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| 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: September 25, 2023 |

| IMOVAX® Polio (Vero Cell Origin) | |
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| 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 +/-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 reinforcing dose at 4 years 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. • 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>Note:</p> <ul style="list-style-type: none"> ○ For current recommendations and information about countries with polio, 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>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 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. <p><u>Adults in Health Care Settings:</u></p> <p>Due to the availability of and protocols for personal protective equipment, and the limited supply of vaccine, assessment of polio immunization (primary series and reinforcing doses) is not routinely recommended for the following</p> |

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| | <p>individuals who work or study in environments with an increased risk of exposure to poliovirus compared to the general population:</p> <ul style="list-style-type: none"> • Laboratory workers handling specimens that may contain poliovirus • Health care workers (HCW) • Health care students - post-secondary institutions are not expected to assess health care students for polio immunization <p>Exceptions can be made for adults in health care settings if they meet any of the high-risk criteria below.</p> <p>High Risk: Adults in the following groups are at increased risk of exposure to poliovirus and should receive a primary series and 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, Ukrainian 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). • 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. • Wastewater workers, working at wastewater treatment plants, who are exposed to sewage. <p>Notes:</p> <ul style="list-style-type: none"> • Combination vaccines containing diphtheria, pertussis, polio and tetanus should be used when indicated. • 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>. • 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). |
| 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 <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 and older, usually as combined vaccine (dTap-IPV). • 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. |

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| | <ul style="list-style-type: none"> • The reinforcing dose of polio is not required if the third dose was given on or after 4 years of age. <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) is recommended for adults who are at increased risk of exposure to polio and who completed the primary series.. See <i>High Risk Indications</i> section. <p>Notes:</p> <ul style="list-style-type: none"> • Oral Polio Vaccine (OPV): <ul style="list-style-type: none"> ○ As of April, 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. ○ When reviewing 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 product was being used at that time. Immunization schedules published by the World Health Organization may assist in confirming what polio product is being used; however, note that the information displayed is reflective of current immunization schedules only. If unable to determine the country where the vaccine was administered or which polio product was administered, assume vaccine administered was OPV. • Fractional Inactivated Polio Vaccine (fIPV): <ul style="list-style-type: none"> ○ 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-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. • For current recommendations refer to World Health Organization (WHO) Global Polio Eradication Initiative: http://polioeradication.org/polio-today/polio-now/public-health-emergency-status/ |

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| | <ul style="list-style-type: none"> 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. |
| 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 |

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| | <ul style="list-style-type: none"> • Trace amounts polymyxin B • Trace amounts neomycin • Trace amounts streptomycin • 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: | |

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- 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.
- 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.

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.
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10. Public Health Agency of Canada. Polio: vaccine advice. <https://travel.gc.ca/travelling/health-safety/travel-health-notices>

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