

Section 7:	Biological Product Information	Standard #: 07.300
Created by:	Province-wide Immunization Program Standards and Quality	
Approved by:	Province-wide Immunization Program, Standards and Quality	
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IMOVAX® Polio (Vero Cell Origin)	
Manufacturer	Sanofi Pasteur SA – Distributed by Sanofi Pasteur Limited
Biological Classification	Inactivated
Indications for Provincially Funded Vaccine	<p>Children (2 months up to and including 17 years of age):</p> <ul style="list-style-type: none"> • Children previously unimmunized with polio vaccine but have already received diphtheria, pertussis and tetanus-containing vaccines. <p>Notes:</p> <ul style="list-style-type: none"> ○ Combination vaccines containing diphtheria, pertussis, polio, tetanus and/or Hib should be used when indicated. ○ Polio vaccine is routinely given as combined diphtheria, tetanus, acellular pertussis, inactivated polio and/or Haemophilus influenzae vaccine at 2, 4, 6 and 18 months with a reinforcing dose at 4 years of age. • 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. <p>Note:</p> <ul style="list-style-type: none"> ○ For current recommendations, refer to World Health Organization (WHO) Global Polio Eradication Initiative: http://polioeradication.org/polio-today/polio-now/public-health-emergency-status/ <p>Adults (18 years of age and older):</p> <p>Note:</p> <ul style="list-style-type: none"> • This vaccine is used when only the polio antigen is required or if combination vaccines are not available. <p>Primary Immunization – Low Risk:</p> <ul style="list-style-type: none"> • Students requiring polio vaccine are eligible until the end of grade 12 regardless of age. • Due to the limited supply of polio vaccine and the low risk of exposure to polio in Alberta and Canada – the recommendation for the routine immunization of unimmunized adults for polio is suspended until further notice. • Adults at high/increased risk of exposure as outlined below should continue to receive a primary series. <p>Note: <i>For questions related to Travel and or For Sale vaccine refer to AHS Travel Health and Contracted Immunization Services resources.</i></p>

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	<p>Primary Immunization – High/Increased Risk: Adults in the following groups are at increased risk of exposure to poliovirus and should receive a primary series:</p> <ul style="list-style-type: none"> • Health care workers (HCW) providing direct patient care who may be exposed to patients excreting the wild or vaccine strains of polio virus (contact with stool, fecal matter or pharyngeal secretions). Refer to Polio Risk Assessment for Health Care Workers Algorithm. Laboratory workers handling specimens that may contain poliovirus. Refer to Polio Risk Assessment for Health Care Workers Algorithm. • Members of communities or specific population groups with disease caused by polio. • 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). • Family members or close contacts of internationally adopted infants who may have been immunized with OPV vaccine. • Individuals receiving travelers from areas where poliovirus is known to be circulating. • Adults travelling for 4 weeks or greater to countries currently exporting and/or infected with polio. <ul style="list-style-type: none"> ○ For current recommendations, refer to World Health Organization (WHO) Global Polio Eradication Initiative: http://polioeradication.org/polio-today/polio-now/public-health-emergency-status/ <p>Note:</p> <ul style="list-style-type: none"> ○ Provincially funded polio vaccine may be used for these adult travelers going to countries where polio is circulating and is only available through Alberta Health Services. <p>Reinforcing vaccine dose: Adults as indicated above who are at increased or high risk of exposure to poliovirus should receive a single life time reinforcing dose:</p> <p>Notes:</p> <ul style="list-style-type: none"> • For adult recipients of HSCT and SOT see Standards: <i>Immunization for Adult Hematopoietic Stem Cell Transplant Recipients</i> and <i>Immunization for Adult Solid Organ Transplant Candidates and Recipients</i>. • Due to the low risk of exposure to polio in Alberta and Canada for post-secondary student placements, post-secondary institutions are not expected to assess healthcare students for polio immunization. Once these students enter the workforce they will be assessed by Workplace Health and Safety staff for risk of exposure to polio at the clinical site where they will be employed and offered appropriate vaccine at that time. • Individuals travelling to countries currently exporting and/or infected with polio may need special immunization documentation verifying polio immunization. These individuals should consult with a Travel Clinic to determine what documentation is required.
Schedule	<p>Primary Series:</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 – 12 months after dose 2

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	<p>Reinforcing dose:</p> <p>Children:</p> <ul style="list-style-type: none"> • Booster dose of polio-containing vaccine is recommended for children 4 years of age usually as combined vaccine (dTAp-IPV). <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. • The reinforcing dose of polio is not required if the third dose was given on or after 4 years of age. • Oral Polio Vaccine (OPV): <ul style="list-style-type: none"> ○ Any doses of OPV received on or after April 1, 2016 are not considered a valid dose within the routine Alberta Immunization Schedule. ○ As of April, 2016 trivalent polio vaccine (OPV) was replaced with either bivalent or monovalent OPV. ○ In order to ensure protection against all three poliovirus types, individuals presenting with a record of OPV received on or after this date will require re-immunization with IPV or an IPV-containing vaccine for any of these doses. <p>Adults (18 years of age and older):</p> <ul style="list-style-type: none"> • One adult lifetime booster of polio-containing vaccine (at least 10 years after the primary series) for those who are at high/increased risk of exposure to polio and who completed the primary series in childhood. See <i>Indications</i> section. <p>Note:</p> <ul style="list-style-type: none"> ○ Unless at high/increased risk of exposure to polio (see Indications Section), reinforcing doses of polio-containing vaccines are not routinely recommended for adults living in Canada. <p>Notes:</p> <ul style="list-style-type: none"> • 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-HB-IPV-Hib 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. • Children travelling to countries where polio is known to be circulating and who are unimmunized or whose series is incomplete for age – an accelerated schedule can be considered (see <i>Standard for Recommended Immunization Schedules – Section 5: Minimum Age and Minimum Intervals Between Vaccine Doses</i>). • For current recommendations refer to World Health Organization (WHO) Global Polio Eradication Initiative: http://polioeradication.org/polio-today/polio-now/public-health-emergency-status/ • A history of polio disease should not be considered as evidence of immunity to polio disease because immunity to one of the serotypes of polio does not produce significant immunity to the other serotypes.

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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 • 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"> • 40 D-antigen units poliovirus type 1 (Mahoney) • 8 D-antigen units poliovirus type 2 (MEF1) • 32 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 • Less than 1 ppm residual calf serum protein • Up to 0.5 mL Medium 199 Hanks* (without phenol red) <p>Note:</p> <ul style="list-style-type: none"> ○ *Medium 199 Hanks (without phenol red) contains amino acids (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	<ul style="list-style-type: none"> • Contains residual calf serum protein.

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Products	<ul style="list-style-type: none"> • 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 for	Individuals 6 weeks of age and older. Not approved for off-license use in Alberta.
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. • November 2016: <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. ○ Travellers 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. 	
Related Resources:	
<ul style="list-style-type: none"> • Polio Vaccine Information Sheet • Polio Risk Assessment for Health Care Workers Algorithm 	
References:	
<ol style="list-style-type: none"> 1. Alberta Health. (2018, December). Alberta Immunization Policy. <i>Adverse Event Following Immunization (AEFI) Policy for Alberta Immunization Providers</i>. Alberta Health. 2. Alberta Health. (2016, November). Alberta Immunization Policy. <i>Poliomyelitis (polio) Vaccine for Residents of Alberta Planning to Travel</i>. Alberta Health, Letter from Office of the Chief Medical Officer of Health. 	

	IMOVAX® Polio (Vero Cell Origin)
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