85-95% protection to measles; 95.5% to mumps; 99.3% to rubella. After 2nd dose 100% protection to all antigens.

[1] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

Measles-Mumps-Rubella-Varicella Vaccine (MMRV)

(live, attenuated)

PRIORIX-TETRA™

Product monograph available at https://ca.gsk.com/en-ca/products/priorix-tetra/

INDICATION [1]	**DOSE / SERIES**[2, 3, 4]
Healthy children 1 year up to and including 12 years of age who require protection against MMR and varicella diseases.	**Dose 1**: 0.5 mL SC (at 12 months) **Dose 2**: 0.5 mL SC (at 18 months) **NOTE:** According to CIG, 1 dose of rubella is considered sufficient for immunity in all ages. Refer to *Appendix 5.2: Publicly Funded MMR Vaccine Eligibility.*
PRECAUTIONS	• Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine. • Physician-diagnosed thrombocytopenia within 6 weeks after first dose of a MMR-containing vaccine. • Family history of congenital immunodeficiency. Refer to SIM Chapter 7, *Immunization of Special Populations* Section 3.1, *Congenital Immunodeficiency* • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 or more weeks. • Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours, as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG). • It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella or varicella-containing vaccine, to any component of PRIORIX-TETRA™. • Recent administration of an immune globulin preparation or blood product [3]. • Pregnancy. • People with active untreated tuberculosis. • Immunocompromised individuals.
VACCINE COMPONENTS	Live, attenuated measles virus (Schwarz strain) not less than $10^{3.0}$ $CCID_{50}$; Live, attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than $10^{4.4}$ $CCID_{50}$; Live, attenuated rubella virus (Wistar RA 27/3 strain) not less than $10^{3.0}$ $CCID_{50}$; Live, attenuated varicella virus (Oka strain) not less than $10^{3.3}$ PFU; amino acids for injection, lactose, mannitol, neomycin sulphate, sorbitol, water for injection. Vaccine and diluent vial stoppers contain rubber. The measles and mumps components of the vaccine are produced in chick embryo cell culture and may therefore contain traces of egg protein. Thimerosal free. Latex-free

:

Measles-Mumps-Rubella-Varicella Vaccine (MMRV)

(live, attenuated)

PRIORIX-TETRA™

EXPECTED REACTIONS	**Local:** Pain, redness and swelling. **Systemic**: • A fever lasting up to 3 days may occur 7 to 10 days after getting this vaccine. Monitor your child and treat their fever (at least 6 to 8 hours after immunization) **if** they are uncomfortable, refusing fluids and not sleeping. • Less than 1 in 3,000 children with high fevers after getting their first dose of MMRV **may** have a febrile seizure. **Febrile seizures are temporary and not harmful to the child. If you are concerned, please talk to a public health nurse.** • Swelling of the jawline (salivary glands), cheeks and neck 7 to 12 days later. • Joint or muscle aches and pain. • Nausea, vomiting, diarrhea or decreased appetite. • Headache, dizziness, fussiness, tiredness. • Lymph nodes swelling near the immunized limb. • A blotchy red rash 4 to 12 days later. • A varicella-like (blister) rash 5 to 26 days after getting immunized. People who have this rash rarely spread the vaccine virus to others. To prevent possible viral spreading, the rash should be covered until the blisters have dried and crusted over**.** **Extremely rare** reactions may include: • A temporary drop of the number of blood cells (platelets) that prevent bleeding (thrombocytopenia) within 6 weeks of being immunized. In most people, this resolves within 3 months without serious complications. • Encephalitis (less than one in one million). The risk of encephalitis from measles disease is about one in 1,000, which is much higher than from this vaccine.
ADVERSE EVENTS	Following the administration of the first dose of PRIORIX-TETRA®, higher incidences of fever (approximately 1.5 fold) were observed when compared to the concomitant administration of PRIORIX® [*MMR*] and VARILRIX® vaccines at separate injection sites (p.6). Review fever management with client.
EFFECTIVENESS	One year after 2nd MMRV dose, 98.8% of all children were protected measles, rubella and varicella and 90.6% were protected against mumps.

[1] Minimum age for vaccine is 9 months in the product monograph and applies to exceptional circumstances only approved by a MHO.

[2] There must be 4 weeks minimum spacing between MMRV doses

[3] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

[4] Individuals who are eligible for a 2-dose varicella series who have **documentation of lab confirmed** varicella after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose as they will have developed immunity. Provide a second dose of varicella-containing vaccine to those without this documentation.

[5] MMRV vaccines are considered interchangeable.

Measles-Mumps-Rubella-Varicella Vaccine (MMRV)

(live, attenuated)

ProQuad™

Product monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/PROQUAD-PM_E.pdf

INDICATION [1]	**DOSE / SERIES** [2, 3, 4]
Healthy children 1 year up to and including 12 years of age who require protection against MMR and varicella diseases.	**Dose 1**: 0.5 mL SC (at 12 months) **Dose 2**: 0.5 mL SC (at 18 months) **NOTE:** According to CIG, 1 dose of rubella is considered sufficient for immunity in all ages. Refer to Appendix 5.2: *Publicly Funded MMR Vaccine Eligibility.*
PRECAUTIONS	• Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine. • Physician-diagnosed thrombocytopenia within 6 weeks after first dose of a MMR-containing vaccine. • Family history of congenital immunodeficiency. Refer to SIM Chapter 7, *Immunization of Special Populations* Section 3.1, Congenital Immunodeficiency • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 or more weeks. • Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided in the peri-immunization period, as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG). • It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella or varicella-containing vaccine, or to any component of ProQuad™**.** • Recent administration of an immune globulin preparation or blood product [3]. • Pregnancy. • People with active untreated tuberculosis. • Immunocompromised individuals.
VACCINE COMPONENTS	Live, attenuated measles virus derived from Enders' attenuated Edmonston strain; live, attenuated mumps virus (JERYL LYNN® (B level) strain; live, attenuated rubella virus (Wistar RA 27/3 strain); live, attenuated Oka/Merck strain of varicella-zoster virus; sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate, potassium chloride, residual components of MRC-5 cells including DNA and protein, neomycin, bovine serum albumin and other buffer and media ingredients. The vaccine may contain minute quantities of egg protein. Preservative, latex and thimerosal free.

Measles-Mumps-Rubella-Varicella Vaccine (MMRV) (live, attenuated)

ProQuad™

EXPECTED REACTIONS	**Local:** Pain, redness and swelling. **Systemic**: • A fever lasting up to 3 days may occur 7 to 10 days after getting this vaccine. Monitor your child and treat their fever (at least 6 to 8 hours after immunization) **if** they are uncomfortable, refusing fluids and not sleeping. • Less than 1 in 3,000 children with high fevers after getting their first dose of MMRV **may** have a febrile seizure. **Febrile seizures are temporary and not harmful to the child. If you are concerned, please talk to a public health nurse.** • Swelling of the jawline (salivary glands), cheeks and neck 7 to 12 days later. • Joint or muscle aches and pain. • Nausea, vomiting, diarrhea or decreased appetite. • Headache, dizziness, fussiness, tiredness. • Lymph nodes swelling near the immunized limb. • A blotchy red rash 4 to 12 days later. • A varicella-like (blister) rash 5 to 26 days after getting immunized. People who have this rash rarely spread the vaccine virus to others. To prevent possible viral spreading, the rash should be covered until the blisters have dried and crusted over**.** **Extremely rare** reactions may include: • A temporary drop of the number of blood cells (platelets) that prevent bleeding (thrombocytopenia) within 6 weeks of being immunized. In most people, this resolves within 3 months without serious complications. • Encephalitis (less than one in one million). The risk of encephalitis from measles disease is about one in 1,000, which is much higher than from this vaccine.
ADVERSE EVENTS	Administration of ProQuad™ (dose 1) to children 12 to 23 months old was associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with M-M-R® II and VARIVAX® administered separately. Review fever management with client.
EFFECTIVENESS	The antibody persistence rates 1 year post-vaccination in recipients **of a single dose** of ProQuad™ were 98.9% (1722/1741) for measles, 96.7% (1676/1733) for mumps, 99.6 (1796/1804) for rubella, and 97.5% (1512/1550) for varicella (≥ 5 gp ELISA units/mL)

[1] Minimum age for this vaccine is 12 months. Consult MHO for recommendations regarding exceptional circumstances.

[2] There must be 4 weeks minimum spacing between MMRV doses

[3] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

[4] Individuals who are eligible for a 2-dose varicella series who have **documentation of lab confirmed** varicella after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose as they will have developed immunity. Provide a second dose of varicella-containing vaccine to those without this documentation.

[5] MMRV vaccines are considered interchangeable.

Meningococcal Conjugate C Vaccine (Men-C-C)

MENJUGATE® Liquid

Product monograph available at: https://ca.gsk.com/en-ca/products/menjugate-liquid/

INDICATIONS [1,5]	DOSE / SERIES
1. Routine for children at 12 months of age. 2. Meningococcal serotype C post-exposure immunoprophylaxis.	**1.** One dose: 0.5 mL IM at 12 months or older **2.** Children 2 - 11 months old: [2, 3] • **Dose 1**: 0.5 mL IM • **Dose 2**: 0.5 mL IM 2 months later Those 12 months and older: [4] • One dose 0.5 mL IM
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal vaccine or to any component of a MENJUGATE brand of Men-C-C vaccine.
VACCINE COMPONENTS	*Neisseria meningitidis* group C (strain C11) oligosaccharide conjugated to *Corynebacterium diphtheriae* protein CRM-$_{197}$, aluminum hydroxide, histidine, sodium chloride, water for injection with bromobutyl rubber stopper and tip cap (styrene butadiene Type II rubber). Although no natural rubber latex is detected in the syringe tip cap, the safe use of Menjugate in latex-sensitive individuals has not been established. Thimerosal free.
EXPECTED REACTIONS	**Local**: redness, swelling and pain at injection site. **Systemic**: fever, decreased appetite, drowsiness, crying, irritability, headache, vomiting, diarrhea or skin rash.
EFFECTIVENESS	Effectiveness: more than 90% in all age groups in the short-term.

[1] Minimum age for vaccine is 6 weeks.
[2] Men-C-C vaccines are interchangeable for infants younger than 12 months of age.
[3] If an infant has a history of receiving their last dose before 12 months of age, give an additional dose at 12 months or older.
[4] The recommended interval between Men-C-C doses is 2 months.
[5] Patients being treated with the terminal complement inhibitor eculizumab (Soliris®) or ravulizumab (Ultomiris®) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e). Individuals should receive meningococcal vaccine at least 2 weeks before receiving the first dose of eculizumab or ravulizumab if possible.

Meningococcal Conjugate C Vaccine (Men-C-C)

NeisVac-C®
Product monograph available at: https://www.pfizer.ca/en/our-products/neisvac-c-meningococcal-group-c-tt-conjugate-vaccine-adsorbed

INDICATIONS [1,5]	**DOSE / SERIES**
1. Routine for children at 12 months of age.	**1.** One dose: 0.5 mL IM at 12 months or older
2. Meningococcal serotype C post-exposure immunoprophylaxis.	**2.** Children 2 - 11 months old: [2, 3] • **Dose 1**: 0.5 mL IM • **Dose 2**: 0.5 mL IM 2 months later Those 12 months and older: [4] • One dose 0.5 mL IM
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal vaccine or to any component of NeisVac-C®.
VACCINE COMPONENTS	One dose 0.5 mL contains: *Neisseria meningitidis* group C polysaccharide 10 mcg, tetanus toxoid, aluminum hydroxide, sodium chloride. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: redness, swelling and pain at injection site. **Systemic**: fever, decreased appetite, drowsiness, crying, irritability, headache, vomiting, diarrhea or skin rash.
EFFECTIVENESS	Effectiveness: more than 90% in all age groups in the short-term.

[1] Minimum age for vaccine is 6 weeks.
[2] Men-C-C vaccines are interchangeable for infants younger than 12 months of age.
[3] If an infant has a history of receiving their last dose before 12 months of age, give an additional dose at 12 months or older.
[4] The recommended interval between Men-C-C doses is 2 months.
[5] Patients being treated with the terminal complement inhibitor eculizumab (Soliris®) or ravulizumab (Ultomiris®) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e). Individuals should receive meningococcal vaccine at least 2 weeks before receiving the first dose of eculizumab or ravulizumab if possible.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

Menactra®

Product monograph: https://pdf.hres.ca/dpd_pm/00042668.PDF

DOSE : 0.5 mL IM

INDICATIONS [1, 5]

1. The school-age 1-dose Men-C-ACYW-135 immunization program will re-commence September 1, 2026 for Grade 8 students (starting with the 2013 cohort). [2, 3]
2. Those 9 months of age and older with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. In meningococcal A, C, Y or W-135 outbreak exposure situations for those 9 months and older.
4. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS	**9 months through 11 months -** 3-dose series a. 1st dose followed by 2nd dose 2 months later. b. Give 3rd at/after 12 months of age, with 2 months between doses 2 and 3. [5]
	12 to 23 months [5] **-** 2-dose series with 2 months between doses
	2 years and older [5] **-** 2-dose series with 2 months between doses
REINFORCE-MENT DOSES	**1 dose every 5 years** for asplenia (congenital, acquired or functional), congenital immunodeficiency, acquired complement deficiency, and HSCT and SOT transplant recipients.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal-containing vaccine, or to any component of Menactra.
VACCINE COMPONENTS	Each dose contains 4 mcg each of meningococcal A, C, Y and W-135 polysaccharides conjugated to a total of approximately 48 mcg of a diphtheria toxoid protein carrier, sodium chloride 4.25 mg, sodium phosphate (dibasic, anhydrous), sodium phosphate (monobasic), water for injection. Vial presentations do not contain latex. Preservative free.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling. **Systemic**: headache, tiredness, diarrhea, irritability, loss of appetite or fever.
EFFECTIVENESS	93-100% of children, adolescents & adults show a ≥4-fold rise in titres at day 28. Duration of protection remains unknown.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

Menactra®

[1] The recommended interval between the administration of any Men-C-C and Men-C-ACYW-135 vaccine doses is 4 weeks (regardless of which vaccine was given first).

[2] Those who missed the Grade 6 program are eligible to be immunized up to and including 21 years old (ineligible upon 22nd birthday).

[3] For students born since January 1, 2013, and who have previously received at least one Men-C-ACYW-135 dose (e.g., for travel, close contact of IMD, previous provincial schedule):

1. If their last Men-C-ACYW-135 vaccine dose was received when younger than 12 years of age, offer the vaccine in Grade 8 starting September 2026.
2. If their last Men-C-ACYW-135 vaccine dose was received at 12 years of age or older, they are considered up to date **for Grade 8**.

[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.

[5] A high-risk child 12 months of age and older does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.

[6] Patients being treated with the terminal complement inhibitor eculizumab (Soliris®) or ravulizumab (Ultomiris®) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e). Individuals should receive meningococcal vaccine at least 2 weeks before receiving the first dose of eculizumab or ravulizumab if possible.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

MenQuadfi™

Product monograph available at: https://pdf.hres.ca/dpd_pm/00077618.PDF

DOSE : 0.5 mL IM

INDICATIONS [1, 5,]

1. The school-age 1-dose Men-C-ACYW-135 immunization program will re-commence September 1, 2026 for Grade 8 students (starting with the 2013 cohort). [2, 3]
2. Those 1 year of age and older with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. In meningococcal A, C, Y or W-135 outbreak exposure situations for those 1 year and older.
4. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS	
	12 to 23 months [5] **-** 2-dose series with at least 2 months between doses
	2 years and older [5] **-** 2-dose series with at least 2 months between doses
REINFORCE-MENT DOSES	**1 dose every 5 years** for asplenia (congenital, acquired or functional), congenital immunodeficiency, acquired complement deficiency, and HSCT and SOT transplant recipients.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal-containing vaccine, or to any component of MenQuadfi
VACCINE COMPONENTS	Each dose contains 10 mcg each of meningococcal A, C, Y and W-135 polysaccharide concentrate conjugated to a tetanus toxoid protein, tetanus toxoid, sodium chloride 3.35 mg, sodium acetate, water for injection. Latex-free. Preservative free.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling. **Systemic**: fever, vomiting, myalgia, malaise, headache. In young children: abnormal crying, drowsiness, loss of appetite, irritability.
EFFECTIVENESS	Information available for age categories in product monograph.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

MenQuadfi

[1] The recommended interval between the administration of any Men-C-C and Men-C-ACYW-135 vaccine doses is 4 weeks (regardless of which vaccine was given first).

[2] Those who missed the Grade 6 program are eligible to be immunized up to and including 21 years old (ineligible upon 22nd birthday).

[3] For students born since January 1, 2013, and who have previously received at least one Men-C-ACYW-135 dose (e.g., for travel, close contact of IMD, previous provincial schedule):

1. If their last Men-C-ACYW-135 vaccine dose was received when younger than 12 years of age, offer the vaccine in Grade 8 starting September 2026.
2. If their last Men-C-ACYW-135 vaccine dose was received at 12 years of age or older, they are considered up to date **for Grade 8**.

[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.

[5] A high-risk child 12 months of age and older does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.

[6] Patients being treated with the terminal complement inhibitor eculizumab (Soliris®) or ravulizumab (Ultomiris®) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e). Individuals should receive meningococcal vaccine at least 2 weeks before receiving the first dose of eculizumab or ravulizumab if possible.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

Menveo™
Product monograph available at: https://pdf.hres.ca/dpd_pm/00056521.PDF

DOSE: 0.5 mL IM

INDICATIONS [1, 5]

1. The school-age 1-dose Men-C-ACYW-135 immunization program will re-commence September 1, 2026 for Grade 8 students (starting with 2013 cohort). [2, 3]
2. Those 6 weeks of age and older with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. In meningococcal A, C, Y or W-135 outbreak exposure situations for those 6 weeks and older.
4. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS	**6 weeks through 6 months**: 4 dose series - 2 months, 4 months and 6 months of age followed by a 4th dose at/after 12 months of age[5].
	7 months through 11 months: 3 dose series - 1st dose, 2nd dose and 3rd dose with 2 month intervals between these 3 doses. • Give 3rd at/after 12 months of age, with 2 months between doses 2 and 3
	12 months and older: 2-dose series with 2 months between doses.
REINFORCE-MENT DOSES	**1 dose every 5 years** for asplenia (congenital, acquired or functional), congenital immunodeficiency, acquired complement deficiency, and HSCT and SOT transplant recipients.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of a meningococcal containing vaccine, or to any component of Menveo™.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135) **Menveo™**	
VACCINE COMPONENTS	5 mcg each of meningococcal C, W-135 and Y oligosaccharides conjugated and 10 mcg of meningococcal A oligosaccharide conjugated to a total of approximately 47 mcg of Cross Reactive Material (CRM197) from *Corynebacterium diphtheriae*, potassium dihydrogen phosphate, sodium chloride, sodium dihydrogen phosphate monohydrate, di-sodium hydrogen phosphate bihydrate, sucrose, water for injection. Thimerosal and latex free.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling at injection site. **Systemic**: headache, tiredness, diarrhea, irritability, loss of appetite or fever.
EFFECTIVENESS	93-100% of children, adolescents & adults show a ≥4-fold rise in titres at day 28.

[1] The recommended interval between the administration of any Men-C-C and Men-C-ACYW-135 vaccine doses is 4 weeks (regardless of which vaccine was given first).

[2] Those who missed the Grade 6 program are eligible to be immunized up to and including 21 years old (ineligible upon 22nd birthday).

[3] For students born since January 1, 2013, and who have previously received at least one Men-C-ACYW-135 dose (e.g., for travel, close contact of IMD, previous provincial schedule):

1. If their last Men-C-ACYW-135 vaccine dose was received when younger than 12 years of age, offer the vaccine in Grade 8 starting September 2026.
2. If their last Men-C-ACYW-135 vaccine dose was received at 12 years of age or older, they are considered up to date **for Grade 8.**

[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.

[5] A high-risk child 12 months of age and older does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.

[6] Patients being treated with the terminal complement inhibitor eculizumab (Soliris®) or ravulizumab (Ultomiris®) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e). Individuals should receive meningococcal vaccine at least 2 weeks before receiving the first dose of eculizumab or ravulizumab if possible.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

NIMENRIX®
Product monograph available at: https://pdf.hres.ca/dpd_pm/00073626.PDF

DOSE: 0.5 mL IM

INDICATIONS [1, 5]

1. The school-age 1-dose Men-C-ACYW-135 immunization program will re-commence September 1, 2026 for Grade 8 students (starting with the 2013 cohort). [2, 3]
2. Those 6 weeks of age and older (no age limit) with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. In meningococcal A, C, Y or W-135 outbreak exposure situations for those 6 weeks and older.
4. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS	**6 weeks to <6 months** 3-dose series • 1st dose followed by 2nd dose 2 months later. • Give 3rd dose at/after 12 months of age, with 2 months between doses 2 and 3. [5]
	6 months to <12 months 2-dose series • 1st dose followed by 2nd dose at/after 12 months of age, with 2 months between doses 1 and 2. [5]
	12 months and older [5] **-** 2-dose series with 2 months between doses
REINFORCE-MENT DOSES	**1 dose every 5 years** for asplenia (congenital, acquired or functional), congenital immunodeficiency, acquired complement deficiency, and HSCT and SOT transplant recipients.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of a meningococcal containing vaccine, or to any component of NIMENRIX™.
VACCINE COMPONENTS	*Neisseria meningitidis* serogroup A polysaccharide, *Neisseria meningitidis* serogroup C polysaccharide, *Neisseria meningitidis* serogroup W-135 polysaccharide, *Neisseria meningitidis* serogroup Y polysaccharide, sucrose, trometamol, sodium chloride, water for injection. Latex-free.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling, bruising at injection site. **Systemic**: headache, tiredness, diarrhea, irritability, loss of appetite, fever.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

NIMENRIX®

EFFECTIVENESS	For all serogroups (A, C, W-135, Y), the persistence of the antibodies elicited by NIMENRIX™ was similar or higher than those induced by the licensed Men-C-ACYW-135 vaccines.

[1] The recommended interval between the administration of any Men-C-C and Men-C-ACYW-135 vaccine doses is 4 weeks (regardless of which vaccine was given first).

[2] Those who missed the Grade 6 program are eligible to be immunized up to and including 21 years old (ineligible upon 22nd birthday).

[3] For students born since January 1, 2013, and who have previously received at least one Men-C-ACYW-135 dose (e.g., for travel, close contact of IMD, previous provincial schedule):

1. If their last Men-C-ACYW-135 vaccine dose was received when younger than 12 years of age, offer the vaccine in Grade 8 starting September 2026.
2. If their last Men-C-ACYW-135 vaccine dose was received at 12 years of age or older, they are considered up to date **for Grade 8.**

[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.

[5] A high-risk child 12 months of age and older does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.

[6] Patients being treated with the terminal complement inhibitor eculizumab (Soliris®) or ravulizumab (Ultomiris®) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e). Individuals should receive meningococcal vaccine at least 2 weeks before receiving the first dose of eculizumab or ravulizumab if possible.

Meningococcal B vaccine (Multicomponent, recombinant, adsorbed)

BEXSERO® (Men-B4C)

Product monograph available at: https://pdf.hres.ca/dpd_pm/00073317.PDF

INDICATIONS[1, 2, 3]	1. Those 6 weeks of age and older with the following medical conditions as noted in Chapter 7 Special Populations: • asplenia – congenital, acquired or functional • sickle cell disease • congenital immunodeficiency • acquired complement deficiency • solid organ or islet cell transplant candidates or recipients as per transplant agency recommendations • hematopoietic stem cell transplant (HSCT) recipients as per transplant agency recommendations • Children up to and including 17 years of age who are infected with HIV 2. In meningococcal B outbreak exposure situations for those 6 weeks and older.
DOSE	0.5 mL IM. Protect from light.
CONTRA-INDICATIONS	BEXSERO should not be administered to individuals who are hypersensitive to this vaccine or to any ingredient in the formulation or components of the container closure.
DOSE/SERIES AND REINFORCE-MENT RECOMMEN-DATIONS BASED ON AGE AT PRESENTATION for those with medical risk factors.	**Infants aged 6 weeks through 5 months** • **4-dose series for infants**: 0.5 mL IM at 2 months, 4 months and 6 months of age followed by a 4th dose after 12 months of age. ○ Minimum 1 month interval between doses 1 & 2 and 2 & 3. ○ Dose 4 **is required** after 1 year old with an interval of at least 6 months between doses 3 & 4.
	Infants aged 6 months through 11 months • **3-dose series**: 0.5 mL IM for 1st dose, 2nd dose and 3rd dose with 2-months interval between the 1st and 2nd doses and the 2nd and 3rd doses. ○ The 3rd dose **is required** after 1 year old with 2-month interval between the second and third dose.
	Children aged 12 months to 23 months old: • **2-dose series** - 0.5 mL IM, with 2-month interval between the 1st and 2nd doses.
	Individuals aged 2 years and older (including adults) • **2-dose series** - 0.5 mL IM, with 1-month interval between the 1st and 2nd doses.
VACCINE COMPONENTS	Recombinant *Neisseria meningitidis* serogroup B NHBA fusion protein; recombinant *Neisseria meningitidis* serogroup B NadA protein; recombinant *Neisseria meningitidis* serogroup B fHbp fusion protein; outer membrane vesicles (OMV) from *Neisseria meningitidis* serogroup B strain NZ98/254 measured as amount of total protein containing the PorA P1.4, aluminum hydroxide, histidine, sodium chloride, sucrose, water for injection. Residue: kanamycin less than 0.01 mcg/dose. Thimerosal free. The tip cap of the syringe may contain natural rubber latex. Although the risk for developing allergic reactions is very small, health professional should consider the benefit-risk prior to administering this vaccine to subjects with known history of hypersensitivity to latex.

Meningococcal B vaccine (Multicomponent, recombinant, adsorbed)

BEXSERO® (Men-B4C)

EXPECTED REACTIONS	Common reactions to the vaccine may include: • Soreness, pain, redness and swelling at the injection site. Extensive swelling of the vaccinated limb, blisters at or around the injection site, and/or a hard lump at the injection site (which may last for more than one month) have also been reported. • Fever, loss of appetite, sleepiness, irritability, headache, vomiting, diarrhea, headache or rash. • Unusual crying in young children. • These reactions are mild and generally last 1 to 2 days. • High fever and seizures are uncommon. • Hypotonic-hyporesponsive episode, syncope or vasovagal responses to injection have been reported as post-market events. • Lymphadenopathy. • Allergic reactions (including anaphylactic reactions) have been reported as post-market events.
EFFECTIVENESS	Immunogenicity information in the product monograph indicates that administration of age-appropriate series provides 75% to 100% immunogenicity among the 4 meningococcal components. Duration of protection is unknown.

NOTES

1. According to the manufacturer (verbal communication, May 2014), there are no recommended interval requirements between BEXSERO® and other meningococcal serotype-containing vaccine that are conjugates or polysaccharides. However, case-by case review of an individual's immunization history in consultation with a MHO consultation may result in specific recommendations for administration of BEXSERO® doses.
2. An increased risk of hemolysis or low hemoglobin has been observed when patients already being treated with SOLIRIS (eculizumab) get vaccinated against serogroup B meningococcal infection with Bexsero® (Alexion Pharma Canada, 2017).
3. Patients being treated with the terminal complement inhibitor eculizumab (Soliris®) or ravulizumab (Ultomiris®) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e). Individuals should receive meningococcal vaccine at least 2 weeks before receiving the first dose of eculizumab or ravulizumab if possible.

Meningococcal group B
Bivalent recombinant lipoprotein [Non-publicly funded]

Trumenba™ (MenB bivalent)
(Pfizer 2022 Product monograph available at https://www.pfizer.ca/files/Trumenba_PM_EN.pdf)

Pneumococcal Conjugate 10-Valent Vaccine

[Non-publicly funded]

SYNFLORIX™ (Pneu-C-10)

(GlaxoSmithKline 2023 monograph available at: https://ca.gsk.com/media/6260/synflorix.pdf)

Pneumococcal Conjugate 13-Valent Vaccine

[Non-publicly funded]

Prevnar® 13 (Pneu-C-13)

(Product monograph https://webfiles.pfizer.com/file/4c36f618-cb1a-412f-9d76-f8a7df560120?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6)

Pneumococcal Conjugate 15-Valent Vaccine

VAXNEUVANCE® (Pneu-C-15)

Product monograph: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/VAXNEUVANCE-PM_E.pdf

Indication	• Children who do not have any medical or lifestyle risk factors and who present when younger than 5 years old. • Minimum age is 6 weeks old. • **This vaccine is not publicly funded for individuals 5 years and older.**
Dose / Primary Series[1]	Dose 1: 2 months of age: 0.5 mL IM Dose 2: 4 months of age: 0.5 mL IM Dose 3: 12 months of age: 0.5 mL IM
Reinforcement	N/A
Precautions	None noted in product monograph.
Contraindications	VAXNEUVANCE® is contraindicated in individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or any diphtheria toxoid-containing vaccine.
Expected reactions	**Local**: pain, swelling, redness, tenderness, induration, urticaria at injection site. **Systemic**: fever, irritability, fatigue, headache, myalgia, decreased appetite, generalized urticaria.
Vaccine components	Suspension for injection Each 0.5 mL dose contains 32 mcg of total pneumococcal polysaccharide (2.0 mcg each of polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F, and 4.0 mcg of polysaccharide serotype 6B) conjugated to 30 mcg of CRM_{197} carrier protein. Non-medicinal ingredients: Each 0.5 mL dose contains 125 mcg of aluminum (as aluminum phosphate adjuvant), 1.55 mg L-histidine, 1 mg of polysorbate 20, 4.50 mg sodium chloride and water for injection. Latex-free. Preservative-free.
Effectiveness	Non-inferior to PREVNAR® 13 for similar strains. VAXNEUVANCE® may not prevent disease caused by *S. pneumoniae* serotypes that are not contained in the vaccine.

[1] If series is interrupted, refer to SIM Ch. 5 Section 1.3A*, Pneu-C-15 Vaccine Schedule for Healthy Children (<5 years old) Delayed by 1 Month or More* and complete series according to age at which child re-presents using minimum intervals as noted in SIM Chapter 5 Section 2.*1 Minimum intervals for Specific Vaccines.*

Pneumococcal Conjugate 20-Valent Vaccine
PREVNAR 20™ (Pneu-C-20)

This vaccine is not publicly funded for individuals who do not meet eligibility criteria for publicly funded immunization.

Product monograph https://webfiles.pfizer.com/file/eaacb9cc-8b8c-4ddf-af69-93e374730387?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6

INDICATIONS:

1. Adults 65 years and older **who have never received any previous pneumococcal vaccines.**
2. Transplant patients (all ages) (e.g., HSCT, solid organ, Islet cell) refer to SIM Ch. 7.
3. Individuals 6 weeks through 64 years of age who have one or more specified risk factors (see next page).
4. Individuals 65 years and older **who have been previously immunized with pneumococcal vaccines** and have one or more specified risk factors approved for their age (see next page).

❖ **Eligibility is based on** age, risk factor, pneumococcal immunization history and interval from the last pneumococcal vaccine dose. **[Refer to** *Age-based Risk Factor Eligibility for Pneu-C-20 Immunization (as noted in Panorama)* for Panorama risk factor names].

Dosage is 0.5 ml IM for all ages

High Risk Infant Series[1]	
Dose 1: 2 months of age: 0.5 mL IM Dose 2: 4 months of age: 0.5 mL IM Dose 3: 6 months of age: 0.5 mL IM Dose 4: 12 months of age: 0.5 mL IM	**Individuals 5-64 years**: One dose; refer to *Pneu-C-20 Immunization Flow Chart for Individuals Through 64 Years of Age.* **Individuals 65 years and older**: One dose; refer to *Pneu-C-20 Immunization Flow Chart for Individuals 65 Years and Older.*

Precautions	None noted in product monograph.
Contraindications	PREVNAR 20 is contraindicated in individuals who are hypersensitive to the active substance or to any component of the vaccine, including diphtheria toxoid.
Expected reactions	**Local**: pain, swelling, redness, tenderness, induration, pruritus and urticaria at injection site, lymphadenopathy. **Systemic**: fever, irritability, fatigue, headache, myalgia, joint pain, decreased appetite, generalized rash.
Vaccine components	Each 0.5 mL dose of the vaccine is formulated to contain approximately 2.2 mcg of each of *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F saccharides, 4.4 mcg of 6B saccharide, 51 mcg CRM_{197} carrier protein, 100 mcg polysorbate 80, 295 mcg succinic acid, 4.4 mg sodium chloride, and 125 mcg aluminum as aluminum phosphate adjuvant. Latex-free. Preservative-free.
Effectiveness	Non-inferior to PREVNAR® 13 for similar strains. PREVNAR 20® may not prevent disease caused by *S. pneumoniae* serotypes that are not contained in the vaccine.

[1] If series is interrupted, refer to Chapter 5, Section 1.3B *Pneu-C-20 Vaccine Schedule for Medically High-Risk Children (<5 years old) Delayed by 1 Month or More* and complete series according to age at which child re-presents using minimum intervals as noted in Chapter 5 Section 2.*1 Minimum intervals for Specific Vaccines.*

Individuals who are 6 weeks old through 64 years old must have these approved conditions to be immunized with Pneu-C-20:

- acquired complement deficiency
- alcoholism
- asplenia
- **current** cancer diagnosis
- CSF disorders
- cochlear implant recipient or candidate
- congenital immunodeficiency
- cystic fibrosis
- diabetes mellitus
- chronic heart disease
- HIV
- homelessness
- illicit drug use
- immunosuppressive disease or medical treatment (high dose steroids, chemotherapy, radiation therapy)
- kidney disease
- liver disease (incl. cirrhosis, hepatitis B, hepatitis C)
- lung disease (except asthma, unless management involves high dose oral corticosteroid therapy)
- neurological conditions that impede the clearance of oral/respiratory secretions
- sickle cell disease/other hemoglobinopathies
- residents of LTC facilities, group homes and personal care homes

Individuals 65 years and older who have been previously immunized with a pneumococcal vaccine must have these approved conditions to be immunized with Pneu-C-20:

- acquired complement deficiency
- asplenia
- **current** cancer diagnosis
- congenital immunodeficiency
- HIV
- immunosuppressive disease or medical treatment (high dose steroids, chemotherapy, radiation therapy)
- kidney disease
- sickle cell disease/other hemoglobinopathies
- residents of LTC facilities, group homes and personal care homes

Age-based Risk Factor Eligibility for Pneu-C-20 Immunization (as noted in Panorama)

- **Refer to SIM Chapter 7 Appendix 7.1 for full risk factor details and qualifying conditions.**

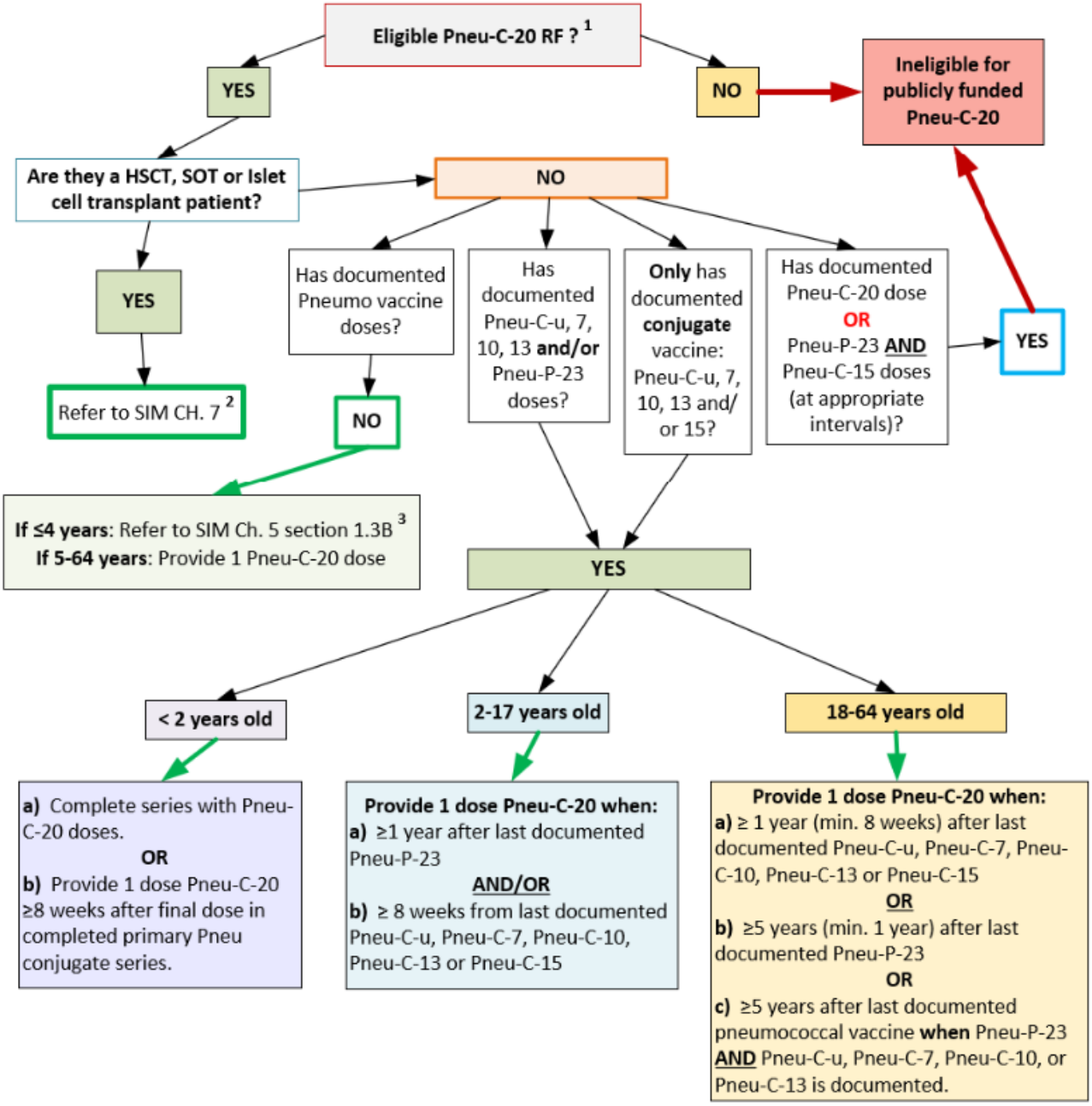
Age 6 weeks through 64 years at presentation

- Chronic Medical Condition - Congenital or Acquired, or Functional Asplenia
- Chronic Medical Condition - Cardiac Disease
- Chronic Medical Condition - CSF Disorder
- Chronic Medical Condition - Cochlear Implant
- Chronic Medical Condition - Cystic Fibrosis
- Chronic Medical Condition - Diabetes Mellitus
- Chronic Medical Condition - Liver Disease
- Chronic Medical Condition - Liver Disease- Hepatitis B
- Chronic Medical Condition - Liver Disease- Hepatitis C
- Chronic Medical Condition - Lung Disease
- Chronic Medical Condition - Malignancies/Cancer
- Chronic Medical Condition - Neurological conditions that impede the clearance of respiratory/oral secretions
- Chronic Medical Condition - Renal Disease
- Chronic Medical Condition - Sickle Cell Disease
- Immunocompromised - Acquired Complement Deficiency
- Immunocompromised - Congenital Immunodeficiency
- Immunocompromised - HIV
- Immunocompromised - Related to Disease
- Immunocompromised - Treatment - Additional info
- Special Population - Homeless
- Special Population - LTC Facility - Resident
- Special Population - Substance Use - illicit non-injection drug use
- Special Population - Substance Use - injection drug use (including steroids)
- Special Population – Personal Care Home Resident
- Special Population - Resident - Group Home

65 Years and Older at Presentation

- Chronic Medical Condition - Congenital or Acquired, or Functional Asplenia
- Chronic Medical Condition - Malignancies/Cancer
- Chronic Medical Condition - Renal Disease
- Chronic Medical Condition - Sickle Cell Disease
- Immunocompromised - Acquired Complement Deficiency
- Immunocompromised - Congenital Immunodeficiency
- Immunocompromised - HIV
- Immunocompromised - Related to Disease
- Immunocompromised - Treatment - Additional info
- Special Population - LTC Facility - Resident
- Special Population – Personal Care Home Resident
- Special Population - Resident - Group Home

Pneu-C-20 Immunization Flow Chart for Individuals Through 64 Years of Age

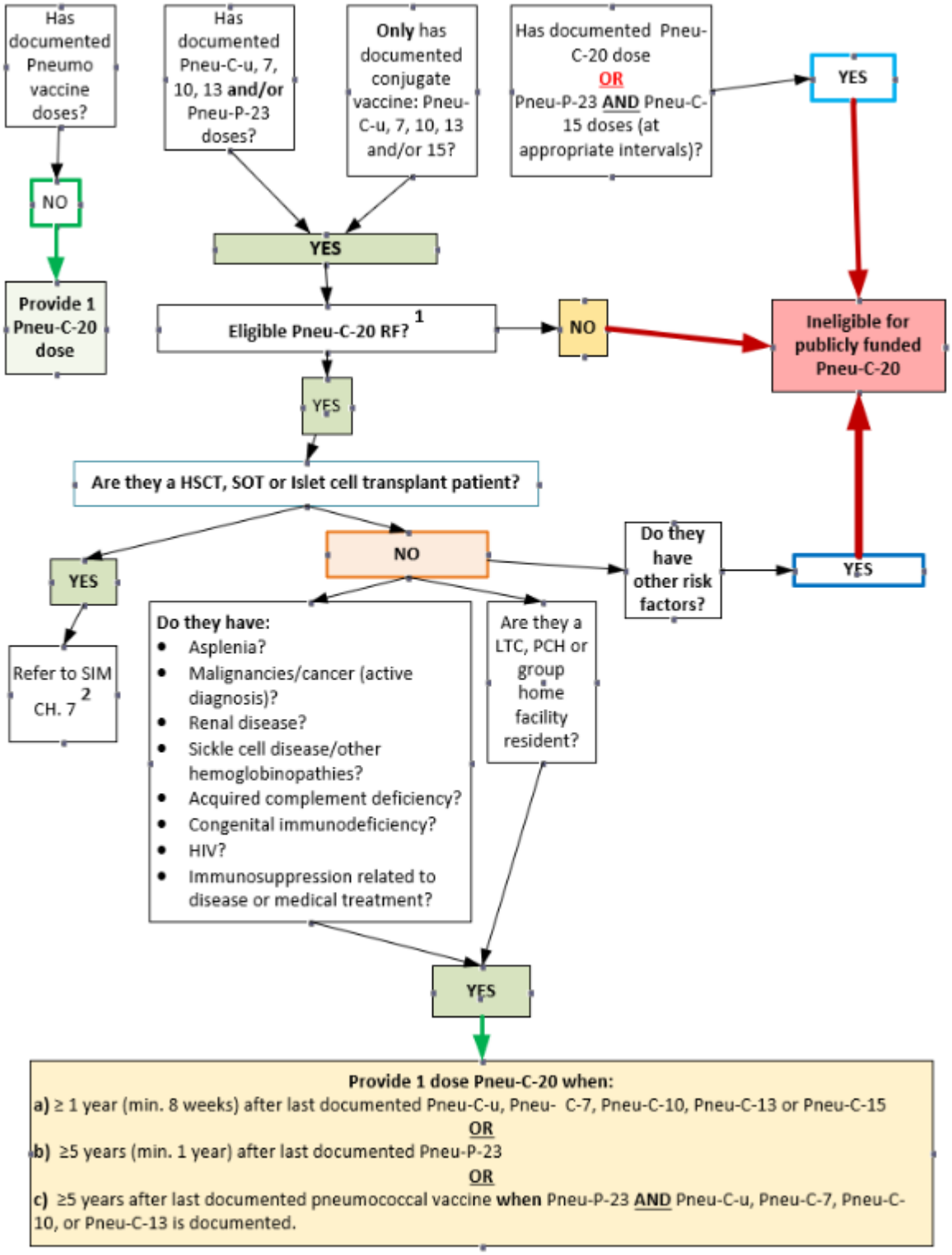


[1] Refer to *Age-based Risk Factor Eligibility for Pneu-C-20 Immunization (as noted in Panorama).*

[2] SIM Chapter 7 Immunization of Special Populations

[3] SIM Chapter 5 Immunization Schedules

Pneu-C-20 Immunization Flow Chart for Individuals 65 Years and Older



[1] Refer to *Age-based Risk Factor Eligibility for Pneu-C-20 Immunization (as noted in Panorama).*

[2] SIM Chapter 7 Immunization of Special Populations

Pneumococcal Conjugate 21-Valent Vaccine (Pneu-C-21)
[NON-PUBLICLY FUNDED]

CAPVAXIVE®
Product monograph available at https://www.merck.ca/en/wp-content/uploads/sites/20/2024/07/CAPVAXIVE-PM_E.pdf)

Pneumococcal Polysaccharide 23-Valent Vaccine (Pneu-P-23)
[NON-PUBLICLY FUNDED]

PNEUMOVAX® 23
Product monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/PNEUMOVAX_23-PM_E.pdf

Poliomyelitis Vaccine (IPV)
(trivalent, inactivated, whole virus, Vero cell origin)
IMOVAX® Polio

Product monograph: https://www.sanofi.com/en/canada/your-health/vaccines-products

INDICATIONS NOTE: IPV is to replace OPV doses (for age requirements) documented as of April 1, 2016	DOSE / SERIES (0.5 mL)
1. Infants and children up to and including 3 years of age who do not require diphtheria, pertussis, tetanus, or Hib. **2**. Children 4 years to 17 years of age who do not require diphtheria or tetanus vaccine. **3.** Adults ≥18 years**.** **4**. Previously unimmunized children and adult solid organ transplant (SOT) candidates and recipients. **5**. HSCT recipients: [1]	**1. Infants and children up to and including 3 years of age:** **Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC given 1 month after dose 1 **Dose 3**: 0.5 mL SC given 6 months after dose 2 [2] **Dose 4**: 0.5 mL SC at school entry (min. interval is 6 months after dose 3). (This dose is not necessary if dose 3 was given on or after the 4th birthday). **2. & 3. Individuals 4 years and older that require a primary series** **Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC given 1 month after dose 1 **Dose 3**: 0.5 mL SC given 6 months after dose 2. **NOTE: At minimum, one dose must be given at or after 4 years of age.** **4.** Use schedule (1) or (2) above as appropriate for age **5. Dose 1**: 0.5 mL SC (1 year after HSCT) **Dose 2**: 0.5 mL SC (2 months after dose 1) **Dose 3**: 0.5 mL SC (1 year after dose 1)
REINFORCEMENT	**Reinforcement doses are not publicly funded**.
CONTRAINDICATIONS	History of anaphylactic reaction to any oral or injectable polio-containing vaccine, or to any IPV vaccine component.
VACCINE COMPONENTS	Each 0.5 mL dose contains: Type 1 (Mahoney) 40 D-antigen units; Type 2 (MEF1) 8 D-antigen units; Type 3 (Saukett) 32 D-antigen units. **Excipients**: 2-phenoxyethanol **Manufacturing Process Residuals**: Formaldehyde, residual calf serum protein. **Trace amounts of:** neomycin, streptomycin and polymyxin B, Medium 199 Hanks (without phenol red). Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Temporary pain, redness and swelling. **Systemic**: Mild fever, fatigue and headache.
EFFECTIVENESS	Immunity following injectable poliovirus vaccine series has been shown to persist for 4 or more years after a primary series.

[1] Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 3.6 *Transplant Recipient - Haematopoietic Stem Cell Transplant. Documentation of a 3-dose primary series given by any route with at least one dose received at 4 years of age or older.*

[2] Dose 3 must be given six months after dose 2 and at least after 1 year of age.

Rabies Vaccine (Rab) Post-Exposure Indication
[Human Diploid Cell Vaccine (HDCV)] (Inactivated whole virus)

IMOVAX® Rabies

Product monograph: https://www.sanofi.com/en/canada/your-health/vaccines-products

INDICATIONS	**ONLY Post-Exposure Prophylaxis is publicly funded:** • As determined by Regional Medical Health Officers. • Refer to the Saskatchewan Communicable Disease Control Manual Rabies chapter.
SERIES	**1. Previously Unimmunized Individuals:** **(1A) Unimmunized immunocompetent individuals to receive a 4 dose series:** • **1 mL IM on days 0 – 3 – 7 – 14** • **Day 0**: 1 mL IM as soon as possible after exposure **PLUS Rabies Immune globulin (RabIg).** • **Days 3, 7**, and **14**: 1 mL IM. **(1B) Unimmunized immunocompromised individuals* to receive a 5 dose series**: • **1 ml IM on days 0 – 3 – 7 – 14 – 28** • **Day 0:** 1 mL IM as soon as possible after exposure **PLUS RabIg.** • **Days 3, 7, 14** and **28:** 1 mL IM. *includes those taking antimalarials and/or any immunosuppressants (e.g., corticosteroids) that can result in immunosuppression. --- **2. Previously Immunized Individuals**: • Refer to the CDC Manual Rabies chapter for information.

Rabies Vaccine (Rab) Post-Exposure Indication [Human Diploid Cell Vaccine (HDCV)] (Inactivated whole virus)

IMOVAX® Rabies

RECONSTITUTION	**Package with Two Needles** 1. Attach the plunger and reconstitution needle to the syringe and reconstitute the freeze-dried vaccine by introducing the diluent provided into the vial of powder. 2. Gently swirl the contents until completely dissolved. 3. Withdraw the suspension from the vial into the syringe. 4. Remove the reconstitution needle and replace it with an appropriate needle for intramuscular injection. **Package with Attached Needle** 1. Reconstitute the freeze-dried vaccine in its vial with the diluent supplied in the syringe. 2. Gently swirl the contents until completely dissolved.
CONTRAINDICATIONS	1. There are **NO** contraindications to rabies vaccine given for post-exposure purposes**.** 2. **DO NOT GIVE RABIES VACCINE IN THE GLUTEAL REGION.** 3. Rabies vaccine and RabIg must not be administered in the same anatomical site. 4. Use separate needles and syringes for each product.
PRECAUTIONS	• Administer vaccine in an emergency room setting if history of anaphylactic reaction to a previous dose of rabies vaccine, IMOVAX® Rabies or to any of the components of IMOVAX® Rabies. • There are insufficient data regarding concurrent use of mefloquine with rabies immunization.
VACCINE COMPONENTS	Rabies virus (WISTAR Rabies PM/WI 38 1503-3M Strain), human albumin, neomycin, phenol red and may contain traces of beta propiolactone. Latex-free.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling and itching at injection site. **Systemic:** Fever, nausea, headache, joint or muscle aches, fatigue, swollen lymph glands and dizziness.
SPECIAL CONSIDERATION	IMOVAX® Rabies is pink to red in color following reconstitution. Also, it does not contain any preservative and should be used immediately after reconstitution or discarded**.**
EFFECTIVENESS	After 3 pre-exposure doses, all vaccinees reached antibody levels to confer protection. 96% showed seroconversion at 5 years.

Rabies Vaccine (Rab) Post-Exposure Indication [Purified Chick Embryo Cell Vaccine (PCECV)] (Inactivated)

RabAvert®

Product monograph: https://pdf.hres.ca/dpd_pm/00078582.PDF

INDICATIONS	**ONLY Post-Exposure Prophylaxis is publicly funded:** • As determined by Regional Medical Health Officers. • Refer to the Saskatchewan Communicable Disease Control Manual Rabies chapter.
SERIES	**1. Previously Unimmunized Individuals:** **(1A) Unimmunized immunocompetent individuals to receive a 4-dose series:** • **1 mL IM on days 0 – 3 – 7 – 14** • **Day 0**: 1 mL IM as soon as possible after exposure **PLUS Rabies Immune globulin (RabIg).** • **Days 3, 7**, and **14**: 1 mL IM. **(1B) Unimmunized immunocompromised individuals* to receive a 5 dose series**: • **1 ml IM on days 0 – 3 – 7 – 14 – 28** • **Day 0:** 1 mL IM as soon as possible after exposure **PLUS RabIg.** • **Days 3, 7, 14** and **28:** 1 mL IM. *includes those taking antimalarials and/or any immunosuppressants (e.g., corticosteroids) that can result in immunosuppression. --- **2. Previously Immunized Individuals**: • Refer to the CDC Manual Rabies chapter for information.

Rabies Vaccine (Rab) Post-Exposure Indication [Purified Chick Embryo Cell Vaccine (PCECV)] (Inactivated)

RabAvert®

RECONSTITUTION	1. Use the **longer of the 2 needles supplied** (21g x 1.5") to withdraw the entire contents of the sterile diluent into the syringe. 2. Insert the needle at a 45° angle and slowly inject the entire contents of the diluent into the vaccine vial. 3. Mix gently to avoid foaming. Unscrew the syringe from the needle to eliminate negative pressure. 4. Reinsert the syringe into the needle. Withdraw the total amount of reconstituted vaccine into the syringe. 5. **Replace the long needle with the smaller needle (25g x 1") for IM injection.**
CONTRAINDICATIONS	1. There are **NO contraindications** to rabies vaccine given for post-exposure purposes**.** 2. **DO NOT GIVE RABIES VACCINE IN THE GLUTEAL REGION.** 3. Rabies vaccine and RabIg must not be administered in the same anatomical site. 4. Use separate needles and syringes for each product
PRECAUTIONS	• Administer vaccine in an emergency room setting if history of anaphylactic reaction to a previous dose of rabies vaccine, RabAvert®, eggs or egg products, or to any of the components of RabAvert®. • There are insufficient data regarding concurrent use of mefloquine with rabies immunization.
VACCINE COMPONENTS	Freeze-dried rabies antigen, polygeline, human serum albumin, neomycin, chlortetracycline, amphotericin B, ovalbumin, potassium glutamate, sodium EDTA and may contain traces of beta propiolactone.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling and itching at injection site. **Systemic:** Fever, nausea, headache, joint or muscle aches, fatigue, swollen lymph glands and dizziness.
SPECIAL CONSIDERATION	RabAvert® does not contain a preservative and should be used immediately after reconstitution or discarded.
EFFECTIVENESS	Antibodies develop 7 days after 2nd dose and persist for at least 5 years after the third dose.

Respiratory Syncytial Virus Vaccine (RSV) (stabilized prefusion F protein subunit, bivalent) [Non-publicly funded]

ABRYSVO™
(Pfizer 2023) product monograph https://pdf.hres.ca/dpd_pm/00073900.PDF

Indications:

- Active immunization of pregnant individuals from 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.
- The prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older by active immunization.

Respiratory Syncytial Virus Vaccine (RSV) (recombinant, AS01E adjuvanted) [Non-publicly funded]

AREXVY
product monograph https://ca.gsk.com/media/6988/arexvy.pdf

Indications:

- The prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in
    - adults 60 years of age and older; and
    - adults 50 through 59 years of age who are at increased risk for RSV disease

Respiratory Syncytial Virus Vaccine (RSV) (mRNA) [Non-publicly funded]

mRESVIA®
Product monograph https://www.modernatx.com/en-CA/products/mresvia

Indication:

- The prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older.

Rotavirus vaccine
(human rotavirus, live, attenuated, oral vaccine) [Non-publicly funded]

ROTARIX™ (Rot-1)
Product monograph available at: https://ca.gsk.com/media/6256/rotarix_pm_en.pdf

Rotavirus Vaccine
(oral live viral pentavalent human-bovine reassortant)

RotaTeq® (Rot-5)

Product monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/ROTATEQ-PM_E.pdf)

- **Under no circumstances should RotaTeq® be injected.**
- **RotaTeq® is to be administered orally without mixing with any other vaccines or solutions.**
- **Do not reconstitute or dilute.**

INDICATIONS [1]	**DOSE / PRIMARY SERIES** [2, 3, 4, 5, 6, 8]
SCHEDULE **Minimum age is 6 weeks old.**	**Dose 1:** 2 mL PO (entire contents of applicator) at 2 months of age. • **Dose 1 must be received between 6 weeks and 14 weeks 6 days of age.** **Dose 2**: 2 mL PO (entire contents of applicator) at 4 months of age. **Dose 3**: 2 mL PO (entire contents of applicator) at 6 months of age. • **Dose 3 must be received by 8 month minus 1 d old.**
REINFORCEMENT	Not indicated at this time.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a rotavirus-containing vaccine or to any RotaTeq® vaccine component. • Infants who have a history of intussusception. • **HIV is not a contraindication to receiving a rotavirus vaccine series**. Infants with a known or suspected immunocompromising condition **excluding HIV should** not receive RotaTeq® without consultation with a specialist or expert in the condition. • Infants diagnosed with Severe Combined Immunodeficiency (SCID) disorder or who have a family history of SCID or recurrent, unexplained early deaths in the family. • Infants with a history of a chronic gastrointestinal tract condition or disease, or any uncorrected congenital malformations (e.g., Meckel's diverticulum). • Infants whose mothers took monoclonal antibody medications during pregnancy. Refer to Chapter 8 Administration of Biological Products *Appendix 8.2 Potentially Immunosuppressive Biologic Agents*
PRECAUTIONS	1. Preterm infants can receive rotavirus vaccine if: a) they are chronologically aged 6 weeks and; b) are clinically stable. If the infant is in hospital, the vaccine can only administered at the time of discharge or after discharge from the neonatal intensive care unit, nursery, etc. 2. Acute gastroenteritis: in infants with moderate to severe gastroenteritis, rotavirus vaccine should be deferred until the condition improves unless deferral will result in scheduling of the first dose at more than 14 weeks 6 days of age. 3. Excretion of the vaccine virus in the stools is known to occur after vaccination and lasts for 10 days on average with peak excretion around the 7th day. Contacts of recent vaccinees should be advised to observe careful hygiene (including washing their hands) when changing children's diapers.
VACCINE COMPONENTS [7]	Human-bovine rotavirus reassortants G1, G2, G3, G4, and P1A, sucrose, sodium citrate dihydrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, diluent and Vero cell culture media. Trace amounts of fetal bovine serum may be present. DNA fragments from porcine circoviruses (PCV) 1 and 2 have been detected in RotaTeq®. The source is porcine-derived material used in the manufacture of the vaccine. PCV-1 and PCV-2 are not known to cause disease in humans. Preservative-free, thimerosal-free and latex-free.

Rotavirus Vaccine
(oral live viral pentavalent human-bovine reassortant)

RotaTeq® (Rot-5)
(Merck Canada Inc. 2023 monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/ROTATEQ-PM_E.pdf)

EXPECTED REACTIONS	• Common temporary reactions such as fever, diarrhea, and vomiting may occur within 1 week after immunization. • Less common temporary reactions include irritability, loss of appetite, flatulence (gas), and abdominal pain. • Intussusception occurs in about 34 out of 100,000 babies in their first year. The current rotavirus vaccines have demonstrated a small increased risk of intussusception (1 to 7 cases per 100,000 doses). Intussusception related to rotavirus vaccines is extremely rare.
EFFECTIVENESS	In phase III clinical studies, 92.9% to 100% of recipients of RotaTeq® achieved a significant rise in serum anti-rotavirus IgA after a three-dose regimen.

- **Under no circumstances should RotaTeq® be injected.**
- **RotaTeq® is to be administered orally without mixing with any other vaccines or solutions.**
- **Do not reconstitute or dilute.**
- **NOTE:** The manufacturer has not addressed RotaTeq® be given via g-tube but the CDC considers administration of rotavirus vaccine via g-tube to be an acceptable practice. Ensure the g-tube is flushed before and after RotaTeq® has been administered (http://www.immunize.org/askexperts/experts_rota.asp).
- Refer to SIM chapter 8 *Appendix 8.4 Oral Vaccine Administration via Enteral Tube*.

[1] Age-appropriate infants who have had rotavirus gastroenteritis before starting or completing the full RotaTeq® series should still initiate or complete the RotaTeq® series because the initial infection frequently provides only partial immunity.
[2] The minimum interval is 4 weeks between all Rot-5 doses.
[3] If an infant spits out or regurgitates any of the Rot-5 dose no replacement dose should be administered.
[4] There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after immunization with RotaTeq® vaccine.
[5] RotaTeq® vaccine may be administered at any time before, concurrently with, or after administration of any live vaccine and blood product, including antibody-containing products.
[6] There are no data on the interchangeability of RotaTeq® and ROTARIX™ vaccines. Whenever possible, the series should be completed with the same product. However, if the product used for a previous dose(s) is not known, complete the series with the available product. If any dose in the series was RotaTeq®, a total of 3 doses of rotavirus vaccine should be administered provided the age limit of 8 months minus 1 day is not exceeded.
[7] DNA fragments from porcine circoviruses (PCV) 1 and 2 have been detected in RotaTeq®. The source is porcine-derived material used in the manufacture of the vaccine. PCV-1 and PCV-2 are not known to cause disease in humans.
[8] For infants in whom the first dose of RV vaccine is inadvertently administered at age 15 weeks or older, the rest of the series should be completed with a minimum of 4 weeks between each dose, and all doses should be administered before 8 months minus 1 day of age (CIG).

Smallpox and Mpox Vaccine (SMV)
Modified Vaccinia Ankara-Bavarian Nordic® (live-attenuated, non-replicating)

IMVAMUNE®

Product monograph: https://pdf.hres.ca/dpd_pm/00070186.PDF

Composition/Platform Vaccine Type, Vaccine Efficacy	• Each single-dose vial of liquid-frozen IMVAMUNE is formulated to have a titer of at least 0.5 x 10^8 infectious units (Inf.U) per 0.5 mL (1 dose) of Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN). • Tris buffer (Tris-hydroxymethyl-amino methane, sodium chloride, water for injection and hydrochloric acid), Trometamol (Tris-hydroxymethyl-amino methane), sodium chloride, water for injection. The vaccine contains trace amounts of host cell DNA and protein, benzonase, gentamicin and ciprofloxacin. • No adjuvants or preservatives
Dosage by Route	**0.5 ml Subcutaneous (SC) injection** ❖ 0.1 ml Intradermal (ID) injection for **only as dose sparing strategy** when there is limited vaccine supply and a second dose is required NOTE: Off-label ID administration is **only for immunocompetent adults** when given as a second dose following a first dose given subcutaneously.
ID Route Administration	• Those <18 years of age, at risk of keloid scars, or moderately to severely immunocompromised should be immunized using the subcutaneous route of administration only.
Series and eligibility	• **Those with a documented history of prior mpox infection need not be vaccinated.** **Post-exposure Prophylaxis (PEP)** (1 dose; see second bullet re second dose) • For individuals with high-risk exposures to a probable or confirmed case of mpox, or within a setting where transmission is happening, PEP should be offered as soon as possible and within 4 days of last exposure and can be considered up to 14 days since last exposure. PEP should not be offered to individuals who are symptomatic and who meet the definition of suspect, probable or confirmed case. • After 28 days, if an individual is assessed as having a predictable ongoing risk of exposure, a second dose may be offered in consultation with a Medical Health Officer. A second dose should not be offered to individuals who are symptomatic and therefore after medical evaluation meet suspect, probable or confirmed mpox case definitions. • For individuals who had received a live replicating 1st or 2nd generation smallpox vaccine in the past and who sustain a high-risk exposure to a probable or confirmed case of mpox, a single dose may be offered (i.e. as a booster dose) at least 28 days after the latest live replicating smallpox vaccine dose. **Pre-exposure Prophylaxis (PrEP)** (2 doses four weeks apart) • **Those working in research laboratory settings** with replicating orthopoxviruses • **High risk individuals that include:** ○ Men who have sex with men (MSM) who meet one or more of the following criteria: ▪ have more than one partner ▪ are in a relationship where at least one of the partners has other sexual partners ▪ have had a confirmed sexually transmitted infection acquired in the last year ▪ have engaged in sexual contact in sex-on-premises venues ○ Sexual partners of individuals who meet the criteria above ○ Individuals who identify as sex workers regardless of gender, sex assigned at

	birth, or sexual orientation ○ Staff or volunteers in sex-on-premises venues where workers may have contact with fomites potentially contaminated with mpox ○ Travellers who engage in risky sexual behaviours regardless of gender, sex assigned at birth, or sexual orientation ○ Individuals who anticipate experiencing any of the above scenarios • ***Travellers who are high risk individuals (as outlined above)*** • ***Travellers who are Canadian healthcare professionals*** *in advance of deployment to support the mpox clade I outbreak in countries where there is a level 2 travel health notice for mpox.* ▪ *Healthcare workers being deployed to these regions should receive 2 doses administered at least 28 days apart, in advance of deployment.* **Imvamune® may be offered to the following individuals who meet eligibility criteria:** • Those who are pregnant or breastfeeding and who are at risk. • Those who are immunocompromised due to disease or treatment and are at risk. • Those younger than 18 years of age where infection could have significant negative outcomes. **For immunocompetent individuals** who have received a live replicating first or second generation smallpox vaccine in the past and who are at high risk for occupational exposure, a single dose may be offered (i.e. as a booster dose), rather than the two dose primary vaccine series. This single dose should be given at least two years after the latest live replicating smallpox vaccine dose.
Contraindications	• Known severe hypersensitivity to a previous vaccine dose or any component of the vaccine. • Egg-allergic individuals may be immunized except if there is a known previous anaphylactic reaction to egg. Egg-allergic vaccine recipients should be kept under observation for 30 minutes following the administration of this vaccine. • Anaphylaxis to previous vaccine dose. If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination.
Precautions	NACI (2022-06-10): • Myocarditis: First generation *orthopoxvirus* vaccines and mRNA COVID-19 vaccines both have a potential risk of cardiac adverse events (myocarditis). Risk for myo- or pericarditis with the newer generation non-replicating attenuated virus vaccine Imvamune® is still unknown. It would be prudent to wait for a period of at least 4 weeks **before** or **after** the administration of mRNA COVID-19 vaccine in order to prevent erroneous attribution of an AEFI to one particular vaccine or the other. This suggested minimum waiting period between vaccines is **precautionary** at this time. Protection from mpox exposure should be prioritized and recent mRNA vaccine receipt should not delay Imvamune® PEP or PrEP if protection is urgent. • In consultation with a physician, the benefit of protection against infection should be weighed against the risk of recurrent myocarditis for individuals with a history of myocarditis/pericarditis linked to a previous dose of live replicating 1st and 2nd generation smallpox vaccine and/or Imvamune®; a precautionary approach is warranted at this time until more information is available. • Imvamune® given as PEP or PrEP should not be delayed due to recent receipt of an mRNA COVID-19 vaccine. If vaccine timing can be planned (i.e. prior to employment within a research laboratory), NACI recommends that Imvamune® be given at least 4 weeks after or before an mRNA vaccine for COVID-19 . • Individuals with the following conditions should discuss vaccination with their physician, who will be able to advise on safe vaccination or on alternative

	preventative measures to avoid infection with smallpox, mpox or other orthopoxviruses: Pregnant or breast feeding women.
Possible reactions	• The adverse reactions listed below have been observed during clinical studies. The most common side effects reported were at the injection site. Most of the reported adverse reactions are mild to moderate in intensity and resolving without intervention within seven days following vaccination. • Local reactions may last longer/be more common if the vaccine was administered by the ID route. **Very common side effects** reported in at least 1 in 10 persons were: • Pain, redness, swelling, hardness, or itching at the injection site. • Tiredness, headache, aching muscles, nausea. **Common side effects** reported in at least 1 in 100 but less than 1 in 10 persons were: • Nodule, discolouration, bruising, warmth at the injection site, chills, fever, pain in extremity, joint pain, or loss of appetite. **Uncommon side effects** reported in at least 1 in 1000 but less than 1 in 100 persons were: • Irritation, bleeding, scaling, inflammation, sensitivity disorder, or reaction at the injection site. • Underarm swelling, malaise, flushing, axillary pain, chest pain, dizziness, sensibility disorder, musculoskeletal stiffness, back pain, neck pain, rash, pruritus, dermatitis, skin discolouration, diarrhea, vomiting, dry mouth, throat pain, flu-like symptoms, cough, sleep disorder, clinically not relevant increase of cardiac enzymes, hepatic enzyme increased, white blood cell count decreased, mean platelet volume decreased, contusion, nose and throat infection, upper respiratory tract infection or temporarily enlarged lymph nodes. **Rare side effects** reported in less than 1 in 1000 persons were: • Rash, anesthesia, dryness, movement impairment or vesicles at the injection site. • Weakness, influenza like illness, oedema peripheral, migraine, peripheral nerve sensations, muscle spasms, musculoskeletal pain, muscular weakness, urticarial, ecchymosis, increased sweating, night sweats, subcutaneous nodule, angioedema, abdominal pain, increased heartbeat, sinusitis, pink eye, mouth and throat pain, influenza, white blood cell count increased, vertigo.
Other Considerations	• IMVAMUNE is a non-replicating live vaccine and it can be co-administered with or given any time before or after another live vaccine, an immune globulin product or tuberculin skin testing. • Cardiac AESIs were reported to occur in 1.4% (91/6,640) of IMVAMUNE recipients and 0.2% (3/1,206) of placebo recipients who were smallpox vaccine-naïve. Cardiac AESIs were reported to occur in 2.1% (16/762) of IMVAMUNE recipients who were smallpox vaccine-experienced. Replicating smallpox vaccines have been associated with myopericarditis. If a vaccinated subject exhibits signs and symptoms potentially associated with a cardiac disorder (e.g. chest pain or discomfort, dyspnea, or palpitations), ECG and troponin I tests should be performed. In case of ECG changes or troponin I elevations, further cardiologic examination should be performed. • Persons who have atopic dermatitis may have more intense reactions or have a flare up after getting this vaccine. • The safety profile of IMVAMUNE® in immune compromised subjects has been shown to be comparable to that recorded for healthy individuals. IMVAMUNE has been studied in more than 690 subjects infected with HIV to evaluate its immunogenicity and safety in an immunocompromised population. Since HIV directly infects T helper cells, and also indirectly impairs other immune system responses, HIV infection can be considered as being exemplary also for other forms of immunodeficiency.

<table>
<tr><td>Storage and Stability</td><td>
Table 1: Approved Imvamune shelf life in Canada for storage at -20°C, -50°C and -80°C from date of manufacture
<table>
<tr><th>Storage temperature</th><th>Approved shelf life from date of manufacture</th></tr>
<tr><td>-20°C ± 5°C</td><td>3 years</td></tr>
<tr><td>-50°C ± 10°C</td><td>5 years</td></tr>
<tr><td>-80°C ± 10°C</td><td>9 years</td></tr>
</table>
Table 2. Approved Imvamune shelf life in Canada for storage at +2°C to +8°C
<table>
<tr><th>Storage temperature</th><th>Approved shelf life</th></tr>
<tr><td colspan="2">After prior storage at -20°C or -80°C (if within approved respective shelf-life)</td></tr>
<tr><td>+2°C to +8°C</td><td>2 months (8 weeks)</td></tr>
</table>
Table 3. Total allowable time for interim shipment and storage at -20°C following long-term storage at -80°C
<table>
<tr><th>Previous Long-Term Storage Temperature</th><th>Total number of cumulative days allowable at -20°C</th></tr>
<tr><td>-80°C ± 10°C (within 9-year shelf life)</td><td>3 months (91 days)</td></tr>
</table>
</td></tr>
<tr><td>Shipment & Temperature Excursions</td><td>Refer to the Storage and Handling of IMVAMUNE Vaccine work standard, and Imvamune: Storage temperatures, shelf life, shipment and supportive temperature excursion information.</td></tr>
<tr><td>Administration and Disposable</td><td>

Thaw in the refrigerator (2-8C) or at room temperature.
To ensure homogeneity upon thawing, the vial should be swirled gently (not shaken) for at least 30 seconds.
After thawing, the drug product should appear as a pale milky colored homogeneous suspension. Visually inspected for any foreign particulate matter prior to administration. In case of foreign particulate matter being visible, the vaccine must not be used.
If a vial is used for multiple doses, it should be discarded after 6 hours following first puncture.
Do not refreeze a vial once it has been thawed.
Store in the original package to protect from light.
Do not use after the expiry date shown on the label, unless batch certification documentation allows for use based on an updated expiry date.

</td></tr>
</table>

Reference:

- NACI (September 2022). NACI Rapid Response – Update interim guidance on the use of Imvamune® in the context of mpox outbreaks. https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-updated-interim-guidance-imvamune-mpox-outbreaks.pdf
- Imvamune: Storage temperatures, shelf life, shipment and supportive temperature excursion information (Feb. 7, 2025) https://www.canada.ca/en/public-health/services/diseases/mpox/technical-documents/imvamune-storage-temperatures-shelf-life-shipment-temperature-excursion.html

Tetanus-Diphtheria Vaccine (Td) (Adsorbed)

Td Adsorbed
Product monograph: https://www.sanofi.com/en/canada/your-health/vaccines-products

INDICATIONS (≥7 years old) [1, 2] For those who have a contraindication to a pertussis-containing vaccine.	**DOSE** 0.5 mL IM
CONTRAINDICATIONS 1. History of anaphylactic reaction to a previous dose of any tetanus or diphtheria-containing vaccine, or to any Td vaccine component. 2. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given • Refer to *Tetanus Immune Globulin* (TIg) in this chapter. • Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management.* 3. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine.	
VACCINE COMPONENTS Tetanus toxoid, diphtheria toxoid. Latex and thimerosal free. • **Td Adsorbed with 2-phenoxyethanol (Preservative):** Aluminum Phosphate (adjuvant) (1.5 mg); 2-Phenoxyethanol (0.6% v/v) and Isotonic solution of Sodium Chloride in Water for Injection (q.s. to 0.5 mL). Formaldehyde is present in trace amounts. • **Td Adsorbed (Preservative Free):** Aluminum Phosphate (adjuvant) (1.5 mg); saline 0.9% (q.s. to 0.5 mL) and Water for Injection (q.s. to 0.5 mL). Formaldehyde is present in trace amounts.	
EXPECTED REACTIONS **Local:** Pain, swelling, redness at injection site. **Systemic**: Fatigue, headache, fever, dizziness, or sore or swollen joints.	
SPECIAL CONSIDERATION For wound prophylaxis, Td and TIg are administered using separate syringes and different sites.	
EFFECTIVENESS May not protect 100% of susceptible individuals.	

[1] Refer to Chapter 5, Section 3.7, Tetanus Prophylaxis in Wound Management.
[2] Tetanus toxoid should not be given routinely to clients who have received a tetanus-containing vaccine in the previous 5 years. Refer to Chapter 5, Section 2.1, *Minimum Intervals for Specific Vaccine Series.*

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)

ADACEL®

Product monograph: https://www.sanofi.com/en/canada/your-health/vaccines-products

INDICATIONS, DOSES and SERIES [*, 1, 2, 3] (0.5 mL IM) (Min. age 4 years old)	
1. Wound Management [1] **2.** Booster (5th) dose at age 4-6 years (school entry) who have met polio vaccine requirements. **3.** Reinforcement dose for Grade 8 students. [2] **4.** Reinforcement dose for adults every 10 years **5.** Pregnant women: Tdap in every pregnancy, ideally between 27-32 weeks gestation. [4] **6.** Unimmunized individuals 7+ years who do not require IPV: 1. Dose 1 2. Dose 2: 1 months after 1st dose 3. Dose 3: 6 months after 2nd dose **7.** Children 7+ and Adolescents who do not require IPV: **A.** Booster dose for those who missed receiving the school entry booster dose. **B.** Incompletely immunized children and adolescents [3]: a. **If the first dose of DTaP-containing vaccine was administered before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as: 1. Dose 1 was administered before the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 1 month after 2nd dose 4. Dose 4: 6 months after 3rd dose (must be given ≥ 4 years old) b. **If the first dose of DTaP-containing vaccine was administered after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as: 1. Dose 1 was administered after the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 6 months after 2nd dose (must be given ≥ 4 years old)	
REINFORCEMENT	Adults every 10 years
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine. 5. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine. 6. Individuals who have experienced other neurological complications following an earlier immunization against diphtheria and/or tetanus.

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap) **ADACEL®**	
VACCINE COMPONENTS	Tetanus toxoid, diphtheria toxoid, acellular pertussis [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)]. **Excipients**: Aluminum phosphate (adjuvant), 2-phenoxyethanol (not present in the preservative-free formulation). **Manufacturing residuals**: Formaldehyde and glutaraldehyde are present in trace amounts. Latex, antibiotic and thimerosal free.
EXPECTED REACTIONS	**Local**: pain, redness and swelling at the injection site. **Systemic:** fatigue, headache, mild fever, dizziness, body aches or nausea.
EFFECTIVENESS	93-100% show protective levels for at least 5 years

***** According to the National Advisory Committee on Immunization (NACI), there is no upper age limit for the administration of Tdap. This differs from the information in the Tdap product monographs.

[1] Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management.*

[2] Children who complete their primary series or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8. See Chapter 5, Appendix 5.3 *Grade 8 Tdap Algorithm.*

[3] There is no minimum interval between a dose of Td and Tdap when Tdap is being given for pertussis protection.

[4] Refer to Chapter 7 *Appendix 7.7: Tdap Immunization Decision Chart for Pregnant Women.*

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)

BOOSTRIX®

Product monograph available at: https://ca.gsk.com/media/6234/boostrix.pdf

INDICATIONS, DOSES and SERIES [*, 1, 2, 3] (0.5 mL IM) (Min. age 4 years old)	
1. Wound Management [1] **2.** Booster (5th) dose at age 4-6 years (school entry) who have met polio vaccine requirements. **3.** Reinforcement dose for Grade 8 students. [2] **4.** Reinforcement dose for adults every 10 years **5.** Pregnant women: Tdap in every pregnancy, ideally between 27-32 weeks gestation. [4] **6.** Unimmunized individuals 7+ years who do not require IPV: 1. Dose 1 2. Dose 2: 1 months after 1st dose 3. Dose 3: 6 months after 2nd dose **9.** Children 7+ and Adolescents years of age who do not require IPV: **A.** Booster dose for those who missed receiving the school entry booster dose. **B.** Incompletely immunized children and adolescents [3]: a. **If the first dose of DTaP-containing vaccine was administered before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as: 1. Dose 1 was administered before the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 1 month after 2nd dose 4. Dose 4: 6 months after 3rd dose (must be given ≥ 4 years old) b. **If the first dose of DTaP-containing vaccine was administered after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as: 1. Dose 1 was administered after the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 6 months after 2nd dose (must be given ≥ 4 years old)	
REINFORCEMENT	Adults every 10 years
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine. 5. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine. 6. Individuals who have experienced other neurological complications following an earlier immunization against diphtheria and/or tetanus.

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap) **BOOSTRIX®**	
VACCINE COMPONENTS	Diphtheria toxoid, three purified pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (69 kDalton outer membrane protein)], and tetanus toxoid. It also contains aluminum (as 0.5 mg aluminum salts), sodium chloride, water for injection. Latex, antibiotic and thimerosal free.
EXPECTED REACTIONS	**Local**: pain, redness and swelling at the injection site. **Systemic:** fatigue, headache, mild fever, dizziness, body aches or nausea.
EFFECTIVENESS	93-100% show protective levels for at least 5 years

***** According to the National Advisory Committee on Immunization (NACI), there is no upper age limit for the administration of Tdap. This differs from the information in the Tdap product monographs.

[1] Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management*.

[2] Children who complete their primary series or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8. See Chapter 5, Appendix 5.3 *Grade 8 Tdap Algorithm*.

[3] There is no minimum interval between a dose of Td and Tdap when Tdap is being given for pertussis protection.

[4] Refer to Chapter 7 *Appendix 7.7: Tdap Immunization Decision Chart for Pregnant Women.*

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV)

ADACEL®-POLIO

Product monograph: https://www.sanofi.com/en/canada/your-health/vaccines-products

INDICATIONS, DOSES and SERIES (0.5 mL IM) (Min. age 4 years old)	
1. Wound Management [5] **2.** Booster (5th) dose at age 4-6 years (school entry) [1, 2] **3.** Unimmunized individuals 7+ years: 1. Dose 1 2. Dose 2: 1 months after 1st dose 3. Dose 3: 6 months after 2nd dose **4.** Children 7+ and Adolescents years of age: **A.** Booster dose for those who missed receiving the school entry booster dose. **B.** Incompletely immunized children 7+ and adolescents [3]: a. **If the first dose of DTaP-containing vaccine was administered before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as [4]: 1. Dose 1 was administered before the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 1 month after 2nd dose 4. Dose 4: 6 months after 3rd dose (must be given ≥ 4 years old) b. **If the first dose of DTaP-containing vaccine was administered after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as: 1. Dose 1 was administered after the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 6 months after 2nd dose (must be given ≥ 4 years old)	
REINFORCEMENT	None
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine. 5. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine. 6. Individuals who have experienced other neurological complications following an earlier immunization against diphtheria and/or tetanus.

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV) ADACEL®-POLIO	
VACCINE COMPONENTS	Tetanus toxoid, reduced diphtheria toxoid, acellular pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)], and inactivated poliomyelitis vaccine [type 1 (Mahoney), type 2 (MEF-1) and type 3 (Saukett)]. **Excipients**: Aluminum phosphate (adjuvant), 2-phenoxyethanol, ethanol, polysorbate 80. **Manufacturing residuals**: Bovine serum albumin, formaldehyde, glutaraldehyde, streptomycin, neomycin and polymyxin B are present in trace amounts. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Temporary pain, swelling and redness where the vaccine was given. Up to 20% of children who get this vaccine may have redness, swelling and pain at the injection site/arm for up to 5 days afterward. The symptoms usually resolve without any treatment (e.g., antihistamines) given. S**ystemic**: Tiredness, headache, mild fever, nausea, body aches and chills.
EFFECTIVENESS	Tetanus, diphtheria and polio antibodies are robust and pertussis antibodies in fully immunized children persist after 3 years of receiving Tdap-IPV as a replacement for DTaP-IPV.

[1] Not required if the 4th dose of DTaP-IPV-Hib or DTaP-IPV was given after the 4th birthday.

[2] Refer to SIM, Chapter 5 *Appendix 5.6: Immunization Recommendations for Children 4-6 years of Age.*

[3] Children who complete their primary series, or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8. See Chapter 5, Appendix 5.3 *Grade 8 Tdap Algorithm*.

[4] As only 3 doses of polio are required, Tdap may be used as one of the doses in this series, ensuring the recommended intervals for polio are maintained.

[5] Refer to Chapter 5, Section 3.7, Tetanus Prophylaxis in Wound Management

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV)

BOOSTRIX®-POLIO

Product monograph available at: https://ca.gsk.com/media/6235/boostrix-polio.pdf)

INDICATIONS, DOSES and SERIES (0.5 mL IM) (Min. age 4 years old) **1.** Wound Management [5] **2.** Booster (5th) dose at age 4-6 years (school entry) [1, 2] **3.** Unimmunized individuals 7+ years: 1. Dose 1 2. Dose 2: 1 months after 1st dose 3. Dose 3: 6 months after 2nd dose **4.** Children 7+ and Adolescents years of age: **A.** Booster dose for those who missed receiving the school entry booster dose. **B.** Incompletely immunized children 7+ and adolescents [3]: a. **If the first dose of DTaP-containing vaccine was administered before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as [4]: 1. Dose 1 was administered before the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 1 month after 2nd dose 4. Dose 4: 6 months after 3rd dose (must be given ≥ 4 years old) b. **If the first dose of DTaP-containing vaccine was administered after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as: 1. Dose 1 was administered after the 1st birthday 2. Dose 2: 1 month after 1st dose 3. Dose 3: 6 months after 2nd dose (must be given ≥ 4 years old)	
REINFORCEMENT	None
PRECAUTION	Acellular pertussis-containing vaccines may be administered to clients with the following conditions once a treatment regimen has been established and their condition has stabilized: • Progressive or unstable neurologic disorder (including infantile spasms for DTaP) • Uncontrolled seizures • Progressive encephalopathy
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine. 5. Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days after receiving a dose of a pertussis-containing vaccine. 6. Individuals who have experienced other neurological complications following an earlier immunization against diphtheria and/or tetanus.

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV) BOOSTRIX®-POLIO	
VACCINE COMPONENTS	Not less than 2.5 limit of flocculation ('Lf'), or 2 IU ('International Units') of diphtheria toxoid; not less than 5 Lf (20 IU) of tetanus toxoid; 8 mcg of pertussis toxoid, 8 mcg of filamentous haemagglutinin, 2.5 mcg of pertactin (69 kDa outer membrane protein), 40 D-antigen units (DU) of Type 1 poliovirus, 8 DU Type 2 polio virus and 32 DU Type 3 polio virus. Aluminum (as aluminum salts), sodium chloride, water for injection and medium 199. Residues*: disodium phosphate, formaldehyde, glutaraldehyde, glycine, monopotassium phosphate, neomycin sulphate, polymyxin B sulphate, polysorbate 80 and potassium chloride. Thimerosal free. Latex –free.
EXPECTED REACTIONS	**Local**: Temporary pain, swelling and redness where the vaccine was given. Up to 20% of children who get this vaccine may have redness, swelling and pain at the injection site/arm for up to 5 days afterward. The symptoms usually resolve without any treatment (e.g., antihistamines) given. S**ystemic**: Tiredness, headache, mild fever, nausea, body aches and chills.
EFFECTIVENESS	Tetanus, diphtheria and polio antibodies are robust and pertussis antibodies in fully immunized children persist after 3 years of receiving Tdap-IPV as a replacement for DTaP-IPV.

[1] Not required if the 4th dose of DTaP-IPV-Hib or DTaP-IPV was given after the 4th birthday.
[2] Refer to SIM, Chapter 5 *Appendix 5.6: Immunization Recommendations for Children 4-6 years of Age*
[3] Children who complete their primary series or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8. See Chapter 5, Appendix 5.3 *Grade 8 Tdap Algorithm.*
[4] As only 3 doses of polio are required, Tdap may be used as one of the doses in this series, ensuring the recommended intervals for polio are maintained.
[5] Refer to Chapter 5, Section 3.7, Tetanus Prophylaxis in Wound Management.

Typhoid Vaccine (Typh-I)
(Salmonella typhi Vi Capsular Polysaccharide) (Inactivated) [Non-publicly funded]

TYPHIM Vi®
Product monograph: https://www.sanofi.com/en/canada/your-health/vaccines-products

Typhoid Vaccine (Typh-O)
(Live Oral Attenuated Ty 21a) [Non-publicly funded]

Vivotif®
Product information available at: https://pdf.hres.ca/dpd_pm/00058906.PDF

Varicella Vaccine (Var) (live, attenuated)

VARILRIX®

Product monograph available at: https://ca.gsk.com/media/6263/varilrix.pdf)

INDICATIONS [1]	**DOSE / Series**
1. Those born since 1993-01-01 are eligible to receive an age or cohort appropriate series. 2. Non-immune HCW/post-secondary healthcare students as specified in Chapter 7. 3. Non-immune non-pregnant women of child-bearing age as specified in Chapter 5 Appendix 5.4, *Publicly Funded Varicella Immunization Eligibility and Panorama Directives.* [2] 4. Susceptible immunocompromised individuals as referred by their specialist via submission of Chapter 7, *Immunization of Special Populations.* Appendix 7.2: *Varicella Immunization Referral Form*.[4]	Two doses of 0.5 mL SC [3] given a minimum of 28 days apart.

CONTRAINDICATIONS

- History of an anaphylactic reaction to a previous dose of any varicella –containing vaccine, or to any component of VARILRIX®.
- Pregnancy. Women of childbearing age should avoid pregnancy for at least 28 days (1 month) post-vaccination.
- People with active untreated tuberculosis.
- Recent administration of an immune globulin preparation **(excluding RhoGam [RhIg])** or blood product [2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* .

PRECAUTIONS

- Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine.
- Family history of congenital immunodeficiency. Refer to SIM, Chapter 7, *Immunization of Special Populations* Section 3.1, *Congenital Immunodeficiency*
- Do TB skin testing on the same day as varicella immunization or delay TB skin testing for ≥ 4 weeks.
- Varicella immunization should be given on the same day as other live vaccines or delayed until 4 weeks after administration of any other live vaccine.
- Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG).
- It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).

VACCINE COMPONENTS: Live, attenuated varicella virus vaccine (Oka-strain), amino acids, lactose, mannitol, sorbitol and water for injection. Neomycin sulphate is present as traces. Thimerosal free.

EXPECTED REACTIONS: Local: soreness, swelling, redness and rash where the needle was given. **Systemic:** fever, nausea, vomiting, diarrhea or decreased appetite, headache, dizziness, fussiness, tiredness. A varicella-like rash 5 to 26 days after getting immunized.

SPECIAL CONSIDERATION: Administer vaccine immediately after reconstitution.

*****Varicella footnotes are continued on next page.

Varicella Vaccine (Var) (live, attenuated)
VARILRIX®

[1] Varicella susceptible is defined as:

- Lack of documented evidence of serological of VZV IgG antibodies; or
- Lack of documented evidence of immunization with 2 doses of a varicella-containing.
- **NOTE**: verbal history of disease is unacceptable evidence of immunity for those born since Jan. 1, 2003.

[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

[3] Individuals who are eligible for a 2-dose varicella series who have documented evidence of **viral culture confirmed** (breakthrough) varicella disease 42 days or more after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose. Provide a second dose of varicella-containing vaccine to those without this documentation as verbal history and/or healthcare practitioner diagnosis of breakthrough disease is unreliable.

[4] Refer to Chapter 7, *Immunization of Special Populations.* Appendix 7.2: *Varicella Immunization Referral Form*.

Varicella Vaccine (Var)
(live, attenuated)

VARIVAX® III
Product monograph available at: https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/VARIVAX_III-PM_E.pdf)

INDICATIONS [1].	DOSE / Series
1. Those born since 1993-01-01 are eligible to receive an age or cohort appropriate series. 2. Non-immune HCW/post-secondary healthcare students as specified in Chapter 7. 3. Non-immune non-pregnant women of child-bearing age as specified in Chapter 5 Appendix 5.4, *Publicly Funded Varicella Immunization Eligibility and Panorama Directives.*[2] 4. Susceptible immunocompromised individuals *when Varilrix is unavailable*, as referred by their specialist via submission of Chapter 7, *Immunization of Special Populations.* Appendix 7.2: *Varicella Immunization Referral Form*.[4]	**Two doses of 0.5 mL SC [3] given a minimum of 28 days apart.**

CONTRAINDICATIONS
- History of an anaphylactic reaction to a previous dose of any varicella –containing vaccine, or to any component of VARIVAX®.
- Pregnancy. Women of childbearing age should avoid pregnancy for at least 28 days (1 month) post-vaccination.
- People with active untreated tuberculosis.
- Recent administration of an immune globulin preparation **(excluding RhoGam [RhIg])** or blood product.[2]

PRECAUTIONS
- Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine.
- Family history of congenital immunodeficiency. Refer to SIM, Chapter 7, *Immunization of Special Populations* Section 3.1, *Congenital Immunodeficiency*
- Do TB skin testing on the same day as varicella immunization or delay TB skin testing for ≥ 4 weeks.
- Varicella immunization for immunocompetent clients should be given on the same day as other live vaccines or delayed until 4 weeks after administration of any other live vaccine.
- Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours after the last dose as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG).
- It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).

VACCINE COMPONENTS: Oka/Merck varicella strain (live, attenuated) ≥1350 PFU. **Excipients**: Sucrose, hydrolyzed gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, water for injection. Manufacturing Process Residuals: The product also contains residual components of MRC-5 cells including DNA and protein, and trace quantities of neomycin and fetal bovine serum from MRC-5 culture media. Preservative (thimerosal) free. Latex-free.

EXPECTED REACTIONS: Local: soreness, swelling, redness and rash where the needle was given. **Systemic:** fever, nausea, vomiting, diarrhea or decreased appetite, headache, dizziness, fussiness, tiredness. A varicella-like rash 5 to 26 days after getting immunized.

SPECIAL CONSIDERATION: Minimum potency remaining at expiry 90 minutes after reconstitution and storage at room temperature. Administer vaccine immediately after reconstitution.

*****Varicella footnotes are continued on next page.

Varicella Vaccine (Var) (live, attenuated)
VARIVAX® III

[1] Varicella susceptible is defined as:

- Lack of documented evidence of serological of VZV IgG antibodies; or
- Lack of documented evidence of immunization with 2 doses of a varicella-containing vaccine.
- **NOTE**: verbal history of disease is unacceptable evidence of immunity for those born since Jan. 1, 2003.

[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

[3] Individuals who are eligible for a 2-dose varicella series who have documented evidence of **viral culture confirmed** (breakthrough) varicella disease 42 days or more after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose. Provide a second dose of varicella-containing vaccine to those without this documentation as verbal history and/or healthcare practitioner diagnosis of breakthrough disease is unreliable.

Yellow Fever Vaccine (YF)

[Non-publicly funded]

YF-VAX®

Product monograph available at: https://www.sanofi.com/en/canada/your-health/vaccines-products

Tuberculin Purified Protein Derivative (PPD) (Mantoux)

TUBERSOL®

Product monograph: https://www.sanofi.com/en/canada/your-health/vaccines-products

INDICATIONS	Screening for latent tuberculosis infection (LTBI).	
DOSE/SERIES	PPD 5 TU 0.1 mL ID in anterior forearm (flexor or dorsal surface) between the wrist and the elbow: • For contact tracing, if the initial skin test is negative, a second test should be given 6 – 12 weeks after the last date of contact. • A second test, done 7 - 21 days after the first test, may be required in certain situations and would be on the advice of TB Control. • A small percentage of persons will only react after a second test or will react to a greater degree (so called "boosting" effect).	
EXPECTED REACTIONS	• **Read result in 48 – 72 hours.** • Possible redness, induration and blistering. • Measure only induration (raised) diameter in millimetres and record this measurement.	
CONTRA-INDICATIONS	• Pregnancy is not a contraindication to tuberculin testing. • A previous Bacille Calmette-Guerin (BCG) vaccine is not a contraindication to tuberculin testing**.** • History of anaphylactic reaction to a previous dose of Tubersol or any of its components. • **Tubersol should not be administered to:** ○ known tuberculin positive reactors; ○ persons with severe blistering tuberculin reactions in the past; ○ persons with documented active tuberculosis or a clear history of treatment for TB infection or disease; or ○ persons with extensive burns or eczema.	
PRECAUTION	Do TB skin testing on the same day as live vaccines are administered, or delay TB skin testing for ≥4 weeks after a live vaccine if possible.	
EXPECTED REACTIONS	Pain, pruritis and bruising at the test site may occur.	
TB skin test result interpretations		Refer to *Canadian Tuberculosis Standards* (7th Ed.) Available at: https://www.canada.ca/en/public-health/services/infectious-diseases/canadian-tuberculosis-standards-7th-edition/edition-16.html
COMPONENTS	Purified protein derivative of *M. tuberculosis*, phenol, polysorbate 80.	

Botulism Immune Globulin (BIg-IV)

BabyBIG
(Cangene USA https://www.infantbotulism.org/general/babybig.php)

This product is not manufactured in Canada and is only available through the *Special Access Program* (SAP). An information binder is shipped with every request for professional reference.

INDICATIONS	To treat patients younger than 12 months of age diagnosed with infant botulism.
INITIAL SERIES	Refer to binder.
REINFORCEMENT	Refer to binder.
CONTRAINDICATIONS	Refer to binder.
COMPONENTS	Refer to binder.
EXPECTED REACTIONS	Refer to binder.
SPECIAL CONSIDERATION	Refer to binder.

Hepatitis B Immune Globulin (HBIg) (Human)

HepaGam B®

KI BioPharma LLC product monograph: https://pdf.hres.ca/dpd_pm/00074625.PDF

NOTE: Vital signs are not required to be taken before or after IM HBIg administration.

INDICATIONS	**DOSE / SERIES** [1]
1. Infant born to known HBsAg positive woman. 2. Infant born to woman at high risk for hepatitis B infection (i.e., intravenous drug use, sex trade work)) whose infectious status is unknown or negative (possible window period) and cannot be determined within 12 hours of birth. 3. Percutaneous or mucosal exposure to HBsAg positive source. 4. Sexual contact with a person who has acute or chronic hepatitis B infection. 5. An at-risk known non-responder to two series of HB vaccine.	1. & 2. Give HBIg 0.5 mL IM within 12 hours of birth, along with first dose of hepatitis B vaccine series [2, 3] 3. Give HBIg 0.06 mL/kg of body weight IM and hepatitis B vaccine IM as required, considering the client's immune status and history of hepatitis B immunization [4, 5] 4. Give HBIg 0.06 mL/kg of body weight IM as soon as possible following the last sexual exposure, along with hepatitis B vaccine series [4, 5] 5. **Dose 1**: HBIg 0.06 mL/kg of body weight IM. **Dose 2**: HBIg 0.06 mL/kg of body weight IM 4 weeks later.
REINFORCEMENT	Currently no recommendations
CONTRA-INDICATIONS	• In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HepaGam B should be given only if the expected benefits outweigh the potential risks. • Patients with a history of anaphylactic or severe system reaction to any component of the product. • Patients who are deficient in IgA. While HepaGam B contains less than 40 mcg/mL IgA, individuals who are deficient in IgA may have the potential to develop IgA antibodies and have an anaphylactoid reaction.
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding HBIg and the administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* • Give HBIg with caution (i.e., in a setting capable of managing anaphylaxis) if the person has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits). • HBIg must be given at a separate anatomic site from hepatitis B vaccine.

Hepatitis B Immune Globulin (HBIg) (Human) **HepaGam B®**	
COMPONENTS	Human plasma protein (≥96% Human IgG), maltose, polysorbate 80. May contain trace amounts of tri-n-butyl phosphate and Triton X-100®
EXPECTED REACTIONS	•Temporary pain, swelling, tenderness and hives where the needles was given. •Headache. •Fever and diarrhea in infants. •Rarely, blot clots may occur after the administration of HB immune globulin.

[1] There is no upper limit to the volume of HBIg that can be administered.

[2] Refer to SIM, Chapter 7, *Immunization of Special Populations*, Section 4.2.1, *Hepatitis B Infant Immunoprophylaxis Protocol* for more information.

[3] There is no outer time limit for administering HBIg in infants less than 12 months of age, when the infant's exposure to the known risk factor(s) is ongoing. For infants less than 8.3 kg, give 0.5 ml HBIg.

[4] HBIg dose for all clients ≥ 8.3 kg is 0.06 ml/kg. Give HBIg as soon as possible, preferably within 48 hours of the exposure. For a percutaneous or permucosal exposure, HBIg may be given up to 7 days following the exposure. If the client presents more than 7 days following a percutaneous or permucosal exposure, give Hepatitis B vaccine only. For sexual exposures, HBIg may be given up to 14 days following the last exposure. If the client presents more than 14 days following a sexual exposure, give HB vaccine only. Refer to *Saskatchewan Post-Exposure Prophylaxis* recommendations available at: http://www.ehealthsask.ca/services/manuals/Pages/hiv-guidelines.aspx

[5] Refer to *Immune Globulin Preparation Maximum Site Volumes*

Hepatitis B Immune Globulin (HBIg) (Human)

HyperHEP B®

Grifols Therapeutics product monograph: https://pdf.hres.ca/dpd_pm/00062962.PDF

NOTE: Vital signs are not required to be taken before or after IM HBIg administration.

INDICATIONS	DOSE / SERIES [1]
1. Infant born to known HBsAg positive woman. **2**. Infant born to woman at high risk for hepatitis B infection (i.e., intravenous drug use, sex trade work) whose infectious status is unknown or negative (possible window period) and cannot be determined within 12 hours of birth. **3.** Percutaneous or mucosal exposure to HBsAg positive source. **4**. Sexual contact with a person who has acute or chronic hepatitis B infection. **5**. An at-risk known non-responder to two series of HB vaccine**.**	**1. & 2**. Give HBIg 0.5 mL IM within 12 hours of birth, along with first dose of hepatitis B vaccine series. [2, 3] **3.** Give HBIg 0.06 mL/kg of body weight and hepatitis B vaccine IM as required, considering the client's immune status and history of hepatitis B immunization. [4, 5] **4.** Give HBIg 0.06 mL/kg of body weight IM as soon as possible following the last sexual exposure, along with hepatitis B vaccine series [4, 5] **5**. **Dose 1**: HBIg 0.06 mL/kg of body weight IM. **Dose 2**: HBIg 0.06 mL/kg of body weight IM 4 weeks later.

CONTRAINDICATIONS	1. Patients who are hypersensitive to the immunoglobulin or to any ingredient in the formulation or component of the container 2. HyperHEP B® should not be administered to patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections. 3. IgA deficient patients with antibodies against IgA and a history of hypersensitivity.
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding HBIg and the administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Give HBIg with caution (i.e., in a setting capable of managing anaphylaxis) if the person has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits). • Clients with severe thrombocytopenia or coagulation disorders that contraindicate IM injections should not be given HBIg unless the benefits outweigh the risks. • HBIg must be given at a separate anatomic site from hepatitis B vaccine.

Hepatitis B Immune Globulin (HBIg) (Human) **HyperHEP B®**	
COMPONENTS	Contains 15-18% human hepatitis B hyperimmune immune globulin≥ 220 IU/mL, glycine. Preservative free. Prefilled syringes contain rubber needle shield and stopper.
EXPECTED REACTIONS	•Temporary pain, swelling, tenderness and hives where the needles was given. •Headache. •Fever and diarrhea in infants. •Rarely, blot clots may occur after the administration of HB immune globulin.

[1] There is no upper limit to the volume of HBIg that can be administered.

[2] Refer to Chapter 7, Section 4.2.1, *Hepatitis B Infants Immunoprophylaxis Protocol* for more information.

[3] There is no outer time limit for administering HBIg in infants less than 12 months of age, when the infant's exposure to the known risk factor(s) is ongoing. For infants less than 8.3 kg, give 0.5 ml HBIg.

[4] HBIg dose for all clients ≥ 8.3 kg is 0.06 ml/kg. Give HBIg as soon as possible, preferably within 48 hours of the exposure. For a percutaneous or permucosal exposure, HBIg may be given up to 7 days following the exposure. If the client presents more than 7 days following a percutaneous or permucosal exposure, give Hepatitis B vaccine only. For sexual exposures, HBIg may be given up to 14 days following the last exposure. If the client presents more than 14 days following a sexual exposure, give HB vaccine only. Refer to *Saskatchewan Post-Exposure Prophylaxis* recommendations available at: http://www.ehealthsask.ca/services/manuals/Pages/hiv-guidelines.aspx

[5] Refer to *Immune Globulin Preparation Maximum Site Volumes*

Immune Globulin (Ig) (Human)

GamaSTAN®

Product monograph: https://pdf.hres.ca/dpd_pm/00050163.PDF

NOTE: Vital signs are not required to be taken before or after IM Ig administration.

INDICATIONS	
1. Recommended and provided free for post-exposure prophylaxis of hepatitis A contacts as outlined in the *Saskatchewan Communicable Disease Control Manual*. [1] **2**. Recommended and provided free for post-exposure prophylaxis of measles contacts as outlined in the *Saskatchewan Communicable Disease Control Manual*. [1]	
CONTRA-INDICATIONS	**Do not give GamaSTAN® intravenously.**
PRECAUTIONS	• Health Canada has advised that the GamaSTAN® S/D product monograph has been updated to strengthen warnings on the rare but serious risk of blood clots. Blood clots have been reported in patients with and without risk factors, and can occur regardless of immunoglobulin dose or route of administration (injection into a muscle, vein or under the skin). [2] • Human Ig products are amongst the safest blood-derived products available. As the method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV, the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products. • Persons with severe thrombocytopenia or coagulation disorders that contraindicate IM injections should not be given IM Ig unless the benefits outweigh the risks. • Give Ig with caution (e.g., in a setting capable of managing anaphylaxis) if the client has a history of anaphylactic reaction following receipt of any human Ig product, or history of anaphylactic reaction to glycine or to latex (assess risks versus benefits). • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, Ig should only be given to such persons if the expected benefits outweigh the risks. • Divide large volumes of Ig into two or more sites. • If administration of Ig is necessary less than 14 days after MMR or varicella vaccine, repeat vaccine as per recommended intervals. Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5 *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*.
COMPONENTS	GamaSTAN® S/D contains 15-18% immune globulin (human) as active ingredient. It also contains 0.16-0.26 M glycine, USP. Preservative free.
EXPECTED REACTIONS	Pain, swelling, tenderness and hives where the needle was given Tiredness, fever, headache, nausea. Rarely, blood clots may occur after the administration of an immune globulin product.

[1] Immune globulin should be given as soon as possible after a known exposure and no later than 2 weeks after the exposure.

[2] Health Canada (Oct. 9, 2014). *Safety information on the risk of blood clots with immunoglobulin products*. Available at: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/41783a-eng.php

Rabies Immune Globulin (RabIg) (Human)

HyperRAB®

(Grifols Therapeutics 2021 monograph available at: https://www.staticweb.grifols.com/documents/3836559/0/HyperRAB+-+English+PM+-+2012-01-30.pdf/64ec0e5e-4f3b-468c-a4ec-3ff664117cf1)

NOTE: Vital signs are not required to be taken before or after IM RabIg administration.

INDICATIONS [1, 2, 4]	**RABIES POST-EXPOSURE PROPHYLAXIS (RPEP):** • As determined by Regional Medical Health Officers. • Refer to the SK CDC Manual Rabies chapter for information. • Rabies vaccine is given in conjunction with RabIg. Rabies vaccine and RabIg must be administered with separate needles and syringes at separate anatomical sites.
DOSE/ INITIAL SERIES [3]	**RABIES POST-EXPOSURE PROPHYLAXIS:** • The recommended dosage for children and adults is the same: 20 IU/kg of body weight. Because of interference with active antibody production, do not exceed recommended dose. ○ **HYPERRAB® is supplied as a 1 ml 300 IU vial or as a 2 ml vial of 300 IU (150 IU/mL) so read the label carefully to ensure correct dose calculation!** ○ The dose of **HYPERRAB® S/D** is calculated as: [20 IU/kg x weight in kg] = _____mL **[vaccine IU concentration/mL]** ○ If anatomically feasible, the full dose of HyperRAB® should be thoroughly infiltrated in the area around the wound. If the wound covers a large area and the HyperRAB® dose has insufficient volume to infiltrate the entire wound, the HyperRAB® dose may be diluted with an equal volume of dextrose, 5% (D5W) in water**. Do not dilute with normal saline.** ○ Inject the remainder, if any, intramuscularly, preferably in the deltoid muscle of the upper arm or lateral thigh muscle using a separate syringe and needle, and anatomical site.
REINFORCEMENT	Currently no recommendations.
CONTRA-INDICATIONS	**There are no contraindications to RabIg given for post-exposure purposes.**
PRECAUTIONS	• If client has a history of anaphylactic reaction following receipt of any human Ig product or to any of the components of a RabIg product, administer RabIg in an emergency room setting. • Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible, that unknown infectious agents may be present in such products.

Rabies Immune Globulin (RabIg) (Human) **HyperRAB®**	
	• Regarding RabIg and the administration of live vaccines, refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent blood products that contain IgA. Administer RabIg in an emergency room setting.
COMPONENTS	Human rabies hyperimmune globulin, glycine, sodium carbonate. Preservative free.
EXPECTED REACTIONS	Temporary tenderness, soreness, pain or stiffness where the needle was given, fever, headache, malaise, rash, chills, nausea, joint or muscle aches.

[1] If RabIg is not administered on day 0, it can be administered up to and including day 7 of the RPEP series. Since vaccine induced antibodies begin to appear within one week, there is no value in administering RabIg more than 8 days after initiation of vaccine.

[2] Provide a written record to a client who receives any immune globulin product.

[3] When notification of an exposure is delayed, RPEP may be started as late as 6 or more months after an exposure.

[4] **RabIg should never be administered in the same syringe or needle or in the same anatomical site as vaccine.**

Rabies Immune Globulin (RabIg) (Human)

KamRAB™

Product monograph: https://valneva.com/products/valnevas-products/

NOTE: Vital signs are not required to be taken before or after IM RabIg administration.

INDICATIONS [1, 2, 4]	**RABIES POST-EXPOSURE PROPHYLAXIS (RPEP):** • As determined by Regional Medical Health Officers. • Refer to the CDC Manual Rabies chapter for information. • Rabies vaccine is given in conjunction with RabIg. Rabies vaccine and RabIg must be administered with separate needles and syringes at separate anatomical sites

INITIAL SERIES [3]	**RABIES POST-EXPOSURE PROPHYLAXIS:**
	• The recommended dosage for children and adults is the same: 20 IU/kg of body weight. Because of interference with active antibody production, do not exceed recommended dose.
	  ○ The dose of RabIg is calculated as:
	  [20 IU/kg x weight in kg] = _____mL
	  [vaccine IU concentration/mL]
	  ○ Infiltrate as much RabIg as possible deep into and around the wound(s) in order to neutralize the virus. When more than one wound site exists, each site should be infiltrated with a portion of the RabIg.
	  ○ If there are extensive wounds, where the calculated dose of RabIg (by weight) is not adequate in volume to infiltrate all wounds, dilute the RabIg 2-3 fold in normal saline to create an adequate volume to infiltrate all wounds (CIG).

REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	**There are no contraindications to RabIg given for post-exposure purposes.**
PRECAUTIONS	• If client has a history of anaphylactic reaction following receipt of any human Ig product, to any of the components of RabIg (glycine) or to latex, administer RabIg in an emergency room setting. • Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible, that unknown infectious agents may be present in such products. • Regarding RabIg and the administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent blood products that contain IgA. Administer RabIg in an emergency room setting.

Rabies Immune Globulin (RabIg) (Human) **KamRAB™**	
COMPONENTS	KamRAB is a sterile, non-pyrogenic aqueous solution of anti-rabies immunoglobulin (≥95% protein as IgG). The product is stabilized with 0.3 M glycine and has a pH of 5.5 ± 0.5. Medicinal ingredients: Anti-rabies immunoglobulin (human antibodies to rabies) Non-medicinal ingredients: glycine, water for injection and sodium hydroxide. No preservatives are added. Latex free.
EXPECTED REACTIONS	Temporary tenderness, soreness, pain or stiffness where the needle was given, fever, headache, malaise, rash, chills, nausea, joint or muscle aches.

[1] If RabIg is not administered on day 0, it can be administered up to and including day 7 of the RPEP series. Since vaccine induced antibodies begin to appear within one week, there is no value in administering RabIg more than 8 days after initiation of vaccine.

[2] Provide a written record to a client who receives any immune globulin product.

[3] When notification of an exposure is delayed, RPEP may be started as late as 6 or more months after an exposure.

[4] **RabIg should never be administered in the same syringe or needle or in the same anatomical site as vaccine.**

Tetanus Immune Globulin (TIg) (Human)

HYPERTET®

(Grifols Therapeutics 2021 monograph available at: https://www.staticweb.grifols.com/documents/3836559/0/HyperTET+-+English+PM+-2012-02-03.pdf/12626081-1a27-43a5-9c05-7125dd4098b9)

NOTE: Vital signs are not required to be taken before or after IM TIg administration.

INDICATIONS	**DOSE / SERIES**
NOTE: **TIg must be given at separate anatomic sites from a tetanus toxoid-containing vaccine.** 1. TIg is indicated for prophylaxis against tetanus following a major or unclean wound in individuals whose immunization history is incomplete or uncertain. Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management*. 2. TIg is indicated when a contraindication to a tetanus toxoid-containing vaccine exists and an individual sustains a major or unclean wound. 3. TIg is indicated in individuals known to have a significant immune deficiency state (e.g., HIV) regardless of their immunization history, following any major or unclean wound. 4. TIg is also indicated, although evidence of effectiveness is limited, in the regimen of treatment of active cases of tetanus.	• Give 250 units IM (entire single dose pre-filled disposable syringe) to adults and children who require TIg. • If a contraindication to tetanus toxoid-containing vaccine exists or a client refuses a tetanus toxoid-containing vaccine, and a client sustains a major or unclean wound, consider offering a 2nd dose of TIg approximately 28 days post the 1st dose of TIg (ImmunoFacts, 2013). **NOTE:** The syringe fill volume for each lot is adjusted to ensure a potency of not less than 250 IU/syringe. The actual fill volume for HYPERTET syringes typically ranges between 0.75 ml and 1.3 ml. The needle on the pre-filled syringe is fixed and cannot be changed.

REINFORCEMENT	None if Td/Tdap/Td-IPV/Tdap-IPV vaccine is given concurrently with TIg.
CONTRA-INDICATIONS	1.Anaphylactic or severe systemic hypersensitivity reactions to Immunoglobulin (Human), or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. 2.HyperTET® should not be administered to patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections. 3.IgA deficient patients with antibodies against IgA and a history of hypersensitivity.
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding TIg and administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Give TIg with caution (i.e., in a setting capable of managing anaphylaxis) if the client has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits).

Tetanus Immune Globulin (TIg) (Human) **HYPERTET®**	
	• Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, TIg should only be given to such persons if the expected benefits outweigh the risks. • In clients who have severe thrombocytopenia or any coagulation disorder that would contraindicate IM injections, TIg should be given only if the expected
COMPONENTS	15%-18% Human tetanus hyperimmune globulin, glycine. Preservative free. Prefilled syringe has rubber needle shield and stopper. Latex-free
EXPECTED REACTIONS	• Temporary pain, soreness and tenderness where the needle was given. • Fever, rash and itching skin. • Rarely, blood clots may occur after the administration of an immune globulin product.

Varicella Zoster Immune Globulin (VarIg) (Human)

VariZIG™

Product monograph available at: https://pdf.hres.ca/dpd_pm/00066418.PDF

NOTE: Vital signs are not required to be taken before or after IM VarIg administration.

INDICATIONS [1, 2]	For post-exposure prevention of varicella in the following high-risk clients who cannot receive varicella vaccine and who are at increased risk of severe varicella disease: **Infants and children:** • Immunocompromised clients (congenital or acquired) due to treatment or disease, including some clients receiving high doses of corticosteroids. • Clients receiving monthly IGIV may not require VariZIG. • Newborn infants whose mothers develop varicella disease 5 days before to 48 hours after delivery. • Hematopoietic stem cell transplant (HSCT) recipients. • Infants and children in neonatal or pediatric intensive care settings, as determined by infectious disease/infection control specialist. **Adults:** • Susceptible pregnant women. • Immunocompromised adults (congenital or acquired) due to disease or treatment, including clients receiving corticosteroid treatment. Clients receiving regular monthly infusions of IGIV may not require VariZIG™. • Hematopoietic stem cell transplant recipients.
DOSE / SERIES	• Give VariZIG IM or IV as soon as possible, and within 96 hours of the first exposure to varicella or zoster. Clinicians may opt to provide VarIg up to 10 days following exposure to attenuated illness. • 125 IU is given for each 10 kg of body weight and is the minimum dose. • The maximum dose is 625 IU. • If VariZIG™ is administered by an intramuscular route, it should be given as an injection into the deltoid muscle or the anterolateral aspects of the upper thigh. Due to the risk of sciatic nerve injury, the gluteal region should not be used as a routine injection site. If the gluteal region is used, use only the upper, outer quadrant.
REINFORCEMENT	If a 2nd varicella exposure occurs more than 3 weeks after a dose of VariZIG™, another dose of VariZIG™ should be given.
SPECIAL HANDLING INSTRUCTIONS	The product should be brought to room or body temperature immediately prior to use. The product should be clear or slightly opalescent. Do not use product that appears cloudy or contains deposits.
CONTRA-INDICATIONS	1 .With known immunity to varicella zoster virus; i.e. with previous varicella infections or varicella vaccination. 2. Who are deficient in IgA. While VariZIG contains less than 40 µg/mL IgA, individuals who are deficient in IgA may have the potential to develop IgA antibodies and have an anaphylactoid reaction. 3 .With a history of anaphylactic or other severe systemic reaction to immune globulins. 4. Who are hypersensitive to this drug or to any ingredient in the formulation or components of the container.

Varicella Zoster Immune Globulin (VarIg) (Human) **VariZIG™**	
PRECAUTIONS	• Regarding VariZIG and administration of live vaccines (MMR & Varicella) refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* • Human Ig products are amongst the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C or HIV; therefore the risk of transmission of these viruses is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products.
COMPONENTS	VariZIG is a sterile solution for injection. It is a gamma globulin (IgG) fraction of human plasma containing antibodies to varicella zoster virus. Non-medicinal ingredients include 10% maltose and 0.03% (w/w) polysorbate 80. Each 125 IU vial contains less than 156 mg human IgG. It contains no preservative and is intended for single use only. VariZIG does not contain mercury and the stopper is latex free.
EXPECTED REACTIONS	• Temporary pain and tenderness at the injection site. • Headache, rash, joint or muscle aches, chills, tiredness, nausea, vomiting, or flushing may occur. • Rarely, blood clots may occur after the administration of an immune globulin product.

[1] A dose of ≥ 2 mg/kg/day of prednisone or equivalent, or more than 20 mg/per day, particularly when given for more than 2 weeks.

[2] Patients receiving monthly infusions of ≥ 400 mg/kg of IVIG and whose most recent infusion was within 3 weeks of exposure do not require VariZIG™.

Botulism Antitoxin (BAT®)

Botulism Antitoxin
Heptavalent (A, B, C, D, E, F, G) – (Equine)
Emergent BioSolutions Canada Inc. 2020 Product monograph:
https://www.emergentbiosolutions.com/wp-content/uploads/2022/01/BAT-Canada-Monograph-English.pdf

INDICATIONS	Treatment of botulism
INITIAL SERIES	Refer to product monograph
REINFORCEMENT	Refer to product monograph
CONTRAINDICATIONS	Refer to product monograph
COMPONENTS	Refer to product monograph
EXPECTED REACTIONS	Refer to product monograph
SPECIAL CONSIDERATION	Refer to product monograph

Diphtheria Antitoxin (DAT)

Diphtheria Antitoxin

Diphtheria antitoxin is ordered via Panorama from RRPL Vaccine Depot when indicated.
A product monograph is included with every vial.

INDICATIONS	For passive transient protection against or treatment of diphtheria infections.
INITIAL SERIES	
REINFORCEMENT	
CONTRAINDICATIONS	
COMPONENTS	
EXPECTED REACTIONS	
SPECIAL CONSIDERATION	