

Section 7:	Biological Product Information	Standard #: 07.300
Created by:	Provincial Immunization Program Standards and Quality	
Approved by:	Provincial Immunization Program Standards and Quality	
Approval Date:	March 1, 2013	Revised: April 22, 2024

IMOVAX® Polio (Vero Cell Origin)	
Manufacturer	Sanofi Pasteur SA – Distributed by Sanofi Pasteur Limited
Biological Classification	Inactivated
Indications for Provincially Funded Vaccine	<p><u>Children (2 months up to and including 17 years of age):</u> Children previously unimmunized with polio vaccine but have already received diphtheria, pertussis and tetanus-containing vaccines.</p> <p>Notes:</p> <ul style="list-style-type: none"> ○ Combination vaccines containing diphtheria, pertussis, polio, tetanus +/-Hib should be used when indicated. ○ Polio vaccine is routinely given as combined diphtheria, tetanus, acellular pertussis, inactivated polio +/- <i>Haemophilus influenzae</i> vaccine at 2, 4, 6 and 18 months with a booster dose at 4 years of age. <ul style="list-style-type: none"> ● Students requiring polio vaccine are eligible until the end of grade 12 regardless of age. ● For children travelling to countries where polio is known to be circulating (exporting and/or infected) and who are unimmunized or whose series is incomplete for age, an accelerated schedule can be considered. Refer to Polio Today - GPEI (polioeradication.org) map of infected countries (includes all the countries listed in red, yellow and green). <ul style="list-style-type: none"> ○ Polio vaccine may need to be privately purchased through a local travel health professional (private travel clinic or pharmacy) if travel timelines do not allow scheduling through public health. <p><u>Adults (18 years of age and older) – Primary Immunization as they present:</u></p> <ul style="list-style-type: none"> ● Adults who have not completed a primary series of polio. <p><u>Adults (18 years of age and older) - High Risk:</u> Adults in the following groups are at increased risk of exposure to poliovirus and should complete a primary series and receive a single lifetime reinforcing dose:</p> <ul style="list-style-type: none"> ● Members of communities or specific population groups with disease caused by polio (e.g., refugees from countries where polio is circulating such as Afghanistan, Pakistan, Dadaab (Kenya) and Ukraine evacuees). ● Close contact with those who may be excreting poliovirus (e.g., people working with refugees or people on humanitarian missions in countries where polio is circulating - exporting and/or infected). Refer to Polio Today – GPEI (polioeradication.org) map of infected countries (includes

	IMOVAX® Polio (Vero Cell Origin)
	<p>all the countries listed in red, yellow and green).</p> <ul style="list-style-type: none"> • Family members or close contacts of internationally adopted infants who may have been immunized with OPV vaccine within the past 6 weeks. • Individuals receiving travelers from areas where poliovirus is known to be circulating. Refer to Polio Today – GPEI (polioeradication.org) map of infected countries (includes all the countries listed in red, yellow and green). • Wastewater workers, working at wastewater treatment plants, who are exposed to sewage. <p><u>Health Care Workers (HCW) in Health Care Settings as they present:</u></p> <p>Health Care Workers should complete a primary series and receive a single lifetime reinforcing dose. This includes:</p> <ul style="list-style-type: none"> • Laboratory workers handling specimens that may contain poliovirus. • Health care workers and health care students who may be exposed to patients excreting the wild or vaccine strains of poliovirus (contact with stool, fecal matter or pharyngeal secretions). <p>Notes:</p> <ul style="list-style-type: none"> • Single antigen polio vaccine is used when only the polio antigen is required. • Combination vaccines containing diphtheria, pertussis, polio and tetanus should be used when indicated. See dTap-IPV vaccine biological page. • For adult recipients of HSCT and SOT see Standards: <ul style="list-style-type: none"> ○ Adult HSCT ○ Adult SOT • Adults travelling for 4 weeks or greater to countries currently exporting and/or infected with polio are not eligible for provincially funded vaccine and should be referred to local travel health professionals (e.g., private travel clinics or pharmacies). Refer to the World Health Organization (WHO) Global Polio Eradication Initiative and Polio Today – GPEI (polioeradication.org) for additional information.
Schedule	<p>Primary Series: (Children and Adults)</p> <ul style="list-style-type: none"> • Dose 1: day 0 • Dose 2: 8 weeks after dose 1 (interval between doses may be shortened to four weeks) • Dose 3: 6 to 12 months after dose 2 <p>Reinforcing dose:</p> <p>Children:</p> <ul style="list-style-type: none"> • A booster dose of polio-containing vaccine is recommended for children 4 years of age and older, usually as combined vaccine (dTap-IPV). <ul style="list-style-type: none"> ○ This dose is not required if the third dose was given on or after 4 years of age. <p>Note:</p> <ul style="list-style-type: none"> • Single antigen polio vaccine is rarely recommended for children and only if they are assessed as up to date for diphtheria, tetanus and pertussis immunization but not up to date for polio.

IMOVAX® Polio (Vero Cell Origin)

Adults (18 years of age and older):

One adult lifetime reinforcing dose of polio-containing vaccine (at least 10 years after the primary series) is recommended only for the following:

- Adults who are at increased risk of exposure to polioviruses who completed the primary series (see high risk indications noted above).
- Laboratory workers handling specimens that may contain poliovirus.
- Health care workers and health care students who may be exposed to patients excreting the wild or vaccine strains of poliovirus (contact with stool, fecal matter or pharyngeal secretions).

Notes:

- Oral Polio Vaccine (OPV):
 - As of April 1, 2016 trivalent polio vaccine (OPV) was replaced with either bivalent or monovalent OPV.
 - Any doses of OPV received on or after April 1, 2016 are not considered a valid dose within the routine Alberta Immunization Schedule.
 - In order to ensure protection against all three poliovirus types, individuals presenting with a record of OPV received on or after April 1, 2016 will require re-immunization with IPV or an IPV-containing vaccine to be considered fully immunized.
 - For Polio vaccine doses administered April 1, 2016 or later where the record does not clearly identify if the dose of vaccine was OPV or IPV, efforts should be made to access immunization schedules (for the year the vaccine was administered) from the country where the vaccine was administered to confirm what polio vaccine product was being used at that time. [Immunization schedules](#) published by the World Health Organization may assist in identifying current immunization schedules rather than historical immunization schedules. If unable to determine the country of vaccine administration or specific polio vaccine product used, then assume OPV vaccine was administered.
- Fractional Inactivated Polio Vaccine (fIPV):
- fIPV is used globally in countries where there are supply issues with IPV.
 - fIPV is administered via the intradermal route.
 - In order to be considered a valid single dose of IPV, an individual must receive 2 doses of fIPV 8 weeks apart.
 - If unable to determine if 2 doses of fIPV were given 8 weeks apart, the dose would be considered not valid.
- Individuals who require additional antigens contained in the combined vaccines should follow the schedule for that vaccine.
- It is acceptable to give an additional dose of inactivated poliomyelitis virus (IPV) vaccine at 6 months of age as DTaP-IPV-Hib or DTaP-IPV-Hib-HB for convenience of administration as a combined vaccine.
- When assessing a schedule for completeness of polio vaccine, individuals should have at least one dose of polio after 4 years of age. More doses may be necessary depending on the timing and spacing of previous doses of polio vaccine.
- A history of polio disease should not be considered as evidence of immunity to polio disease because immunity to one of the strains of polio does not produce significant immunity to the other strains.

	IMOVAX® Polio (Vero Cell Origin)
Preferred Use	Not applicable
Dose	0.5 mL
Route	SC
Contraindications/ Precautions	<p>Contraindications:</p> <ul style="list-style-type: none"> • Known severe hypersensitivity to any component of the vaccine or its container. • Anaphylaxis or other allergic reaction to a previous dose of vaccine containing polio antigen. <p>Precautions:</p> <ul style="list-style-type: none"> • Each dose of vaccine may contain undetectable traces of neomycin, streptomycin and polymyxin B.
Possible Reactions	<p>Common:</p> <ul style="list-style-type: none"> • Pain and redness at the injection site • Fever <p>Uncommon:</p> <ul style="list-style-type: none"> • Injection site mass <p>Rare:</p> <ul style="list-style-type: none"> • Anaphylaxis • Lymphadenopathy • Mild transitory arthralgia and myalgia • Convulsions • Headache • Transient and mild paraesthesia • Agitation, irritability, somnolence • Rash, urticaria • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	<ul style="list-style-type: none"> • May be considered for pregnant women who require immediate protection and are at increased risk of exposure to wild poliovirus. Use of this vaccine during pregnancy may be considered in consultation with your MOH based on the individual's risk of disease versus benefit of the vaccine. • Limited data have not revealed an increased risk of adverse events associated with polio vaccine administered to pregnant women.
Lactation	Can be administered to eligible breastfeeding women. It is not known if Imovax® Polio is excreted in human milk.
Composition	<p>Each 0.5 mL dose of vaccine contains:</p> <ul style="list-style-type: none"> • 29 D-antigen units poliovirus type 1 (Mahoney) • 7 D-antigen units poliovirus type 2 (MEF1) • 26 D-antigen units poliovirus type 3 (Saukett) • 1.0% or less 2-phenoxyethanol • 0.02% or less formaldehyde • Trace amounts polymyxin B • Trace amounts neomycin • Trace amounts streptomycin

	IMOVAX® Polio (Vero Cell Origin)
	<ul style="list-style-type: none"> • Less than 1 ppm residual calf serum protein • Trace amounts Medium 199 Hanks* (without phenol red) <p>Note:</p> <ul style="list-style-type: none"> • *Medium 199 Hanks (without phenol red) is a complex mixture of aminoacids (including phenylalanine), mineral salts, vitamins and other components (including glucose), supplemented with polysorbate 80, diluted in water for injections.
Blood/Blood Products	<ul style="list-style-type: none"> • Does not contain human blood or blood products. • The poliovirus is cultured on Vero cells (a continuous line of monkey kidney cells).
Bovine/Porcine Products	<ul style="list-style-type: none"> • Contains residual calf serum protein. • Porcine-derived products are used in the manufacturing processes.
Latex	There is no latex in the vaccine or the vaccine packaging.
Interchangeability	<ul style="list-style-type: none"> • For individuals who began their polio immunization series with OPV prior to April 1, 2016, immunization may be completed with IPV; there is no need to restart the vaccine series. • OPV doses given on or after April 1, 2016 are not considered valid in the routine Alberta immunization schedule and should be repeated.
Administration with Other Products	<ul style="list-style-type: none"> • May be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine. • The same limb may be used if necessary, but different sites on the limb must be chosen. • Oral poliomyelitis vaccine (OPV) should be given at least 2 weeks apart from rotavirus vaccine. <ul style="list-style-type: none"> ○ OPV is not available in Canada. If historical records indicate rotavirus vaccine and OPV are given at less than 2 weeks apart, consider both vaccines as valid doses.
Appearance	Clear and colourless
Storage	<ul style="list-style-type: none"> • Store at +2°C to +8°C. • Do not freeze. • Do not use beyond the labeled expiry date. • Store in original packaging when possible to protect from light.
Vaccine Code	IPV
Antigen Code	POL
Licensed Use	Individuals 6 weeks of age and older.
Off-License Use	Not approved for off-license use in Alberta.
Program Notes:	
<ul style="list-style-type: none"> • 1956: IPV introduced into the routine childhood immunization program. • 1962: Oral polio vaccine (OPV) administered in AB. • 1994 July: IPV replaced OPV in routine immunization in combination with Diphtheria, Tetanus and Pertussis vaccine. • 2016 November: <ul style="list-style-type: none"> ○ Unimmunized adults at low risk of exposure not eligible for provincially funded vaccine. ○ HCWs that might be exposed to patients excreting polio eligible for primary series and single life time reinforcement. 	

IMOVAX® Polio (Vero Cell Origin)

- Travelers to countries exporting and/or infected with polio and staying 4 weeks or longer eligible for primary series and reinforcing dose for adults.
- 2018 December: OPV doses given on or after April 1, 2016 are not considered valid in the routine AB immunization schedule and should be repeated.
- 2022 April 20: Added indication for polio vaccine for individuals identified as Ukrainian evacuees. Due to the limited supply of IPV vaccine, dTap-IPV is the vaccine of choice for adults who require polio immunization only.
- 2022 May 18 – Addition of examples of communities and specific population groups with polio.
- 2023 Sep 25:
 - Updated to offer a primary series and reinforcing dose to wastewater workers who handle sewage at wastewater treatment plants.
 - Updated to indicate that adults receiving polio vaccine for the purpose of travel or health care students are not eligible for provincially funded vaccine and must purchase vaccine through a local travel health professional.
 - Clarification that current practice is not to assess and immunize all health care workers, including lab workers, for polio immunization due to the generally low risk of exposure to polio in Alberta and Canada, availability of PPE and the limited supply of vaccine.
 - Information on fIPV included in scheduling notes.
- 2023 October 2: Updated to clarify countries where polio is circulating.
- 2024 January 29: Removed limited supply constraints, adults in health care settings should complete a primary series and have a single lifetime reinforcing dose, and adults previously unimmunized with polio vaccine should receive a primary series.
- 2024 April 2: Updated definition of HCW in scheduling section to include: Health care workers and health care students who may be exposed to patients excreting the wild or vaccine strains of poliovirus (contact with stool, fecal matter or pharyngeal secretions).

Related Resources:

- Polio Vaccine Information Sheet

References:

1. Alberta Health. (2023 August). Alberta Immunization Policy. *Adverse Event Following Immunization (AEFI) Policy for Alberta Immunization Providers*. Alberta Health.
2. Alberta Health, Health System Accountability and Performance Division (2024 January 29). Alberta Immunization Policy. *Polio Vaccine: IMOVAX Polio (Vero Cell Origin)*. Alberta Health, Public Health and Compliance Division.
3. Centers for Disease Control and Prevention. (2021). Epidemiology and Prevention of Vaccine-Preventable Diseases. <https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>
4. Centers for Disease Control and Prevention (2017) Guidance for Assessment of Poliovirus Vaccination Status and Vaccination of Children Who Have Received Polio Vaccine Outside of the United States. *Morbidity and Mortality Weekly Report (MMWR)*, 66(01);23-25. DOI: <http://dx.doi.org/10.15585/mmwr.mm6601a6>.
5. Centers for Disease Control and Prevention. (2014) Morbidity and Mortality Weekly Report (MMWR). Interim CDC Guidance for Polio Vaccination for Travel to and from Countries Affected by Wild Poliovirus. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6327a4.htm>.
6. Centers for Disease Control and Prevention. (2018). Health Information for International Travel. Yellow Book. <https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/poliomyelitis>.
7. National Advisory Committee on Immunization. (2023). Canadian Immunization Guide (Evergreen Edition). Ottawa, ON: Public Health Agency of Canada. [Canadian Immunization Guide - Canada.ca](https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html)
8. Pan American Health Organization (2017 June). What is a fractional dose of IPV. [What is a Fractional Dose of IPV \(JA2017-06\) - PAHO/WHO | Pan American Health Organization](https://www.paho.org/en/topics/what-is-a-fractional-dose-of-ipv)
9. Public Health Agency of Canada. (2023 Aug 31) Polio: vaccine advice for travelers. [Travel health](https://www.canada.ca/en/public-health/services/vaccines-and-immunization/immunization-travelers/polio.html)

	IMOVAX® Polio (Vero Cell Origin)
notices	<ol style="list-style-type: none">10. Sanofi Pasteur Limited. (2023 October 30). Product Monograph. <i>IMOVAX Polio: Inactivated Poliomyelitis Vaccine (Vero Cell Origin)</i>. https://products.sanofi.ca/en/imovax-polio.pdf11. World Health Organization. (2023). <i>Global Polio Eradication Initiative</i> [Internet]. Public Health Emergency status – GPEI (polioeradication.org)12. World Health Organization. (2023). Polio Today [Internet]. Polio Global Eradication Initiative. https://polioeradication.org/polio-today/13. World Health Organization (2017 April). Use of fractional dose IPV in routine immunization programs: Considerations for decision making. fipv-considerations-for-decision-making-april2017.pdf (who.int)