Poliovirus Vaccine Inactivated  
Rx Only

IPOL

AHFS Category: 80.12  
IPV  
Rx only

DESCRIPTION

IPOL®, Poliovirus Vaccine Inactivated, produced by Sanofi Pasteur SA, is a sterile suspension of three types of poliovirus: Type 1 (Mahoney), Type 2 (MEF-1), and Type 3 (Saukett). IPOL 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. (1) (2) 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. (3) (4)

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 deactivation by B-irradiation 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 IPV vaccine, D-antigen content is determined in vitro using the D-antigen ELISA assay. IPV vaccine is produced from vaccine concentrates diluted with M-199 medium. Also present are 0.5% of 2-phenoxyethanol and 0.5% of polymyxin B are used in vaccine production; and, although purification procedures eliminate serum tested for adventitious agents prior to use, originated from countries free of bovine spongiform encephalopathy.

CLINICAL PHARMACOLOGY

Polioviruses are 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.

Table 1: US Studies with IPOL Vaccine Administered Using IPV only or Sequential IPV-OPV Schedules

<table>
<thead>
<tr>
<th>Age (months) for</th>
<th>Post Dose 2</th>
<th>Post Dose 3</th>
<th>Pre Booster</th>
<th>Post Booster</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type 1</td>
<td>Type 2</td>
<td>Type 3</td>
<td>Type 1</td>
</tr>
<tr>
<td></td>
<td>%DA</td>
<td>%DA</td>
<td>%DA</td>
<td>%DA</td>
</tr>
<tr>
<td>STUDY 1 (11)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I(s) I(s) NA I(s)</td>
<td>56</td>
<td>97</td>
<td>100</td>
<td>97</td>
</tr>
<tr>
<td>O O NA O</td>
<td>22</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>I(s) O NA O</td>
<td>17</td>
<td>95</td>
<td>100</td>
<td>95</td>
</tr>
<tr>
<td>I(s) I(s) NA I(s)</td>
<td>17</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>STUDY 2 (10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I(c) I(c) NA I(s)</td>
<td>94</td>
<td>98</td>
<td>97</td>
<td>96</td>
</tr>
<tr>
<td>I(c) I(c) NA I(s)</td>
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<td>99</td>
<td>100</td>
<td>99</td>
</tr>
<tr>
<td>I(c) I(c) NA I(s)</td>
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<td>95</td>
<td>99</td>
<td>96</td>
</tr>
<tr>
<td>I(c) I(c) NA I(s)</td>
<td>101</td>
<td>99</td>
<td>99</td>
<td>95</td>
</tr>
<tr>
<td>STUDY 3 (10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I(c) I(c) I(c) O</td>
<td>91</td>
<td>98</td>
<td>99</td>
<td>100</td>
</tr>
<tr>
<td>I(c) I(c) I(c) O</td>
<td>96</td>
<td>100</td>
<td>98</td>
<td>99</td>
</tr>
<tr>
<td>I(c) I(c) I(c) O</td>
<td>91</td>
<td>96</td>
<td>97</td>
<td>100</td>
</tr>
</tbody>
</table>

1 IPOL vaccine given either separately in association with DTP in two sites (s) or combined (c) with DTP in a dual chambered syringe  
O OPV  
* N = number of children from whom serum was available  
† Detectable antibody (neutralizing titer ≥1:4)  
‡ IPOL vaccine given subcutaneously  
§ NA – No poliovirus vaccine administered  
¶ IPOL vaccine given intramuscularly

In one study, (13) the persistence of DA in infants receiving two doses of IPOL 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, (12) 66% 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 vaccine, or a combination vaccine containing IPV vaccine and DTP, was administered to more than 3,000 infants between 2 to 18 months of age using IPV only schedules and immunogenic 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), 95% 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). (14)

In infants immunized with three doses of an unlicensed combination vaccine containing IPV 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 IPV vaccine combined with DTP vaccine. (11) 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. (15)

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 1:8. (4) (14) (16) (17) (18) (19) (20) (21) (22) There is also evidence of induction of herd immunity with IPV, (15) (23) (24) (25) (26) and that this herd immunity is sufficiently maintained in a population vaccinated only with IPV. (26) VAPP has not been reported in association with administration of IPV vaccine. (27)

It is expected that IPV developed will eliminate the risk of VAPP in both recipients and contacts compared to a schedule that included OPV. (7)

INDICATIONS AND USAGE

IPOL vaccine 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. (28)
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. (29) Following the eradication of poliomyelitis caused by wild poliovirus from the Western Hemisphere (including North and South America) (30), an IPV-only schedule was recommended to eliminate VAPP. (7)

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 available in the US and is not recommended for routine immunization. (7) Previous clinical studies with poliovirus vaccines usually due to only a single poliovirus type) or incomplete immunization with OPV are not contraindications to completing the primary series of immunization with IPV 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
Routine primary poliovirus vaccination of adults (generally those 18 years of age or older) residing in the US is not recommended. 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. (28)

Persons with previous wild poliovirus disease who are incompletely immunized or unimmunized should be given additional doses of IPV 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: (28) (31)

- Travelers to regions or countries where poliomyelitis is endemic or epidemic.
- Healthcare workers in close contact with patients who may be excreting poliomyelitis.
- Laboratory workers handling specimens that may contain poliomyelitis.

- Members of communities or specific population groups with disease caused by wild poliomyelitis.

IMMUNODEFICIENCY AND ALTERED IMMUNE STATUS

IPOL 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 IPV vaccine in individuals receiving immunoglobulin could be impaired, and patients with an altered immune status may or may not develop a protective response against paralytic poliomyelitis after administration of IPV. (32)

As with any vaccine, vaccination with IPV vaccine will not protect 100% of individuals. Use with other vaccines: refer to DOSAGE AND ADMINISTRATION section for this information.

CONTRAINdications

IPOL 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 vaccination 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. (28)

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. (11) Local reactions are usually mild and transient in nature. Although no causal relationship between IPV vaccine and Guillain-Barré Syndrome (GBS) has been established, (28) 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.

Ephedrine injection (1:1000) and other appropriate agents should be available to control immediate 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 response against paralytic poliomyelitis. (32) Healthcare providers 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.

ADVERSE REACTIONS

There are no known interactions of IPV 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 IPV 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, and hepatitis B vaccines used concomitantly or in combination with IPV vaccine, no interferences have been observed on the immunological end points accepted for clinical protection. (11) (36) (See DOSAGE AND ADMINISTRATION section.)

If IPV vaccine has been administered to persons receiving immunosuppressive therapy, an adequate intercurrent regimens may be present (see PRECAUTIONS – GENERAL section).

The following adverse events have been identified during postapproval use of IPV 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: aggregation, 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 convolution, headache, paresthesia, somnolence, syncope
• Skin and subcutaneous tissue disorders: rash, urticaria

Reporting of Adverse Events

The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act of 1986, requires physicians and other healthcare 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. (39) (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 healthcare providers to the US Department of Health and Human Services (DHHS) Vaccine Adverse Event Reporting System (VAERS). Report 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)

REFERENCES

11 Unpublished data available from Sanofi Pasteur SA.
12 Unpublished data available from Sanofi Pasteur Inc.

Product Information as of May 2022

Manufactured by:
Sanofi Pasteur Inc.
Marcy L’Etoile France
US Govt License #1724