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| Section 7 | Biological Product Information | Standard # 07.300 |
| Created and approved by | Provincial Immunization Program Standards and Quality | |
| Approval date | March 1, 2013 | Revised January 31, 2025 |

| | IMOVAX Polio (Vero Cell Origin) |
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| Manufacturer | Sanofi Pasteur SA – Distributed by Sanofi Pasteur Limited |
| 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 who have already received diphtheria, pertussis and tetanus-containing vaccines. <p>Note:</p> <ul style="list-style-type: none"> Combination vaccines containing diphtheria, pertussis, polio, tetanus and/or Hib and/or Hepatitis B should be used when indicated. 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 the World Health Organization- Polio Global Eradication Initiative to see where polio is known to be circulating. Children travelling to countries currently exporting and/or infected with polio and who have not completed their primary series may need to privately purchase polio vaccine through a local travel health professional (private travel clinic or pharmacy) if travel timelines do not allow scheduling through public health. <p>Adults (18 years of age and older):</p> <p>Adults - Primary Immunization as they present:</p> <ul style="list-style-type: none"> Adults who have not completed a primary series. <p>Adults - High Risk:</p> <p>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 (for example, 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 (for example, people working with refugees or people on humanitarian missions in countries where polio is circulating - exporting and/or infected). Refer to the World Health Organization- Polio Global Eradication Initiative. Family members or close contacts of internationally adopted infants who may have been immunized with oral polio vaccine (OPV) within the past 6 weeks. Individuals receiving travelers from areas where poliovirus is known to be circulating. Refer to World Health Organization- Polio Global Eradication Initiative. Wastewater workers, working at wastewater treatment plants, who are exposed to sewage. |

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| | <p>Health Care Workers (HCW) in Health Care Settings as they present:</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>Note:</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. For those requiring diphtheria, pertussis and tetanus-containing vaccines – see Biological Product Information Tdap-IPV Combined Vaccine Biological Page. • For adult recipients of Hematopoietic Stem Cell Transplant (HSCT) and Solid Organ Transplant (SOT), see: <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 (for example, private travel clinics or pharmacies). |
| Schedule | <p>Primary Series: (Children and Adults)</p> <ul style="list-style-type: none"> • Dose 1: day 0 • Dose 2: 8 weeks after first dose (interval between doses may be shortened to four weeks) • Dose 3: 6 to 12 months after second dose <ul style="list-style-type: none"> ◦ It is acceptable to give an additional dose of IPV vaccine at 6 months of age as DTaP-IPV-Hib or DTaP-IPV-Hib-HB for convenience of administration as a combined vaccine. <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 (Tdap-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. • 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. <p>Adults (18 years of age and older):</p> <p>One adult lifetime reinforcing dose of polio-containing vaccine (at least 10 years after the primary series) is recommended only for the following:</p> <ul style="list-style-type: none"> • Adults who are at increased risk of exposure to polioviruses who completed the primary series (see high risk indications noted above). • Health care workers (see indications noted above). <p>Note:</p> <ul style="list-style-type: none"> • Individuals who require additional antigens contained in the combined vaccines should follow the schedule for that 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. |

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| | <p>Oral Polio Vaccine (OPV):</p> <ul style="list-style-type: none"> As of April 1, 2016, trivalent OPV was replaced with either bivalent or monovalent OPV. Any OPV doses received on or after April 1, 2016, are not considered as valid doses within the routine Alberta Immunization Schedule. <p>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.</p> <ul style="list-style-type: none"> 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 consider the dose invalid as polio unspecified. <p>Fractional Inactivated Polio Vaccine (fIPV):</p> <ul style="list-style-type: none"> fIPV is used globally in countries where there are supply issues with IPV. <ul style="list-style-type: none"> 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 invalid. |
| Preferred Use | N/A |
| 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 | <p>Consult with the MOH/designate.</p> <ul style="list-style-type: none"> Limited data has not revealed an increased risk of adverse events associated with polio vaccine administered during pregnancy. May be considered during pregnancy for individuals who require immediate protection and are at increased risk of exposure to wild poliovirus. |

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| | <ul style="list-style-type: none"> MOH will make a recommendation based on the individual's risk of disease versus benefit of vaccine. |
| Lactation | <p>May use for individuals who are breastfeeding/chestfeeding.</p> <ul style="list-style-type: none"> 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"> Active Ingredients: <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). Non-medicinal Ingredients: <ul style="list-style-type: none"> 1% or less 2-phenoxyethanol. Manufacturing Process Residuals: <ul style="list-style-type: none"> 0.02% or less formaldehyde Less than 1 ppm residual calf serum protein. Trace Amounts: <ul style="list-style-type: none"> neomycin streptomycin polymyxin B 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 amino acids (including phenylalanine), mineral salts, vitamins and other components (including glucose), supplemented with polysorbate 80, diluted in water for injections. |
| Blood/Blood Products | <p>Does not contain human blood or blood products.</p> <ul style="list-style-type: none"> Poliovirus is cultured on Vero cells (a continuous line of monkey kidney cells). |
| Bovine/Porcine Products | <p>Bovine Products:</p> <ul style="list-style-type: none"> Contains residual calf serum protein. <p>Porcine Products:</p> <ul style="list-style-type: none"> Porcine-derived products are used in the manufacturing processes. |
| Latex | Does not contain latex in the vaccine or the vaccine packaging. |
| Interchangeability | <p>Individuals who began their polio immunization series with OPV prior to April 1, 2016:</p> <ul style="list-style-type: none"> Complete series with IPV. There is no need to restart the vaccine series. <p>Individuals who received OPV doses on or after April 1, 2016:</p> <ul style="list-style-type: none"> Doses are invalid as per Alberta immunization schedule. Repeat doses using IPV. |
| Administration with Other Products | <p>May be given at the same time as other inactivated and live vaccines.</p> <ul style="list-style-type: none"> Use a separate needle and syringe for each vaccine. The same limb may be used if necessary, but use different sites on the limb. Rotavirus vaccine doses should be spaced at least 2 weeks apart from any OPV doses. <ul style="list-style-type: none"> If historical records indicated rotavirus vaccine and OPV were given at less than 2 weeks apart, consider both vaccines as valid doses. OPV is not available in Canada. |
| Appearance | Clear and colourless. |
| Storage | <ul style="list-style-type: none"> Store at +2°C to +8°C Do not freeze |

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| | <ul style="list-style-type: none"> Do not use beyond the labeled expiry date. |
| Vaccine Code | IPV |
| Antigen Code | POL |
| Licensed for | 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: 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 lifetime reinforcement. 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 September 25: <ul style="list-style-type: none"> 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 receiving it prior to placement 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 note. 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). 2024 May 6: References to dTap changed to Tdap to align with national standards. 2024 September 24: World Health Organization link indicating where polio is circulating updated. 2025 January 31: Request to offer polio vaccine to children through the school program until grade 12 removed, as this is the Roles and Responsibilities policy. |
| Related Resources | <ul style="list-style-type: none"> Polio (IPV) Vaccine Information Sheet |
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