A.H.F.S. Category 80:12

Poliovirus Vaccine Inactivated

IPOL®

℞ only

Caution: Federal (USA) law prohibits dispensing without prescription.

DESCRIPTION

IPOL®, Poliovirus Vaccine Inactivated, produced by Aventis Pasteur SA, is a sterile suspension of three types of poliovirus: Type 1 (Mahoney), Type 2 (MEF-1), and Type 3 (Saukett). IPOL® is a highly purified, inactivated poliovirus vaccine produced by microcarrier culture.[1,2] This culture technique and improvements in purification, concentration and standardization of poliovirus antigen produce a more potent and consistent immunogenic vaccine than the IPV available in the US prior to 1988. 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, originated from countries free of bovine spongiform encephalopathy. For viral growth the culture medium is replaced by M-199, 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 titer, the monovalent viral suspensions are inactivated at + 37°C for at least 12 days with 1:4000 formalin.

Each sterile immunizing 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 IPOL®, D-antigen content is determined *in vitro* using the D-antigen ELISA assay and immunogenicity is determined by *in vivo* testing in animals. IPOL® 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 serum protein is less than 1 ppm in the final vaccine.

The vaccine is clear and colorless and should be administered intramuscularly or subcutaneously.

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.[3]

Prior to the introduction of conventional (non-enhanced) 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 its present 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).[4]

Poliovirus Vaccine Inactivated induces the production of neutralizing antibodies against each type of virus which are related to protective efficacy and induces antibody responses in most children after administering fewer doses[5] than the vaccine available in the United States prior to 1988.

Studies in developed[5] and developing[6,7] countries with a similar enhanced inactivated poliovirus vaccine produced by the same technology with the use of different cell substrate (primary kidney cells) have shown that 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.[8]

In the US, 219 infants received three doses of IPV at two, four and eighteen months of age manufactured by the same process as IPOL® except the cell substrate for IPV was 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.[9]

IPOL® 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.[10,11] 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 IPOL® depending on studies.

TABLE 1 US STUDIES WITH IPOL® ADMINISTERED USING IPV ONLY OR SEQUENTIAL IPV-OPV SCHEDULES

Age (months) for 2 Dose 1	4 Dose 2	6 Dose 3	12 to 18 Booster	Post Dose 2 N*	Type 1 %DA**	Type 2 %DA	Type 3 %DA	Post Dose 3 N*	Type 1 %DA	Type 2 %DA	Type 3 %DA	Pre Booster N*	Type 1 %DA	Type 2 %DA	Type 3 %DA	Post Booster N*	Type 1 %DA	Type 2 %DA	Type 3 %DA
STUDY 1[11¶]																			
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[10§]																			
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[10§]																			
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)
† NA – No poliovirus vaccine administered
¶ IPOL® given subcutaneously
§ IPOL® given intramuscularly
I IPOL® 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,[11] the persistence of DA in infants receiving two doses of IPOL® 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,[10] 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, IPOL®, or a combination vaccine containing IPOL® 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).[12]

In infants immunized with three doses of an unlicensed combination vaccine containing IPOL® 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 IPOL® combined with DTP vaccine.[8] 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.[13]

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.[12,14,15-21] There is also evidence of induction of herd immunity with IPV,[13,22-25] and that this herd immunity is sufficiently maintained in a population vaccinated only with IPV.[25]

Paralytic polio and VAPP have not been reported in association with administration of IPOL®. 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.[26]

INDICATIONS AND USAGE

IPOL® is indicated for active immunization of infants (as young as 6 weeks of age), children and adults for the prevention of poliomyelitis caused by poliovirus Types 1, 2, and 3.[27]

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.[28] Following the eradication of poliomyelitis caused by wild poliovirus from the Western Hemisphere (including North and South America)[29] VAPP is the only cause of paralytic poliomyelitis in the US.[30] The use of IPV has been suggested as a way to reduce VAPP incidence.[30]

All children should receive four doses of IPV at ages 2, 4, 6 to 18 months and 4 to 6 years. OPV is no longer recommended for routine immunization.[26] In the special circumstances that OPV is acceptable, please refer to the manufacturer's latest package insert for the appropriate administration schedule and all other issues related to the use of OPV.

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 IPOL®.

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
Routine primary poliovirus vaccination of adults (generally those 18 years of age or older) residing in the US is not recommended. Unimmunized adults residing in a household when a child is receiving OPV and/or adults who have increased risk of exposure to either oral vaccine or wild poliovirus and have not been adequately immunized should receive polio vaccination in accordance with the schedule given in the **DOSAGE AND ADMINISTRATION** section.[27]

Persons with previous wild poliovirus disease who are incompletely immunized or unimmunized should be given additional doses of IPOL® if they fall into one or more categories listed previously.

The following categories of adults are at an increased risk of exposure to wild polioviruses:[27,31]
- Travelers to regions or countries where poliomyelitis is endemic or epidemic.
- Health-care 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.
- Incompletely vaccinated or unvaccinated adults in a household (or other close contacts) with children given OPV. The adult should be informed of the risk of VAPP associated with contact of those receiving OPV.

IMMUNODEFICIENCY AND ALTERED IMMUNE STATUS
Patients with recognized immunodeficiency are at greater risk of developing paralysis when exposed to live poliovirus than persons with a normal immune system. Under no circumstances should oral poliovirus vaccine be used in such patients or introduced into a household where such a patient resides.[27]

IPOL® 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 IPOL® 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.[32]

As with any vaccine, vaccination with IPOL® may not protect 100% of susceptible individuals.

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

CONTRAINDICATIONS
IPOL® 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
This product contains dry natural latex rubber as follows: The stopper to the vial contains no rubber of any kind. In the case of the syringe, the needle cover contains dry natural latex rubber, but the plunger for the syringe contains no rubber of any kind.

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.[8] Local reactions are usually mild and transient in nature.

Although no causal relationship between IPOL® and Guillain-Barré Syndrome (GBS) has been established,[27] 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 side reactions. This includes a review of the patient's history with respect to possible sensitivity to the vaccine or similar vaccines and to possible sensitivity to dry natural latex rubber.

Health-care 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.

Health-care 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 IPOL® is not contraindicated in individuals infected with HIV.[33,34,35]

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

A separate, sterile syringe and needle or a sterile disposable unit must be used for each patient to prevent transmission of hepatitis or other infectious agents from person to person. Needles should not be recapped and should be disposed of according to biohazard waste guidelines.

INFORMATION FOR PATIENTS

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

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

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

The health-care provider should provide the Vaccine Information Materials (VIMs) which are required to be given with each immunization.

DRUG INTERACTIONS

There are no known interactions of IPOL® with drugs or foods. Simultaneous administration, with separate syringes at separate sites, of other parenteral vaccines is not contraindicated. The first two doses of IPOL® may be administered at separate sites using separate syringes concomitantly with DTP, 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 IPOL®, no interferences have been observed on the immunological end points accepted for clinical protection.[8,14,36] (See **DOSAGE AND ADMINISTRATION** section.)

If IPOL® 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

REPRODUCTIVE STUDIES – PREGNANCY CATEGORY C

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

NURSING MOTHERS

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

PEDIATRIC USE

SAFETY AND EFFECTIVENESS OF IPOL® IN INFANTS BELOW SIX WEEKS OF AGE HAVE NOT BEEN ESTABLISHED.[10,19] (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.[10,11]

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.[9] Erythema, induration and pain occurred in 3.2%, 1% and 13%, respectively, of vaccinees within 48 hours post-vaccination. Temperatures of ≥ 39°C (≥ 102°F) 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.[10] Although no causal relationship has been established, deaths have occurred in temporal association after vaccination of infants with IPV.[37]

Four additional US studies using IPOL® in more than 1,300 infants,[10] 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[10] PERCENTAGE OF INFANTS PRESENTING WITH LOCAL OR SYSTEMIC REACTIONS AT 6, 24, AND 48 HOURS OF IMMUNIZATION WITH IPOL® ADMINISTERED INTRAMUSCULARLY CONCOMITANTLY AT SEPARATE SITES WITH AvP¶ WHOLE-CELL DTP VACCINE AT 2 AND 4 MONTHS OF AGE AND WITH AvP ACELLULAR PERTUSSIS VACCINE (TRIPEDIA®) AT 18 MONTHS OF AGE

REACTION	AGE AT IMMUNIZATION								
	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, IPOL® 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.								

¶ AvP (Aventis Pasteur Inc.) formerly known as Connaught Laboratories, Inc.
§ Data are from the IPOL® administration site, given intramuscularly.
* The adverse reaction profile includes the concomitant use of AvP whole-cell DTP vaccine or Tripedia® with IPOL®. Rates are comparable in frequency and severity to that reported for whole-cell DTP given alone.
† Children vaccinated with Tripedia® vaccine.

DIGESTIVE SYSTEM
Anorexia and vomiting occurred with frequencies not significantly different as reported when DTP was given alone without IPV or OPV.[10]

NERVOUS SYSTEM
Although no causal relationship between IPOL® and GBS has been established,[27] GBS has been temporally related to administration of another inactivated poliovirus vaccine.

Reporting of Adverse Events
The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act of 1986, requires physicians and other health-care providers who administer vaccines to maintain permanent vaccination records and to report occurrences of certain adverse events to the US Department of Health and Human Services. Reportable events include those listed in the Act for each vaccine and events specified in the package insert as contraindications to further doses of that vaccine.[38,39,40]

Reporting by parents or guardians of all adverse events after vaccine administration should be encouraged. Adverse events following immunization with vaccine should be reported by health-care providers to the US Department of Health and Human Services (DHHS) Vaccine Adverse Event Reporting System (VAERS). Reporting forms and information about reporting requirements or completion of the form can be obtained from VAERS through a toll-free number 1-800-822-7967.[38,39,40]

Health-care providers also should report these events to the Director of Scientific and Medical Affairs, Aventis Pasteur Inc., Discovery Drive, Swiftwater, PA 18370 or call 1-800-822-2463.

DOSAGE AND ADMINISTRATION
Parenteral drug products should be inspected visually for particulate matter and/or discoloration prior to administration whenever solution and container permit. If these conditions exist, the vaccine should not be administered.

After preparation of the injection site, immediately administer IPOL® intramuscularly or subcutaneously. In infants and small children, the mid-lateral aspect of the thigh is the preferred site. In older children and adults IPOL® should be administered intramuscularly or subcutaneously in the deltoid area.

Care should be taken to avoid administering the injection into or near blood vessels and nerves. After aspiration, 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 IPOL® 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. For this series, a booster dose of IPOL® is administered at 4 to 6 years of age.[41]

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 IPOL®, no interferences have been observed on the immunological end points accepted for clinical protection.[8,14,36] (See DRUG INTERACTIONS section.) If the third dose of IPOL® is given between 12 to 18 months of age, it may be desirable to administer this dose with Measles, Mumps, and Rubella (MMR) and/or other vaccines using separate syringes at separate sites,[27] but no data on the immunological interference between IPOL® and these vaccines exist.

Use in Previously Vaccinated Children
Children and adolescents with a previously incomplete series of IPOL®/OPV or IPOL® only should receive sufficient additional doses of IPOL® to complete the series. OPV is no longer recommended for routine immunization and is recommended only in special circumstances[26] (see **General Recommendations** section).

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

The need to routinely administer additional doses is unknown at this time.[27]

Adults
Unvaccinated Adults
A primary series of IPOL® 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 doses given at a 1 to 2 month interval and a third 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 IPOL® should be given at least 1 month apart. Likewise, if only 1 or 2 months are available, two doses of IPOL® should be given at least 1 month apart. If less than 1 month is available, a single dose of IPOL® is recommended.[27]

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 dose of IPOL®. Additional doses needed to complete a primary series should be given if time permits.[27]

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 dose of IPOL®.

The preferred injection site of IPOL® for adults is in the tissue of the deltoid area.

HOW SUPPLIED
Syringe, 0.5 mL with integrated needle (1 x 1 Dose package – Product No. 49281-860-51) (10 x 1 Dose package Product No. 49281-860-52)

Vial, 10 Dose – Product No. 49281-860-10

STORAGE
The vaccine is stable if stored in the refrigerator between 2°C and 8°C (35°F and 46°F). The vaccine must not be frozen.

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