PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

IMOVAX® POLIO

Inactivated Poliomyelitis Vaccine (Vero Cell Origin)

Each 0.5 mL dose contains Poliovirus (Formaldehyde Inactivated)
[Type 1 Mahoney, Type 2 MEF1, Type 3 Saukett]

Suspension for Injection

Active Immunizing Agent
(for the Prevention of Poliomyelitis)

ATC Code: J07BF03 Poliomyelitis, trivalent, inactivated, whole virus

Sanofi Pasteur Limited
Toronto, Ontario, Canada

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RECENT MAJOR LABEL CHANGES

4 DOSAGE AND ADMINISTRATION	08/2023
7 WARNINGS AND PRECAUTIONS	04/2023

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

IMOVAX® Polio is indicated for active immunization against poliomyelitis caused by poliovirus types 1, 2 and 3 from 2 months of age in infants, children and adults both for primary immunization and for boosters. (See DOSAGE AND ADMINISTRATION)

For more information on this vaccine, refer to NACI recommendations[1].

1.1 Pediatrics

Pediatrics (6 weeks to <18 years of age): Safety and efficacy of IMOVAX® Polio have been established in children 6 weeks of age and older.

2 CONTRAINDICATIONS

- Immunization with IMOVAX® Polio should be deferred in the presence of any acute illness, including febrile illness, to avoid superimposing adverse effects from the vaccine on the underlying illness or mistakenly identifying a manifestation of the underlying illness as a complication of vaccine use. A minor illness such as mild upper respiratory infection is not reason to defer immunization.
- Allergy to any component of IMOVAX® Polio, or its container, or an anaphylactic or other allergic reaction to a previous dose of IMOVAX® Polio is a contraindication to vaccination. For a complete listing, see the DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING section of the product monograph.

4 DOSAGE AND ADMINISTRATION

4.2 Recommended Dose and Dosage Adjustment

Children

Primary Immunization:

- A primary series of IMOVAX® Polio consists of three 0.5 mL doses administered subcutaneously. The interval between the first two doses should be at least four weeks, but preferably eight weeks. The third dose should follow at least six months but preferably 12 months later. The primary schedule is usually integrated with combination infant vaccines against diphtheria, tetanus, pertussis and Haemophilus influenzae type b, beginning at 2 months of age.
- Alternatively, three doses of 0.5 mL may be administered at intervals of 8 weeks, followed by a fourth dose of 0.5 mL approximately 12 months after the third dose.
- Although it is recommended that immunization be started at 2 months of age, if for any reason it is delayed, the same schedule may be used.

Booster Doses:

[1] The National Advisory Committee on Immunization (NACI) provides additional guidance on vaccines in Canada. Please refer to the published chapter on Poliomyelitis vaccine.

- All children who received a primary series of IMOVAX® Polio, or a combination of IPV and OPV, should be given a booster dose at age 4 - 6 years, unless the last dose of the primary series was administered on or after the fourth birthday. An additional booster dose should be given at age 14 - 16 years unless OPV was used exclusively during the primary series. Whether there is a need to administer additional doses routinely is unknown at this time.
- A final total of at least four doses is necessary to complete a series of primary and booster doses. Children and adolescents with a previously incomplete series of IPV should receive sufficient additional doses to reach this number.
- For children who began their polio immunization series in a country where OPV is used, immunization may be completed using IPV; there is no need to re-start the series. Conversely, children who have been started on an immunization series with IPV and who move to an area where OPV is used may receive the necessary doses of OPV to complete their series.

Adults

- For unimmunized adults at increased risk, primary immunization with IPV is recommended as two doses given at an interval of 4 to 8 weeks with a further dose 6 months to 1 year later. Additional considerations are as follows:
  - Travellers who will be departing within 4 weeks should receive a single dose of IPV and the remaining doses later, at the recommended intervals.
  - Unimmunized parents/child-care workers: in those rare instances in which infants receive OPV, there is a very small risk of OPV-associated paralysis to unimmunized parents or to other household contacts. It will generally not be practical for such persons to be fully protected with IPV before the infant is immunized; their risk may be reduced if they are given one dose of IPV at the same time as the first dose is given to the infant. Arrangements should be made for the adults to complete their basic course of immunization.
  - Incompletely immunized adults at increased risk (see INDICATIONS, Adults) who have previously received less than a full primary course of IPV or OPV should receive the remaining dose(s) of poliovirus vaccine as IPV, regardless of the interval since the last dose.
  - Adults and adolescents who are at greater risk of exposure to poliovirus than the general population (see above) may be given a single dose of IPV if more than 10 years have elapsed since the last dose of their **complete** IPV and/or OPV vaccination series.

4.4 Administration

Inspect for extraneous particulate matter and/or discolouration before use. If these conditions exist, the product should not be administered.

For information on vaccine administration see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

SHAKE THE PRE-FILLED SYRINGE WELL to uniformly distribute the suspension before administration.

Aseptic technique must be used. Use a separate sterile needle and syringe, or a sterile disposable unit, for each individual dose to prevent disease transmission.

Administer IMOVAX® Polio subcutaneously. In infants and small children, the mid-lateral aspect of the thigh is the preferred site; in older children and adults, the deltoid or triceps area is preferred. IMOVAX® Polio should not be administered into the buttocks due to the varying amount of fatty tissue in this region, nor by the intradermal route, since these methods of administration may induce a weaker immune response.

Do not inject into a blood vessel. Do not inject intravenously.

Needles should not be recapped and should be disposed of properly.

Give the patient a permanent personal immunization record. In addition, it is essential that the physician or nurse record the immunization history in the permanent medical record of each patient. This permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

4.5 Missed Dose

Time intervals between doses longer than those recommended for routine primary immunization do not necessitate additional doses as long as a final total of four doses is reached.

If a dose is missed, it can be given at any time.

5 OVERDOSAGE

Not documented.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

Table 1 Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Subcutaneous injection	Suspension for Injection **Active Ingredients:** Each 0.5 mL dose contains Poliovirus (Formaldehyde Inactivated) [Type 1 Mahoney, Type 2 MEF1, Type 3 Saukett]	2-phenoxyethanol

Description

IMOVAX® Polio is a clear, colourless suspension.

Each 0.5 mL dose contains:

Active Ingredients:

Poliovirus Type 1 Mahoney (Formaldehyde Inactivated)[1]	29 D-antigen units[2]
Poliovirus Type 2 MEF1 (Formaldehyde Inactivated)[1]	7 D-antigen units[2]
Poliovirus Type 3 Saukett (Formaldehyde Inactivated)[1]	26 D-antigen units[2]

[1] Cultivated on Vero cells

[2] These antigen quantities are strictly the same as those previously expressed as 40-8-32 D-antigen units, for virus type 1, 2 and 3respectively, when measured by another suitable immunochemical method.

Other Ingredients:

Excipients:

2-phenoxyethanol	≤1.0%

Manufacturing Process Residuals:

Formaldehyde	≤0.02%
Residual calf serum protein	<1 ppm

Trace amounts of neomycin, streptomycin and polymyxin B, Medium 199 Hanks (without phenol red) up to 0.5 mL.

Packaging

IMOVAX® Polio is available in a single dose package containing one 0.5 mL syringe.

The stopper of the syringe for this product does not contain latex (natural rubber).

7 WARNINGS AND PRECAUTIONS

General

As with any vaccine, immunization with IMOVAX® Polio may not protect 100% of susceptible persons.

IPV should not be used for control of outbreaks of poliomyelitis if OPV is available.

Before administration, take all appropriate precautions to prevent adverse reactions. This includes a review of the patient's history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindications to immunization and current health status.

Before administration of IMOVAX® Polio, health-care providers should inform the patient, parent or guardian of the benefits and risks of immunization, inquire about the recent health status of the patient and comply with any local requirements regarding information to be provided to the patient before immunization and the importance of completing the immunization series.

It is important that the patient, parent or guardian be questioned concerning any symptoms and/or signs of an adverse reaction after a previous dose of vaccine. (See CONTRAINDICATIONS and ADVERSE REACTIONS).

Hematologic

As with any injectable vaccine, IMOVAX-Polio must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Immune

As with all other products, Epinephrine Hydrochloride Solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. Health-care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management. (1) For instructions on

recognition and treatment of anaphylactic reactions, see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

As each dose may contain undetectable traces of neomycin, streptomycin and polymyxin B, which are used during vaccine production, caution should be exercised when the vaccine is administered to subjects with hypersensitivity to these antibiotics (and other antibiotics of the same classes).

Immunocompromised persons (whether from disease or treatment) may not obtain the expected immune response. If possible, consideration should be given to delaying vaccination until after the completion of any immunosuppressive treatment. (1) Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response might be limited.

Neurologic

Syncope can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent falling and injury and to manage syncope.

Respiratory

The potential risk of apnea and the need for respiratory monitoring for 48-72 h should be considered when administering the primary immunization series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

7.1 Special Populations

7.1.1 Pregnant Women

There are limited data on the use of this vaccine in pregnant women[2]. Animal studies are insufficient with respect to effects on pregnancy and embryo/fetal development, parturition and postnatal development. No clinical trials with inactivated poliomyelitis vaccine have been conducted on pregnant women. Although there is no convincing evidence documenting adverse effects of inactivated poliomyelitis vaccine on the pregnant woman or the developing fetus, it is prudent on theoretical grounds to avoid vaccinating pregnant women.

7.1.2 Breast-feeding

It is not known whether IMOVAX® Polio is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when IMOVAX® Polio is administered to a nursing woman[3].

7.1.3 Pediatrics

Pediatrics (6 weeks to <18 years of age): Safety and efficacy of IMOVAX® Polio have been established in children 6 weeks of age and older.

[2] NACI provides additional information on the use of vaccines in pregnant women and during breast-feeding. Please refer to the current NACI recommendations for pregnant women.

[3] NACI provides additional information on the use of vaccines in pregnant women and during breast-feeding. Please refer to the current NACI recommendations for breast-feeding.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Local reactions are usually mild and transient in nature. Systemic adverse reactions reported in infants receiving IPV concomitantly at separate sites or combined with DPT-containing (Diphtheria Tetanus Pertussis) vaccines have been similar to those associated with administration of DPT-containing vaccines alone.

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

The local reactogenicity of IMOVAX® Polio was evaluated in two multicentre randomized clinical trials involving a total of 395 patients and local reactions were uncommonly to very commonly reported:

- injection site redness: in 0.7% to 2.4% of subjects in each trial
- injection site pain: 0.7% to 34%
- injection site mass: 0.4%

8.2.1 Clinical Trial Adverse Reactions – Pediatrics

In a multicentre randomized Phase III study involving 205 children, fever >38.1°C was commonly to very commonly observed (in 10% of children after the first dose, in 18% of children after the second dose, in 7% of children after the third dose).

In another multicentre randomized Phase III study involving 324 children, it was concluded that IMOVAX® Polio combined or associated with DPT vaccine was as well-tolerated as DPT vaccine administered alone.

8.5 Post-Market Adverse Reactions

These frequencies are based on spontaneous reporting rates and have been calculated using number of reports and estimated number of vaccinated patients.

IMOVAX® Polio is rarely administered alone according to the childhood immunization schedules.

Whatever the adverse event reported during the post-marketing experience, its frequency remained very rare (<0.01%).

The most frequently reported adverse events are local reactions and fever (respectively around 20% and 10% of adverse events reported).

Blood and Lymphatic System Disorders

Very rare (<0.01%)	lymphadenopathy

General Disorders and Administration Site Conditions

Very rare (<0.01%)	injection site reactions such as injection site edema, injection site pain, injection site rash or injection site mass within 48 hours following the vaccination and lasting one or two days

	transient mild fever (pyrexia) within 24 to 48 hours following the vaccination

Immune System Disorders

Very rare (<0.01%)	type I hypersensitivity reaction to one component of the vaccine such as allergic reaction, anaphylactic reaction or anaphylactic shock

Musculoskeletal and Connective Tissue Disorders

Very rare (<0.01%)	mild and transitory arthralgia and myalgia within a few days after the vaccination

Nervous System Disorders

Very rare (<0.01%)	short-lasting convulsions, febrile convulsions, within a few days following the vaccination
	headache
	transient and mild paraesthesia (mainly of limbs) within two weeks after the vaccination

Psychiatric Disorders

Very rare (<0.01%)	within the first hours or days following the vaccination and shortly resolving: agitation, somnolence, irritability

Skin and Subcutaneous Tissue Disorders

Very rare (<0.01%)	rash, urticaria

Nervous System

Although no causal relationship between IMOVAX® Polio and Guillain-Barré syndrome (GBS) has been established, GBS has been temporally related to administration of another inactivated poliovirus vaccine.

An extensive review by the (US) Institute of Medicine of adverse events associated with vaccination suggested that no serious adverse events have been associated with IPV. Although no causal relationship has been established, deaths have occurred in temporal association after vaccination of infants with IPV.

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

There are no known interactions of IMOVAX® Polio with drugs or foods.

Administering the most widely used live and inactivated vaccines during the same patient visit has produced seroconversion rates and rates of adverse reactions similar to those observed when the vaccines are administered separately. Simultaneous administration using separate syringes at separate sites is suggested, particularly when there is concern that an individual may not return for subsequent vaccination.

The first two doses of IMOVAX® Polio may be administered at separate sites using separate syringes concomitantly with DPT, acellular pertussis, *Haemophilus influenzae* type b (HIB), and hepatitis B vaccines. From historical data on the antibody responses to diphtheria, tetanus, whole-cell or acellular

pertussis, Hib, or hepatitis B vaccines used concomitantly or in combination with IMOVAX® Polio, no interferences have been observed on the immunological end points accepted for clinical protection.

IMOVAX® Polio may be administered simultaneously with other parenteral vaccines at separate sites with separate syringes.

Except in the case of immunosuppressive therapy (see WARNINGS, Immune), no significant clinical interaction with other treatments or biological products has been documented.

IMOVAX® Polio should not be mixed in the same syringe with other parenterals.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

IMOVAX® Polio induces the production of neutralizing antibodies against each type of virus which are related to protective efficacy.

10.2 Pharmacodynamics

IMOVAX® Polio is a highly purified, inactivated poliovirus vaccine produced by microcarrier culture. These methods allow for the production of vaccine that induces antibody responses in most children after administering only two doses.

Studies in developed and developing countries with a similar inactivated poliovirus vaccine produced by the same technology have shown that a direct relationship exists between the antigenic content of the vaccine and the frequency of seroconversion, antibody titre and immunologic memory.

Inactivated poliovirus vaccine (IPV) reduces fecal and pharyngeal excretion of poliovirus. Field studies in the US and Europe have demonstrated herd immunity in populations immunized with IPV.

10.3 Pharmacokinetics

Duration of Effect

Immunity following injectable poliovirus vaccines has been shown to persist for 4 or more years after a primary series.

11 STORAGE, STABILITY AND DISPOSAL

Store at 2° to 8° C (35° to 46° F). **Do not freeze**. Discard product if exposed to freezing.

Do not use after expiration date.

12 SPECIAL HANDLING INSTRUCTIONS

The vaccine should be clear and colourless: do not use the vaccine if it has a cloudy appearance.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Inactivated Poliomyelitis Vaccine (Vero Cell Origin)

Product Characteristics:

IMOVAX® Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] is a sterile suspension of three types of Poliovirus (Formaldehyde Inactivated): Type 1 Mahoney, Type 2 MEF1 and Type 3 Saukett. IMOVAX® Polio is a highly purified, inactivated poliovirus vaccine produced by microcarrier culture. The viruses are grown in cultures of Vero cells, a continuous line of monkey kidney cells, by the microcarrier technique. The cells are grown in Eagle MEM modified medium, supplemented with newborn calf serum tested for adventitious agents prior to use, obtained from countries believed to be free of bovine spongiform encephalopathy. For viral growth the culture medium is replaced by M-199[4] without calf serum.

After clarification and filtration, viral suspensions are concentrated by ultrafiltration, and purified by three liquid chromatography steps: one column of anion exchanger, one column of gel filtration and again one column of anion exchanger. After re-equilibration of the purified viral suspension, with Medium M-199 and adjustment of the antigen titre, the monovalent viral suspensions are inactivated at +37°C for at least 12 days with 1:4,000 formalin.

This vaccine fulfills European Pharmacopoeia and WHO requirements.

14 CLINICAL TRIALS

14.2 Study Results

IMOVAX® Polio induces antibody responses in most children after administering only two doses.

Studies in developed and developing countries with a similar inactivated poliovirus vaccine produced by the same technology have shown that a direct relationship exists between the antigenic content of the vaccine and the frequency of seroconversion, antibody titre and immunologic memory.

A study involving two-month-old infants who had received IMOVAX® Polio demonstrated that seroconversion to all three types of poliovirus occurred in 99% of these infants after two doses of vaccine and immunologic memory in 100% as revealed by high titres of neutralizing antibody in response to a booster dose at 18 months.

An additional study was carried out in infants receiving two primary doses and a single booster dose of either IMOVAX® Polio, or a combined schedule of IMOVAX® Polio followed by oral poliovirus vaccine (OPV). Excellent neutralizing antibody levels and immunologic memory were attained in all infants, regardless of the schedule or type of vaccine. Detectable neutralizing antibodies were induced by IMOVAX® Polio after two doses of vaccine in 98.3% (type 1), 100% (type 2) and 97.5% (type 3) of the children. A booster dose resulted in detectable neutralizing antibodies in 98.2% (type 1) and 100%

[4] 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.

(types 2 and 3) of the children. A combined schedule of two doses of IMOVAX® Polio and an OPV booster gave 100% seroconversion.

14.4 Immunogenicity

DETAILED PHARMACOLOGY

IPV is able to induce secretory antibody (IgA) produced in the pharynx and gut and reduces pharyngeal excretion of poliovirus type 1 from 75% in children with neutralizing antibodies at levels less than 1:8 to 25% in children with neutralizing antibodies at levels more than 1:64.

Field studies in the US and Europe have demonstrated herd immunity in populations immunized with IPV. Approximately 98.5% of vaccinees demonstrated detectable circulating antibody and/or a booster response signifying immunologic memory to type 1 poliovirus 10 years after initial immunization with a Swedish IPV in a study on long-term persistence of circulating antibody.

Immunity following injectable poliovirus vaccines has been shown to persist for 4 or more years after a primary series.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

Data in animals including single dose, repeated dose and local tolerance studies revealed no unexpected findings and no target organ toxicity.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

IMOVAX® Polio

Inactivated Poliomyelitis Vaccine (Vero Cell Origin)

Read this carefully before **IMOVAX® Polio** is given to you or your child. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your (or your child's) medical condition and treatment and ask if there is any new information about **IMOVAX® Polio**.

What is IMOVAX® Polio used for?

IMOVAX® Polio is a vaccine used to prevent poliomyelitis (also known as polio). Polio is a disease caused by three types of poliovirus. People can get polio from drinking water or eating food with the polio virus in it. It is also spread from person to person. While most infections do not result in illness, severe infections can kill nerve cells. This leaves muscles permanently weak or damaged. About 1 in every 100 persons infected with the virus becomes paralyzed. Polio can paralyze muscles used for breathing, talking, eating and walking. It can also cause death. This vaccine may be given to adults and children 2 months of age and older.

How does IMOVAX® Polio work?

IMOVAX® Polio causes your body to produce its own natural protection against polio viruses. After you get an IMOVAX® Polio injection, your body begins to make substances called antibodies. Antibodies help your body to fight disease. When you are exposed to polio viruses, the antibodies will help to keep you from getting sick.

What are the ingredients in IMOVAX® Polio?

Medicinal ingredients: Killed purified viruses from three strains of poliomyelitis viruses

Non-medicinal ingredients: 2-phenoxyethanol, calf serum protein, formaldehyde, neomycin, polymyxin B, streptomycin.

IMOVAX® Polio comes in the following dosage forms:

A syringe containing a liquid vaccine dose of 0.5 mL.

Do not use IMOVAX® Polio if:

- You have a known allergic reaction to any component of the vaccine or its container.
- You have a fever or serious illness. Delay the vaccination until you feel better. If you have a mild illness (such as a mild cold) you may have the vaccine. Ask your doctor, nurse or pharmacist for advice.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you (or your child) take IMOVAX® Polio. Talk about any health conditions or problems you may have, including if you (or your child):

- **Have a disease of the immune system or taking a medical treatment that affects the immune system**. The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.

- **Have a bleeding disorder or are on blood-thinning medications.** Tell the person giving you the injection about your condition. There is a risk of excessive bleeding where you get the injection if it is not done carefully.
- **Are pregnant or breast-feeding.** It is important that you understand the risks and benefits of vaccination. IMOVAX® Polio should be given to a pregnant or nursing woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.
- **Fainting can occur following, or even before, any needle injection.** Therefore, tell your doctor or nurse if your child fainted with a previous injection.

Tell your healthcare professional about all the medicines you (or your child) take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

- There are no known interactions of IMOVAX® Polio with drugs or food.

IMOVAX® Polio must not be mixed with other vaccines or medicinal products in the same syringe.

How to take IMOVAX® Polio:

IMOVAX® Polio will be given to you by a healthcare professional in a healthcare setting. The vaccine is given under the skin (subcutaneously), preferably in the deltoid (shoulder) region.

- Most people get polio vaccine when they are children. Children usually get 5 doses of IPV: at 2 months of age, a dose 2 months later, at 18 months of age and booster doses at 4 - 6 years and 14 - 16 years.
- Most adults do not need polio vaccine because they were already vaccinated as children. But some adults are at higher risk and should consider polio vaccination: people travelling to areas of the world where polio is common, laboratory workers who might handle polio virus, people who may be in contact with children who received oral polio vaccine, and people in communities or groups with disease caused by the polio virus.
- People who have not received at least 4 doses of any polio vaccines during their lifetime should do so using IMOVAX® Polio. People in any of the higher risk groups may need a polio vaccine booster if more than 10 years have elapsed since the last dose of their **complete** polio vaccination series.

Usual dose:

For persons 2 months of age and older, the recommended dose is 0.5 mL.

Overdose:

Not applicable to this vaccine.

If you think you, or a person you are caring for, have taken too much IMOVAX® Polio, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If a dose is missed, it can be given at any time.

What are possible side effects from using IMOVAX® Polio?

These are not all the possible side effects you may have when taking IMOVAX® Polio. If you experience any side effects not listed here, tell your healthcare professional.

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of IMOVAX® Polio causing serious harm is extremely small. The small risks associated with IMOVAX® Polio are much less than the risks associated with getting the disease against which it protects.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after receiving IMOVAX® Polio.

Serious side effects are extremely rare. Side effects of this polio vaccine (IPV) are generally mild and last for only a few days after getting the needle. Some people get mild pain, swelling and redness at the spot where the vaccine was given. This is not a complete list of side effects.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur Limited cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php) and send it to your local Health Unit.

Storage:

Store in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze.** Discard product if it has been exposed to freezing.

Do not use vaccine after expiration date.

Keep out of reach and sight of children.

If you want more information about IMOVAX® Polio:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; manufacturer's website (www.sanofi.ca) or by calling 1-888-621-1146 (no charge).

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