

**PRODUCT MONOGRAPH**

**IMOVAX<sup>®</sup> Polio**

**Inactivated Poliomyelitis Vaccine (Vero Cell Origin)**

Dosage Form: Solution for Injection

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

Active Immunizing Agent  
(for the Prevention of Poliomyelitis)

Manufactured by:  
**Sanofi Pasteur SA**  
Lyon, France

Distributed by:  
**Sanofi Pasteur Limited**  
Toronto, Ontario, Canada

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## IMOVAX® Polio

### Inactivated Poliomyelitis Vaccine (Vero Cell Origin)

#### PART I: HEALTH PROFESSIONAL INFORMATION

##### SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Subcutaneous injection	Solution for injection Each 0.5 mL dose is formulated to contain: purified inactivated poliomyelitis vaccine: Type 1 (Mahoney) 40 D antigen units, Type 2 (MEF1) 8 D antigen units, Type 3 (Saukett) 32 D antigen units	2-phenoxyethanol, formaldehyde, residual calf serum protein, neomycin, streptomycin and polymyxin B, Medium 199 Hanks (without phenol red)

##### DESCRIPTION

IMOVAX® Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] is a sterile suspension of three types of poliovirus: Type 1 (Mahoney), Type 2 (MEF1) and Type 3 (Saukett). This vaccine is prepared from types 1, 2 and 3 of poliomyelitis virus cultured on Vero cells, purified and then inactivated by formaldehyde.

##### INDICATIONS AND CLINICAL USE

IMOVAX® Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] is indicated for active immunization against poliomyelitis caused by poliovirus types 1, 2 and 3 in infants, children and adults both for primary immunization and for boosters. (See DOSAGE AND ADMINISTRATION.)

##### Infants, Children and Adolescents

It is recommended that all infants, unimmunized children and adolescents not previously immunized be vaccinated routinely against paralytic poliomyelitis. (1) (2)

## Children Incompletely Immunized

Children of all ages should have their immunization status reviewed and be considered for supplemental immunization.

## Adults

All adults at risk of exposure to poliovirus should have their immunization status reviewed. For those who are unvaccinated, who have a history of incomplete immunization, or for whom immunization is uncertain, a primary series of IMOVAX<sup>®</sup> Polio is recommended. (See DOSAGE AND ADMINISTRATION, Adults.) The following categories of persons are at increased risk of exposure to poliovirus: (1) (3)

- travellers to areas of countries where poliomyelitis is still transmitted (4) or may be a risk; (5)
- laboratory workers handling specimens that may contain polioviruses;
- health-care workers in close contact with persons who may be excreting wild or vaccine strains of polioviruses;
- unimmunized parents or child-care workers who will be caring for children or unimmunized adults who may be in contact with children (6) in countries where OPV is used, (1) or in rare instances in which infants receive OPV in a country in which inactivated poliomyelitis vaccine (IPV) is normally used.
- members of communities or specific population groups with disease caused by wild poliovirus. (7)

IMOVAX<sup>®</sup> Polio can be used for completing immunization series in cases of previous clinical poliomyelitis (usually due to only a single poliovirus type) or incomplete immunization with OPV.

## Pediatrics

Safety and efficacy of IMOVAX<sup>®</sup> Polio have been shown in children 6 weeks of age and older.

## CONTRAINDICATIONS

Immunization with IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] 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. (1)

Allergy to any component of IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)], or its container, or an anaphylactic or other allergic reaction to a previous dose of IMOVAX<sup>®</sup> Polio is a contraindication to vaccination. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the product monograph.

## WARNINGS AND PRECAUTIONS

### General

As with any vaccine, immunization with IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] may not protect 100% of susceptible persons.

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.

IMOVAX<sup>®</sup> 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.

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<sup>®</sup> 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.)

### 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.

## **Special Populations**

### ***Pregnant Women***

There are limited data on the use of this vaccine in pregnant woman. 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 woman.

The National Advisory Committee on Immunization (NACI) states that IPV is not contraindicated in pregnancy, but its administration should be delayed until after the first trimester, if possible, to minimize any theoretical risk. If risk of exposure is imminent, IPV should be given and is always the vaccine of choice except for outbreak control. (1)

### ***Nursing Women***

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

The National Advisory Committee on Immunization states that inactivated polio vaccine may safely be given to lactating mothers who have not previously been immunized or are travelling to an endemic area. (1)

## **ADVERSE REACTIONS**

### **Adverse Drug 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)

### **Clinical Trial Adverse Drug Reactions**

Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

The local reactogenicity of IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] was evaluated in two multicentre randomized clinical trials involving a total of 395 patients and local reactions were uncommonly to very commonly reported: (8)

- 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%

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). (8)

In an other multicentre randomized Phase III study involving 324 children, it was concluded that IMOVAX<sup>®</sup> Polio combined or associated with DPT vaccine was as well-tolerated as DPT vaccine administered alone. (8)

### **Post-Market Adverse Drug Reactions**

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

IMOVAX<sup>®</sup> 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

#### **Musculo-skeletal 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<sup>®</sup> Polio and Guillain-Barré syndrome (GBS) has been established, GBS has been temporally related to administration of another inactivated poliovirus vaccine. (9)

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. (7) Although no causal relationship has been established, deaths have occurred in temporal association after vaccination of infants with IPV. (9)

Health professionals should report any adverse occurrences temporally related to the administration of the product in accordance with local requirements and to the Global Pharmacovigilance Department, Sanofi Pasteur Limited, 1755 Steeles Avenue West, Toronto, ON, M2R 3T4, Canada. 1-888-621-1146 (phone) or 416-667-2435 (fax).

## **DRUG INTERACTIONS**

There are no known interactions of IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] 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. (1) 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<sup>®</sup> 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<sup>®</sup> Polio, no interferences have been observed on the immunological end points accepted for clinical protection.

IMOVAX<sup>®</sup> 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<sup>®</sup> Polio should not be mixed in the same syringe with other parenterals.

## DOSAGE AND ADMINISTRATION

### Children

#### *Primary Immunization*

A primary series of IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] 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*

All children who received a primary series of IMOVAX<sup>®</sup> 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. (2)

A final total of at least four doses are 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. (1)

### 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: (1)

Travellers who will be departing within 4 weeks should receive a single dose of IPV and the remaining doses later, at the recommended intervals. (1)

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. (1)

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. (1)

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.

### **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.

### **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 solution before administration.

Administer IMOVAX<sup>®</sup> Polio subcutaneously. In infants and small children, the mid-lateral aspect of the thigh is the preferred site; in older children and adults in the deltoid or triceps area.

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.

## OVERDOSAGE

Not documented.

## ACTION AND CLINICAL PHARMACOLOGY

### Mechanism of Action

IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] induces the production of neutralizing antibodies against each type of virus which are related to protective efficacy.

### Pharmacodynamics

IMOVAX<sup>®</sup> Polio is a highly purified, inactivated poliovirus vaccine produced by microcarrier culture. (10) (11) (12) (13) These methods allow for the production of vaccine that induces antibody responses in most children after administering only two doses. (14)

Studies in developed (14) and developing (14) (24) 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. (15) (16) (17) (18) Field studies in the US and Europe have demonstrated herd immunity in populations immunized with IPV. (19) (20) (21) (22) (23)

### Duration of Effect

Immunity following injectable poliovirus vaccines has been shown to persist for 4 or more years after a primary series. (24)

## STORAGE AND STABILITY

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.

## SPECIAL HANDLING INSTRUCTIONS

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

## DOSAGE FORMS, COMPOSITION AND PACKAGING

### Dosage Forms

IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] is available in a ten dose package containing ten 0.5 mL syringes.

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

### Composition

IMOVAX<sup>®</sup> Polio contains: purified inactivated poliomyelitis vaccine: Type 1 (Mahoney) 40 D antigen units, Type 2 (MEF1) 8 D antigen units, Type 3 (Saukett) 32 D antigen units.

Other ingredients: 2-phenoxyethanol  $\leq 1.0\%$ , formaldehyde  $\leq 0.02\%$ , 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.

Full product monograph available on request.

Visit us at [www.sanofipasteur.ca](http://www.sanofipasteur.ca)

Vaccine Information Service: 1-888-621-1146 or 416-667-2779.

Product information as of December 2006.

Manufactured by:

**Sanofi Pasteur SA**

Lyon, France

Distributed by:

**Sanofi Pasteur Limited**

Toronto, Ontario, Canada

R4-1206 Canada

## PART II: SCIENTIFIC INFORMATION

### PHARMACEUTICAL INFORMATION

#### Drug Substance

Proper name: Inactivated Poliomyelitis Vaccine (Vero Cell Origin)

#### Composition

IMOVAX<sup>®</sup> Polio contains: purified inactivated poliomyelitis vaccine: Type 1 (Mahoney) 40 D antigen units, Type 2 (MEF1) 8 D antigen units, Type 3 (Saukett) 32 D antigen units.

Other ingredients: 2-phenoxyethanol ≤1.0%, 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.

This vaccine fulfills European Pharmacopoeia and WHO requirements.

#### Product Characteristics

#### Composition

IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] is a sterile suspension of three types of poliovirus: Type 1 (Mahoney), Type 2 (MEF1) and Type 3 (Saukett). IMOVAX<sup>®</sup> Polio is a highly purified, inactivated poliovirus vaccine produced by microcarrier culture. (10) (11) 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<sup>a</sup> 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.

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<sup>a</sup> 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.

## CLINICAL TRIALS

IMOVAX<sup>®</sup> Polio [Inactivated Poliomyelitis Vaccine (Vero Cell Origin)] induces antibody responses in most children after administering only two doses. (14)

Studies in developed (14) and developing (25) (26) 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<sup>®</sup> 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. (27)

An additional study was carried out in infants receiving two primary doses and a single booster dose of either IMOVAX<sup>®</sup> Polio, or a combined schedule of IMOVAX<sup>®</sup> Polio followed by oral poliovirus vaccine (OPV). (28) 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<sup>®</sup> 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% (Types 2 and 3) of the children. A combined schedule of two doses of IMOVAX<sup>®</sup> Polio and an OPV booster gave 100% seroconversion.

## DETAILED PHARMACOLOGY

Poliomyelitis is a disease that may cause irreversible paralysis in a certain proportion of infected persons. It is a highly infectious disease caused by three types of the enterovirus poliovirus. (1) It is primarily spread by the fecal-oral route of transmission but may also be spread by the pharyngeal route. Following introduction of poliovirus vaccine in Canada in 1955, indigenous disease has been virtually eliminated.

The last significant outbreak of poliomyelitis occurred in 1978-79, when there were 11 cases of paralytic disease among unimmunized contacts of imported cases. The last case of poliomyelitis attributed to imported, wild virus occurred in 1988. (1) However, circulation of wild viruses does occur in rare circumstances, (29) and it remains crucial that the highest possible level of vaccine-induced immunity be maintained in the population.

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. (30) (31) (32) (15) (16) (17) (18) (33) (20)

Field studies in the US and Europe have demonstrated herd immunity in populations immunized with IPV. (19) (20) (21) (22) (23) 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. (1)

Immunity following injectable poliovirus vaccines has been shown to persist for 4 or more years after a primary series. (24)

## **TOXICOLOGY**

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

Full product monograph available on request.

Visit us at [www.sanofipasteur.ca](http://www.sanofipasteur.ca)

Vaccine Information Service: 1-888-621-1146 or 416-667-2779.

Product information as of December 2006.

Manufactured by:

**Sanofi Pasteur SA**

Lyon, France

Distributed by:

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Toronto, Ontario, Canada

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## References List

- 1 National Advisory Committee on Immunization (NACI): Part 1 - General Considerations; Diphtheria Toxoid; Poliomyelitis Vaccine. Canadian Immunization Guide, Sixth ed. Her Majesty the Queen in right of Canada, represented by the Minister of Public Works and Government Services Canada, 2002. p. 1-18,22,27-8,31,185-90.
- 2 Immunization Practices Advisory Committee (ACIP), Poliomyelitis Prevention: Enhanced-potency inactivated poliomyelitis vaccine supplementary statement. MMWR 1987;36(48):795-8.
- 3 Recommendation of the Immunization Practices Advisory Committee (ACIP), Poliomyelitis Prevention. MMWR 1982;31(3):22-6,31-4.
- 4 WHO Travel Book. International travel and health [cited 2004 Sep 10]. Available from [www.who.int/ith/chapter06\\_01.html](http://www.who.int/ith/chapter06_01.html)
- 5 Public Health Agency of Canada. Disease Information Poliomyelitis on line at [www.phac-aspc.gc.ca/tmp-pmv/info/polio\\_e.html](http://www.phac-aspc.gc.ca/tmp-pmv/info/polio_e.html)
- 6 CDC Imported vaccine-associated paralytic poliomyelitis - United States, 2005. MMWR 2006;55(04):97-9.
- 7 CDC Poliomyelitis prevention in the United States. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP) MMWR 2000;49(RR-5):13.
- 8 Data on File at Sanofi Pasteur SA.
- 9 Stratton KR, et al, eds. Adverse Events Associated with Childhood Vaccines; Evidence bearing on causality. Washington (DC): National Academy Press. 1994:201,204,295-9.
- 10 van Wezel AL, et al. Inactivated poliovirus vaccine: current production methods and new developments. Rev Infect Dis 1984;6(Suppl 2):S335-40.
- 11 Montagnon BJ, et al. Industrial scale production of inactivated poliovirus vaccine prepared by culture of vero cells on microcarrier. Rev Infect Dis 1984;6(Suppl 2):S341-4.
- 12 Montagnon BJ, et al. Experience with Vero cells at Pasteur Merieux Connaught. Dev Biol Stand 1999;98:137-40.
- 13 Montagnon BJ, Vincent-Falquet JC. Experience with the Vero cell line. Dev Biol Stand 1998;93:119-23.
- 14 Salk J, et al. Antigen content of inactivated poliovirus vaccine for use in a one- or two-dose regimen. Ann Clin Res 1982;14:204-12.
- 15 Marine WM, et al. Limitation of fecal and pharyngeal poliovirus excretion in Salk-vaccinated children. A family study during a Type 1 poliomyelitis epidemic. Amer J Hyg 1962;76:173-75.
- 16 Bottiger M, et al. Vaccination with attenuated Type 1 poliovirus, the Chat strain. II. Transmission of virus in relation to age. Acta Paed Scand 1966;55:416-21.
- 17 Dick GWA, et al. Vaccination against poliomyelitis with live virus vaccines. Effect of previous Salk vaccination on virus excretion. Brit Med J 1961;2:266-9.

- 18 Wehrle PF, et al. Transmission of poliovirus; III. Prevalence of polioviruses in pharyngeal secretions of infected household contacts of patients with clinical disease. *Pediatrics* 1961;27:762-64.
- 19 Bottiger M. Long-term immunity following vaccination with killed poliovirus vaccine in Sweden, a country with no circulating poliovirus. *Rev Infect Dis* 1984;6(Suppl 2):S548-51.
- 20 Chin TDY. Immunity induced by inactivated poliovirus vaccine and excretion of virus. *Rev Infect Dis* 1984;6(Suppl 2):S369-70.
- 21 Salk D. Herd effect and virus eradication with use of killed poliovirus vaccine. *Dev Biol Stand* 1981;47:247-55.
- 22 Bijerk H. Surveillance and control of poliomyelitis in the Netherlands. *Rev Infect Dis* 1984;6(Suppl 2):S451-6.
- 23 Lapinleimu K. Elimination of poliomyelitis in Finland. *Rev Infect Dis* 1984;6(Suppl 2):S457-60.
- 24 Plotkin SA, Vidor E. Poliovirus Vaccine -- Inactivated. In: Plotkin SA, Orenstein WA, editors. *Vaccines*. 4th ed. Philadelphia, PA: Elsevier Inc. (USA); 2004. p. 638.
- 25 Salk J, et al. Killed poliovirus antigen titration in humans. *Dev Biol Stand* 1978;41:110-32.
- 26 Salk J, et al. Theoretical and practical considerations in the application of killed poliovirus vaccine for the control of paralytic poliomyelitis. *Dev Biol Stand* 1981;47:181-98.
- 27 McBean AM, et al. Serologic response to oral polio vaccine and enhanced-potency inactivated polio vaccines. *Am J Epidemiol* 1988;128:15-28.
- 28 Faden H, et al. Combined use of inactivated and live polio vaccines: A tale of two vaccines and a solution to the controversy? *Pediatric Research* 1988;23(4):368A.
- 29 National Advisory Committee on Immunization (NACI): Genomic analysis of type 3 wild poliovirus isolates in southern Alberta. *CCDR* 1993;19(13):96-9.
- 30 Murdin AD, et al. Inactivated poliovirus vaccine: past and present experience. *Vaccine* 1996;8:735-46.
- 31 Vidor E, et al. The place of DTP/eIPV vaccine in routine paediatric vaccination. *Rev Med Virol* 1994;4:261-77.
- 32 Plotkin SA, et al. Inactivated polio vaccine for the United States: a missed vaccination opportunity. *Pediatr Infect Dis J* 1995;14:835-9.
- 33 Adenyi-Jones SC, et al. Systemic and local immune responses to enhanced-potency inactivated poliovirus vaccine in premature and term infants. *J Pediatr* 1992;120(5):686-9.

**IMPORTANT: PLEASE READ**

**PART III: CONSUMER INFORMATION**

**IMOVAX® Polio**

Inactivated Poliomyelitis Vaccine (Vero Cell Origin)

This leaflet is part III of a three-part "Product Monograph" published when IMOVAX® Polio was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about IMOVAX® Polio. Contact your doctor, nurse or pharmacist if you have any questions about the vaccine.

**ABOUT THIS MEDICATION**

**What the medication is 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.

**What it does:**

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.

**When it should not be used:**

IMOVAX® Polio should not be used in the following situations:

Do not give IMOVAX® Polio to anyone who has had an allergic reaction to any component of the vaccine or its container.

Do not give IMOVAX® Polio to a person who has a fever or serious illness. Wait until the person is better before giving the vaccine. A person who has had a mild illness (such as a mild cold) may have the vaccine. Ask your doctor, nurse or pharmacist for advice.

**What the medicinal ingredient is:**

Each 0.5 mL dose of IMOVAX® Polio contains killed purified viruses from three strains of poliomyelitis viruses

**What the important nonmedicinal ingredients are:**

calf serum protein, formaldehyde, neomycin, polymyxin B, streptomycin and 2-phenoxyethanol

*For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.*

**What dosage forms it comes in:**

A syringe containing a liquid vaccine dose of 0.5 mL for subcutaneous injection.

**WARNINGS AND PRECAUTIONS**

BEFORE you use IMOVAX® Polio talk to your doctor, nurse or pharmacist if you or your child has any of the following conditions:

- **Persons with diseases 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.
- **Persons who have bleeding disorders 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.
- **Pregnant or breast-feeding women.** 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.

## INTERACTIONS WITH THIS MEDICATION

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

## PROPER USE OF THIS MEDICATION

For persons 2 months of age and older, the recommended dose is 0.5 mL. The vaccine should be 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<sup>®</sup> 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.

Overdose:

Not applicable to this vaccine.

Missed Dose:

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

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of IMOVAX<sup>®</sup> Polio causing serious harm is extremely small. The small risks associated with IMOVAX<sup>®</sup> 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<sup>®</sup> 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 needle was given.

This is not a complete list of side effects. For any unexpected effects after receiving IMOVAX<sup>®</sup> Polio, contact your doctor, nurse or pharmacist.

## HOW TO STORE IT

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 the reach of children.

## REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, Health Canada collects information on serious and unexpected effects of vaccine(s). If you suspect you have had a serious or unexpected reaction to this vaccine you may notify Health Canada by:

Telephone: 613-952-6339

Fax 613-946-0224

By email: VAAES@phac-aspc.gc.ca

By regular mail:

The Vaccine Safety Unit

Immunization & Respiratory Infections Division

Centre for Infectious Disease Prevention & Control

Public Health Agency of Canada

PL 0602C Bldg #6, Tunney's Pasture

Ottawa, Ontario

K1A 0K9

**NOTE: Before contacting Health Canada, you should contact your physician, nurse or pharmacist.**

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.sanofipasteur.ca> or by contacting the sponsor, Sanofi Pasteur Limited, 1755 Steeles Avenue West, Toronto, Ontario, M2R 3T4. Phone: 1-888-621-1146 or 416-667-2779.

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