IMOVAX POLIO, suspension for injection in a prefilled syringe or multidose Poliomyelitis vaccine (inactivated)

THERAPEUTIC INDICATIONS

Prophylaxis of poliomyelitis.

DESCRIPTION

IMOVAX POLIO, Poliovirus Vaccine Inactivated, produced by Sanofi Pasteur, is a sterile suspension of three types of poliovirus: Type 1 (Mahoney), Type 2 (MEF-1), and Type 3 (Saukett). IMOVAX POLIO vaccine is a highly purified, inactivated poliovirus vaccine with enhanced potency. Each of the three strains of poliovirus is individually grown in vero cells, a continuous line of monkey kidney cells cultivated on microcarriers. The cells are grown in Eagle MEM modified medium, supplemented with newborn calf bovine serum tested for adventitious agents prior to use, originated from countries free of bovine spongiform encephalopathy. For viral growth, the culture medium is replaced by M-199, without calf bovine serum. This culture technique and improvements in purification, concentration, and standardization of poliovirus antigen produce a more potent and consistent immunogenic vaccine than the inactivated poliovirus vaccine (IPV) available in the US prior to 1988.

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 titer, the monovalent viral suspensions are inactivated at +37°C for at least 12 days with 1:4000 formalin.

Each dose (0.5 mL) of trivalent vaccine is formulated to contain 40 D antigen units of Type 1, 8 D antigen units of Type 2, and 32 D antigen units of Type 3 poliovirus. For each lot of IMOVAX POLIO vaccine, D-antigen content is determined *in vitro* using the D-antigen ELISA assay. IMOVAX POLIO vaccine is produced from vaccine concentrates diluted with M-199 medium. Also present are 0.5% of 2- phenoxyethanol and a maximum of 0.02% of formaldehyde per dose as preservatives. Neomycin, streptomycin, and polymyxin B are used in vaccine production; and, although purification procedures eliminate measurable amounts, less than 5 ng neomycin, 200 ng streptomycin, and 25 ng polymyxin B per dose may still be present. The residual calf bovine serum albumin is less than 50 ng/dose in the final vaccine.

The vaccine is clear and colorless and should be administered intramuscularly or subcutaneously. The vial stopper is not made with natural rubber latex.

CLINICAL PHARMACOLOGY

Poliomyelitis is caused by poliovirus Types 1, 2, or 3. It is primarily spread by the fecal-oral route of transmission but may also be spread by the pharyngeal route.

Approximately 90% to 95% of poliovirus infections are asymptomatic. Nonspecific illness with low-grade fever and sore throat (minor illness) occurs in 4% to 8% of infections. Aseptic meningitis occurs in 1% to 5% of patients a few days after the minor illness has resolved. Rapid onset of asymmetric acute flaccid paralysis occurs in 0.1% to 2% of infections, and residual paralytic disease involving motor neurons (paralytic poliomyelitis) occurs in approximately 1 per 1,000 infections.

Prior to the introduction of inactivated poliovirus vaccines in 1955, large outbreaks of poliomyelitis occurred each year in the United States (US). The annual incidence of paralytic disease of 11.4 cases/100,000 population declined to 0.5 cases by the time oral poliovirus vaccine (OPV) was introduced in 1961. Incidence continued to decline thereafter to a rate of 0.002 to 0.005 cases per 100,000 population. Of the 127 cases of paralytic poliomyelitis reported in the US between 1980 and 1994, six were imported cases (caused by wild polioviruses), two were "indeterminate" cases, and 119 were vaccine associated paralytic poliomyelitis (VAPP) cases associated with the use of live, attenuated oral poliovirus vaccine (OPV). An all IPV schedule was adopted in 1999 to eliminate VAPP cases.

Poliovirus Vaccine Inactivated induces the production of neutralizing antibodies against each type of virus which are related to protective efficacy. Antibody response in most children was induced after receiving fewer doses of IPV vaccine than the vaccine available in the United States prior to 1988.

Studies in developed and developing , countries with a similar enhanced IPV manufactured by the same process as IMOVAX POLIO vaccine in primary monkey kidney cells have shown a direct relationship exists between the antigenic content of the vaccine, the frequency of seroconversion, and resulting antibody titer. Approval in the US was based upon demonstration of immunogenicity and safety in US children.

In the US, 219 infants received three doses of a similar enhanced IPV at two, four, and eighteen months of age manufactured by the same process as IMOVAX POLIO vaccine except the cell substrate for IPV was using primary monkey kidney cells. Seroconversion to all three types of poliovirus was demonstrated in 99% of these infants after two doses of vaccine given at 2 and 4 months of age. Following the third dose of vaccine at 18 months of age, neutralizing antibodies were present at a level of ≥1:10 in 99.1% of children to Type 1 and 100% of children to Types 2 and 3 polioviruses.

IMOVAX POLIO vaccine was administered to more than 700 infants between 2 to 18 months of age during three clinical studies conducted in the US using IPV only schedules and sequential IPV-OPV schedules. Seroprevalence rates for detectable serum neutralizing antibody (DA) at a ≥1:4 dilution were 95% to 100% (Type 1); 97% to 100% (Type 2) and 96% to 100% (Type 3) after two doses of IMOVAX POLIO vaccine depending on studies.

Table 1: US Studies with IMOVAX POLIO Vaccine Administered Using IPV Only or Sequential IPV- OPV Schedules

Age (months) for				Post Dose 2				Post Dose 3				Pre Booster				Post Booster			
2	4	6	12 to 18		Type 1	Type 2	Type 3		Type 1	Type 2	Type 3		Type 1	Type 2	Type 3		Type 1	Type 2	Type 3
Dose 1	Dose 2	Dose 3	Booster	N*	%DA†	%DA	%DA	N*	%DA	%DA	%DA	N*	%DA	%DA	%DA	N*	%DA	%DA	%DA
STUDY 1 ‡																			
I(s)	I(s)	NA§	I(s)	56	97	100	97	–	–	–		53	91	97	93	53	97	100	100
O	O	NA	O	22	100	100	100	–	–	–		22	78	91	78	20	100	100	100
I(s)	O	NA	O	17	95	100	95	–	–	–		17	95	100	95	17	100	100	100
I(s)	I(s)	NA	O	17	100	100	100	–	–	–		16	100	100	94	16	100	100	100
STUDY 2 ¶																			
I(c)	I(c)	NA	I(s)	94	98	97	96	–	–	–		100	92	95	88	97	100	100	100
I(s)	I(s)	NA	I(s)	68	99	100	99	–	–	–		72	100	100	94	75	100	100	100
I(c)	I(c)	NA	O	75	95	99	96	–	–	–		77	86	97	82	78	100	100	97
I(s)	I(s)	NA	O	101	99	99	95	–	–	–		103	99	97	89	107	100	100	100
STUDY 3 ¶																			
I(c)	I(c)	I(c)	O	91	98	99	100	91	100	100	100	41	100	100	100	40	100	100	100
I(c)	I(c)	O	O	96	100	98	99	94	100	100	99	47	100	100	100	45	100	100	100
I(c)	I(c)	I(c) + O	O	91	96	97	100	85	100	100	100	47	100	100	100	46	100	100	100

* N = Number of children from whom serum was available

† Detectable antibody (neutralizing titer ≥1:4)

‡ IMOVAX POLIO vaccine given subcutaneously

§ NA – No poliovirus vaccine administered

¶ IMOVAX POLIO vaccine given intramuscularly

I IMOVAX POLIO vaccine given either separately in association with DTP in two sites (s) or combined (c) with DTP in a dual chambered syringe

O OPV

In one study, the persistence of DA in infants receiving two doses of IMOVAX POLIO vaccine at 2 and 4 months of age was 91% to 100% (Type 1), 97% to 100% (Type 2), and 93% to 94% (Type 3) at twelve months of age. In another study, 86% to 100% (Type 1), 95% to 100% (Type 2), and 82% to 94% (Type 3) of infants still had DA at 18 months of age.
In trials and field studies conducted outside the US, IMOVAX POLIO vaccine, or a combination vaccine containing IMOVAX POLIO vaccine and DTP, was administered to more than 3,000 infants between 2 to 18 months of age using IPV only schedules and immunogenicity data are available from 1,485 infants. After two doses of vaccine given during the first year of life, seroprevalence rates for detectable serum neutralizing antibody (neutralizing titer ≥1:4) were 88% to 100% (Type 1); 84% to 100% (Type 2) and 94% to 100% (Type 3) of infants, depending on studies. When three doses were given during the first year of life, post-dose 3 DA ranged between 93% to 100% (Type 1); 89% to 100% (Type 2) and 97% to 100% (Type 3) and reached 100% for Types 1, 2, and 3 after the fourth dose given during the second year of life (12 to 18 months of age).
In infants immunized with three doses of an unlicensed combination vaccine containing IMOVAX POLIO vaccine and DTP given during the first year of life, and a fourth dose given during the second year of life, the persistence of detectable neutralizing antibodies was 96%, 96%, and 97% against poliovirus Types 1, 2, and 3, respectively, at six years of age. DA reached 100% for all types after a booster dose of IMOVAX POLIO vaccine combined with DTP vaccine. A survey of Swedish children and young adults given a Swedish IPV only schedule demonstrated persistence of detectable serum neutralizing antibody for at least 10 years to all three types of poliovirus.

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.
There is also evidence of induction of herd immunity with IPV, and that this herd immunity is sufficiently maintained in a population vaccinated only with IPV.

VAPP has not been reported in association with administration of IMOVAX POLIO vaccine. It is expected that an IPV only schedule will eliminate the risk of VAPP in both recipients and contacts compared to a schedule that included OPV.

Posology

Primary vaccination:
From 2 months of age, 3 successive injections of 0.5 ml should be administered at intervals of one or two months.
From 6 weeks of age, IMOVAX POLIO may be administered following the 6-, 10-, 14-week schedule, as per the recommendations of the Expanded Programme on Immunisation of the World Health Organisation.
For nonvaccinated adults, 2 successive injections of 0.5 ml should be given at intervals of one or, preferably, two months.
Booster

For children older than 12 months , a 4th dose (1st booster) is administered 6-12 months after the 3rd injection.
For adults, a 3rd dose (1st booster) is administered 6 to 12 months after the 2nd injection.
A booster is given every 5 years in children and adolescents and every 10 years in adults.

INDICATIONS AND USAGE

This vaccine is indicated for the prevention of poliomyelitis in infants, children and adults, for primary and booster vaccinations.

INFANTS, CHILDREN AND ADOLESCENTS

General Recommendations
It is recommended that all infants (as young as 6 weeks of age), unimmunized children, and adolescents not previously immunized be vaccinated routinely against paralytic poliomyelitis.
Previous clinical poliomyelitis (usually due to only a single poliovirus type) or incomplete immunization with OPV are not contraindications to completing the primary series of immunization with Imovax Polio vaccine.

Children Incompletely Immunized
Children of all ages should have their immunization status reviewed and be considered for supplemental immunization as follows for adults. 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 (see **DOSAGE AND ADMINISTRATION** section).

ADULTS

General Recommendations
. Unimmunized adults who are potentially exposed to wild poliovirus and have not been adequately immunized should receive polio vaccination in accordance with the schedule given in the **DOSAGE AND ADMINISTRATION** section. Persons with previous wild poliovirus disease who are incompletely immunized or unimmunized should be given additional doses of IMOVAX POLIO vaccine if they fall into one or more categories listed.

The following categories of adults are at an increased risk of exposure to wild polioviruses:
• Travelers to regions or countries where poliomyelitis is endemic or epidemic.
• Healthcare workers in close contact with patients who may be excreting polioviruses.
• Laboratory workers handling specimens that may contain polioviruses.
• Members of communities or specific population groups with disease caused by wild polioviruses.

IMMUNODEFICIENCY AND ALTERED IMMUNE STATUS

IMOVAX POLIO vaccine should be used in all patients with immunodeficiency diseases and

members of such patients' households when vaccination of such persons is indicated. This includes patients with asymptomatic HIV infection, AIDS or AIDS-Related Complex, severe combined immunodeficiency, hypogammaglobulinemia, or agammaglobulinemia; altered immune states due to diseases such as leukemia, lymphoma, or generalized malignancy; or an immune system compromised by treatment with corticosteroids, alkylating drugs, antimetabolites or radiation.
Immunogenicity of IMOVAX POLIO vaccine in individuals receiving immunoglobulin could be impaired, and patients with an altered immune state may or may not develop a protective response against paralytic poliomyelitis after administration of IPV.

As with any vaccine, vaccination with IMOVAX POLIO vaccine may not protect 100% of individuals.

Use with other vaccines: refer to DOSAGE AND ADMINISTRATION section for this information.

CONTRAINDICATIONS

IMOVAX POLIO vaccine is contraindicated in persons with a history of hypersensitivity to any component of the vaccine, including 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, and polymyxin B.
No further doses should be given if anaphylaxis or anaphylactic shock occurs within 24 hours of administration of one dose of vaccine.
Vaccination of persons with an acute, febrile illness should be deferred until after recovery; however, minor illness, such as mild upper respiratory infection, with or without low grade fever, are not reasons for postponing vaccine administration.

WARNINGS

Neomycin, streptomycin, polymyxin B, 2-phenoxyethanol, and formaldehyde are used in the production of this vaccine. Although purification procedures eliminate measurable amounts of these substances, traces may be present (see **DESCRIPTION** section), and allergic reactions may occur in persons sensitive to these substances (see **CONTRAINDICATIONS** section).

Systemic adverse reactions reported in infants receiving IPV concomitantly at separate sites or combined with DTP have been similar to those associated with administration of DTP alone. Local reactions are usually mild and transient in nature.
Although no causal relationship between IMOVAX POLIO vaccine and Guillain-Barré Syndrome (GBS) has been established, GBS has been temporally related to administration of another inactivated poliovirus vaccine. Deaths have been reported in temporal association with the administration of IPV (see **ADVERSE REACTIONS** section).

PRECAUTIONS

GENERAL

Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse

reactions. This includes a review of the patient's history with respect to possible sensitivity to the vaccine or similar vaccines.

Healthcare providers should question the patient, parent or guardian about reactions to a previous dose of this product, or similar product.
Epinephrine injection (1:1000) and other appropriate agents should be available to control immediate allergic reactions.
Healthcare providers should obtain the previous immunization history of the vaccinee, and inquire about the current health status of the vaccinee.

Immunodeficient patients or patients under immunosuppressive therapy may not develop a protective immune response against paralytic poliomyelitis after administration of IPV.

Administration of IMOVAX POLIO vaccine is not contraindicated in individuals infected with HIV.

Special care should be taken to ensure that the injection does not enter a blood vessel.

Syncope (fainting) has been reported following vaccination with IMOVAX POLIO. Procedures should be in place to avoid injury from fainting.

INFORMATION FOR PATIENTS

Patients, parents, or guardians should be instructed to report any serious adverse reactions to their healthcare provider.

The healthcare provider should inform the patient, parent, or guardian of the benefits and risks of the vaccine.

The healthcare provider should inform the patient, parent, or guardian of the importance of completing the immunization series.

The healthcare provider should provide the Vaccine Information Statements (VISs) which are required to be given with each immunization.

DRUG INTERACTIONS

There are no known interactions of IMOVAX POLIO vaccine with drugs or foods. Concomitant administration of other parenteral vaccines, with separate syringes at separate sites, is not contraindicated. The first two doses of IMOVAX POLIO vaccine may be administered at separate sites using separate syringes concomitantly with DTaP, acellular pertussis, *Haemophilus influenzae* type b (Hib), and hepatitis B vaccines. From historical data on the antibody responses to diphtheria, tetanus, acellular pertussis, Hib, or hepatitis B vaccines used concomitantly or in combination with IMOVAX POLIO vaccine, no interferences have been observed on the immunological end points accepted for clinical protection. (See **DOSAGE AND ADMINISTRATION** section.)
If IMOVAX POLIO vaccine has been administered to persons receiving immunosuppressive

therapy, an adequate immunologic response may not be obtained. (See **PRECAUTIONS – GENERAL** section.)

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

Long-term studies in animals to evaluate carcinogenic potential or impairment of fertility have not been conducted.

PREGNANCY

Animal reproduction studies have not been conducted with IMOVAX POLIO vaccine. It is also not known whether IMOVAX POLIO vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. IMOVAX POLIO vaccine should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

It is not known whether IMOVAX POLIO vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when IMOVAX POLIO vaccine is administered to a nursing woman.

PEDIATRIC USE

SAFETY AND EFFECTIVENESS OF IMOVAX POLIO VACCINE IN INFANTS BELOW SIX WEEKS OF AGE HAVE NOT BEEN ESTABLISHED. (See **DOSAGE AND ADMINISTRATION** section.)

In the US, infants receiving two doses of IPV at 2 and 4 months of age, the seroprevalence to all three types of poliovirus was demonstrated in 95% to 100% of these infants after two doses of vaccine.

ADVERSE REACTIONS

Body System As A Whole

In earlier studies with the vaccine grown in primary monkey kidney cells, transient local reactions at the site of injection were observed. Erythema, induration and pain occurred in 3.2%, 1% and 13%, respectively, of vaccinees within 48 hours post-vaccination. Temperatures of ≥39°C were reported in 38% of vaccinees. Other symptoms included irritability, sleepiness, fussiness, and crying. Because IPV was given in a different site but concurrently with Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP), these systemic reactions could not be attributed to a specific vaccine. However, these systemic reactions were comparable in frequency and severity to that reported for DTP given alone without IPV. Although no causal relationship has been established, deaths have occurred in temporal association after vaccination of infants with IPV. Four additional US studies using IMOVAX POLIO vaccine in more than 1,300 infants, between

2 to 18 months of age administered with DTP at the same time at separate sites or combined have demonstrated that local and systemic reactions were similar when DTP was given alone.

Table 2 : Percentage of Infants Presenting with Local or Systemic Reactions at 6, 24, and 48 Hours of Immunization with IMOVAX POLIO Vaccine Administered Intramuscularly Concomitantly at Separate Sites with Sanofi* Whole-Cell DTP Vaccine at 2 and 4 Months of Age and with Sanofi Acellular Pertussis Vaccine (Tripedia®) at 18 Months of Age

	AGE AT IMMUNIZATION								
REACTION	2 Months (n=211)			4 Months (n=206)			18 Months† (n=74)		
	6 Hrs.	24 Hrs.	48 Hrs.	6 Hrs.	24 Hrs.	48 Hrs.	6 Hrs.	24 Hrs.	48 Hrs.
Local, IMOVAX POLIO vaccine alone‡									
Erythema >1"	0.5%	0.5%	0.5%	1.0%	0.0%	0.0%	1.4%	0.0%	0.0%
Swelling	11.4%	5.7%	0.9%	11.2%	4.9%	1.9%	2.7%	0.0%	0.0%
Tenderness	29.4%	8.5%	2.8%	22.8%	4.4%	1.0%	13.5%	4.1%	0.0%
Systemic§									
Fever >102.2°F	1.0%	0.5%	0.5%	2.0%	0.5%	0.0%	0.0%	0.0%	4.2%
Irritability	64.5%	24.6%	17.5%	49.5%	25.7%	11.7%	14.7%	6.7%	8.0%
Tiredness	60.7%	31.8%	7.1%	38.8%	18.4%	6.3%	9.3%	5.3%	4.0%
Anorexia	16.6%	8.1%	4.3%	6.3%	4.4%	2.4%	2.7%	1.3%	2.7%
Vomiting	1.9%	2.8%	2.8%	1.9%	1.5%	1.0%	1.3%	1.3%	0.0%
Persistent Crying	Percentage of infants within 72 hours after immunization was 0.0% after dose one, 1.4% after dose two, and 0.0% after dose three.								

* Sanofi Pasteur Inc. formerly known as Aventis Pasteur Inc.

† Children who have been vaccinated with Tripedia vaccine.

‡ Data are from the IMOVAX POLIO vaccine administration site, given intramuscularly.

§ The adverse reaction profile includes the concomitant use of Sanofi whole-cell DTP vaccine or Tripedia vaccine with IMOVAX POLIO vaccine. Rates are comparable in frequency and severity to that reported for whole-cell DTP given alone.

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Digestive System

Anorexia and vomiting occurred with frequencies not significantly different as reported when

DTP was given alone without IPV or OPV.

Nervous System

Although no causal relationship between IMOVAX POLIO vaccine and GBS has been established, GBS has been temporally related to administration of another inactivated poliovirus vaccine.

Post-marketing Experience

The following adverse events have been identified during postapproval use of IMOVAX POLIO vaccine. Because these events are reported voluntarily from a population of uncertain size, it may not be possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting or strength of evidence for a causal relationship.

- ***Blood and lymphatic system disorders:*** lymphadenopathy
- ***General disorders and administration site conditions:*** agitation, injection site reaction including injection site rash and mass
- ***Immune system disorders:*** type I hypersensitivity including allergic reaction, anaphylactic reaction, and anaphylactic shock
- ***Musculoskeletal and connective tissue disorders:*** arthralgia, myalgia
- ***Nervous system disorders:*** convulsion, febrile convulsion, headache, paresthesia, and somnolence
- ***Skin and subcutaneous tissue disorders:*** rash, urticarial

Reporting of Adverse Events

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health (www.health.gov.il) according to the National Regulation by using an online form https://sideeffects.health.gov.il

DOSAGE AND ADMINISTRATION

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The vial and its packaging should be inspected prior to use for evidence of leakage or a faulty seal. If evidence of such defects are observed, the vaccine should not be used. Do not remove the vial stopper or the metal seal holding it in place.
After preparation of the injection site, using a suitable sterile needle and aseptic technique, immediately administer IMOVAX POLIO vaccine intramuscularly or subcutaneously. In infants and small children, the mid-lateral aspect of the thigh is the preferred site. In older children and adults, IMOVAX POLIO vaccine should be administered intramuscularly or subcutaneously in the deltoid area. IMOVAX POLIO should not be combined through reconstitution or mixed with any

other vaccine.
To help avoid HIV (AIDS), HBV (Hepatitis), and other infectious diseases due to accidental needlesticks, contaminated needles should not be recapped or removed, unless there is no alternative or that such action is required by a specific medical procedure.

Care should be taken to avoid administering the injection into or near blood vessels and nerves. If blood or any suspicious discoloration appears in the syringe, do not inject but discard contents and repeat procedures using a new dose of vaccine administered at a different site.

DO NOT ADMINISTER VACCINE INTRAVENOUSLY.

Children
The primary series of IMOVAX POLIO vaccine consists of three 0.5 mL doses administered intramuscularly or subcutaneously, preferably eight or more weeks apart and usually at ages 2, 4, and 6 to 18 months. Under no circumstances should the vaccine be given more frequently than four weeks apart. The first immunization may be administered as early as six weeks of age.

Use with Other Vaccines

From historical data on the antibody responses to diphtheria, tetanus, whole-cell or acellular pertussis, Hib, or hepatitis B vaccines used concomitantly with IMOVAX POLIO vaccine, no interferences have been observed on the immunological end points accepted for clinical protection. (See **DRUG INTERACTIONS** section.)

If the third dose of IMOVAX POLIO vaccine is given between 12 to 18 months of age, it may be desirable to administer this dose with Measles, Mumps, and Rubella (MMR) vaccine and/or other vaccines using separate syringes at separate sites, but no data on the immunological interference between IMOVAX POLIO vaccine and these vaccines exist.

Use in Previously Vaccinated Children

Children and adolescents with a previously incomplete series of polio vaccine should receive sufficient additional doses of IMOVAX POLIO vaccine to complete the series.

Interruption of the recommended schedule with a delay between doses does not interfere with the final immunity. There is no need to start the series over again, regardless of the time elapsed between doses.

The need to routinely administer additional doses is unknown at this time.

Adults
Unvaccinated Adults
A primary series of IMOVAX POLIO vaccine is recommended for unvaccinated adults at increased risk of exposure to poliovirus. While the responses of adults to primary series have not been studied, the recommended schedule for adults is two 0.5 mL doses given at a 1 to 2 month interval and a third 0.5 mL dose given 6 to 12 months later. If less than 3 months but more than 2 months are available before protection is needed, three doses of IMOVAX POLIO vaccine should

be given at least 1 month apart. Likewise, if only 1 or 2 months are available, two 0.5 mL doses of IMOVAX POLIO vaccine should be given at least 1 month apart. If less than 1 month is available, a single 0.5 mL dose of IMOVAX POLIO vaccine is recommended.

Incompletely Vaccinated Adults
Adults who are at an increased risk of exposure to poliovirus and who have had at least one dose of OPV, fewer than three doses of conventional IPV or a combination of conventional IPV or OPV totaling fewer than three doses should receive at least one 0.5 mL dose of IMOVAX POLIO vaccine.
Additional doses needed to complete a primary series should be given if time permits.

Completely Vaccinated Adults
Adults who are at an increased risk of exposure to poliovirus and who have previously completed a primary series with one or a combination of polio vaccines can be given a 0.5 mL dose of IMOVAX POLIO vaccine.
The preferred injection site of IMOVAX POLIO vaccine for adults is in the deltoid area.

HOW SUPPLIED

0.5 ml of suspension for injection in a prefilled syringe (type I glass) with a plunger stopper (elastomer) – box of 1 or of 20.

0.5 ml of suspension for injection in a prefilled syringe (type I glass) with a plunger stopper (elastomer), a tip-cap (elastomer), and with 1 to 2 separate needles – box of 1.

5 ml (10 doses) of suspension for injection in a vial (type I glass) with a stopper (elastomer) – box of 1.

All pack sizes may not be marketed.

STORAGE

The vaccine is stable if stored in the refrigerator at 2°C to 8°C. The vaccine must not be frozen.

Protect from light.

The expiry date of the product is indicated on the packaging materials

Shelf life after opening

Syringe- use immediately after opening

Vial- 28 days when maintained between 2ºC-8 ºC

Manufacturing Authorisation holder: Sanofi Israel Ltd., Greenwork Park, P.O box 47, Yakum

Manufacturing Authorisation number: 054-07-22784-00

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