IPOL

Inactivated Poliomyelitis Vaccine (VERO)

Description

IPOL (inactivated poliomyelitis vaccine), produced by Sanofi Pasteur S.A., is a clear, colourless sterile suspension of three strains of poliovirus: Type 1 (Mahoney), Type 2 (MEF-I) and Type 3 (Saukett). The viruses are grown in cultures of VERO cells, a continuous line of monkey kidney cells, by the microcarrier technique. The viruses are concentrated, purified and made non infectious by inactivation with formaldehyde.

Each sterile 0.5mL immunising dose of trivalent vaccine is formulated to contain:

Active substance:

Inactivated Polio virus type 1 (Mahoney)		40D antigen units
Inactivated Polio virus type 2 (MEF-1)		8D antigen units
Inactivated Polio virus type 3 (Saukett)		32D antigen units

Excipients:

2-phenoxyethanol[1]		2 – 3 microlitres
Formaldehyde		2 – 20 mcg
Medium 199[2]	up to	0.5 mL

[1]2-phenoxyethanol contained in a solution of 2-phenoxyethanol at 50% in ethanol.

[2]Medium 199 Hanks (without phenol red) is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins and other components (including glucose), supplemented with polysorbate 80, diluted in water for injections. Hydrochloric acid or sodium hydroxide is added for pH adjustment.

Traces of neomycin, streptomycin and polymyxin B used in vaccine production may be present. Trace amounts of bovine serum albumin may also be present.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Pharmacology

IPOL is a highly purified inactivated poliovirus vaccine produced by microcarrier culture. In 4 studies of primary infant vaccination with a two dose schedule of Inactivated Poliomyelitis Vaccine (IPV), 409 of a total of 419 infants had protective levels of serum antibody to all three of the poliovirus types after completion of the schedule. Mucosal response, measured by IgA in stool and saliva was significantly lower with IPV than with Oral Poliomyelitis Vaccine (OPV).

Data on antibody persistence are limited and so the optimal time for boosters, upon completion of the primary course, has not been established.

Indications

IPOL is indicated for active immunisation of infants, children and adults for the prevention of poliomyelitis. Recommendations for the use of live and inactivated poliovirus vaccines are described in the national immunisation guidelines.

1. **General Recommendations.** It is recommended that all infants, unimmunised children and adolescents not previously immunised be vaccinated routinely against paralytic poliomyelitis. ***IPOL should be offered to patients who have refused OPV, or in whom OPV is contraindicated.***

2. **IPOL is also indicated for:**

    - The primary vaccination of immunocompromised individuals of all ages (see PRECAUTIONS), and household contacts of such individuals (when vaccination is indicated)
    - unvaccinated or inadequately vaccinated (*) adults, particularly if at increased risk of exposure to live poliovirus, including:
        - Travellers to areas or countries where poliomyelitis is epidemic or endemic;
        - Laboratory workers handling specimens which may contain polioviruses;
        - Health care workers in close contact with patients who may be excreting polioviruses.

    (*) Such as those who had not completed a primary series of vaccination or not received a booster dose since infancy.

Contraindications

- Known systemic hypersensitivity to any component of IPOL or serious reaction after previous administration of the vaccine or vaccine containing the same substances.

- Vaccination should be postponed in cases of febrile or acute disease.

Precautions

As each dose may contain undetectable traces of neomycin, streptomycin and polymixin 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).

As each dose contains 2-phenoxyethanol, formaldehyde and polysorbate 80, caution should be exercised when the vaccine is administered to subjects with hypersensitivity to these products.

As with other injectable vaccines, appropriate medical treatment and supervision should always be available in case of anaphylactic reactions. Adrenaline (1:1000) and other appropriate agents should be available for immediate use in case of an anaphylactic or sudden sensitivity reaction.

The immunogenicity of IPOL could be reduced by immunosuppressive treatment or immunodeficiency. In such cases it is recommended to postpone the vaccination until the end of the treatment or disease. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response might be limited.

Do not administer by intravascular injection: ensure that the needle does not penetrate a blood vessel.

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

Interaction with other medicines.

There are no known interactions of IPOL with drugs or foods. Simultaneous administration of other parenteral vaccines is not contraindicated.

Different syringes and separate injection sites must be used in case of concomitant administration.

Use in Pregnancy. (Category B2).

Animal reproduction studies have not been conducted with IPOL. IPOL should be given to pregnant women only if clearly needed. There is no convincing evidence of risk to the foetus from immunisation of pregnant women using inactivated virus vaccines.

Adverse Reactions

Clinical Trial Experience

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

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

In a multicentre, randomized, phase III study involving 205 children, cases of fever >38.1°C were reported (in 10% of children after the first dose, in 18% after the second dose and in 7% after the third dose).

In another multicentre randomized phase III study involving 324 children, it was concluded that IPOL combined or associated with DTP vaccines was as well tolerated as DTP vaccine alone.

In primary immunisation of infants (2 to 12 months) most studies investigated the safety of IPV (IPOL) with combined vaccines, especially with DTPa. Systemic safety assessment of these studies showed that irritability is the most frequent (13.6 to 37.1%); drowsiness (1.5 to 23%) second most frequent; diarrhoea (2.1 to 9.4%); vomiting (0.7 to 7.6%) and fever over 39°C (0.5 to 3.0%).

Clinical trials supporting the use of IPV as a booster in toddlers showed that cases of fever > 38.1°C range from 12 to 29% and fever over 39°C range from 2.7 to 5.2% and irritability is the second most frequent event.

Data from Post-Marketing Surveillance

These frequencies are based on spontaneous reporting rates and have been calculated using number of reports and estimated number of vaccinated patients. Adverse events are very rarely reported (<0.01%) during post-marketing surveillance. However, the exact frequency cannot be precisely calculated.

IPOL is rarely injected alone in childhood immunisation schedules.

The most frequently reported adverse events are local reactions and fever (respectively around 20% to 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 oedema, 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%)
    - Reaction of type I hypersensitivity to one component of the vaccine such as allergic reaction, anaphylactic reaction or anaphylactic shock.

Musculoskeletal and Connective Tissue Disorders:

- Very Rare (<0.01%)
    - Mild and transitory arthralgia and myalgia within a few days after the vaccination.

Nervous System Disorders:

- Very Rare (<0.01%)
    - Short-lasting convulsions, fever 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

Although no causal relationship between IPOL and Guillain-Barre Syndrome (GBS) has been established, GBS has been temporally related to administration of another IPV.

Dosage and Administration

IPOL is for subcutaneous injection only. Do not administer intravenously. Do not administer orally and do not mix with any other preparation in the same syringe.

After preparation of the injection site, immediately administer the vaccine subcutaneously. In infants and small children, the mid-lateral aspect of the thigh is the preferred site. In adults the vaccine should be administered in the deltoid or triceps region.

Primary Immunisation: (see INDICATIONS). Three doses of 0.5 mL each should be administered subcutaneously at intervals of eight weeks.

In infancy the primary schedule is usually integrated with DTPa (Diphtheria and Tetanus Toxoids and Pertussis Vaccine) immunisation, beginning at 6 to 8 weeks of age.

Booster doses: (see INDICATIONS). All children who have received the initial three doses in infancy should be given a booster dose of 0.5 mL IPOL at 4 years of age.

Adults: (see INDICATIONS). Adults at risk of exposure (see INDICATIONS) who are unvaccinated should receive a primary series of IPOL as outlined above; those with incomplete primary immunisation should receive the remaining doses of the primary series, regardless of the interval since the last dose: those who have previously completed a primary series of poliomyelitis vaccine should receive a single booster dose of 0.5 mL. For those exposed to a continuing risk of infection, a single booster dose is desirable every 10 years.

A primary series of injections of IPOL may be preferred to oral vaccination because of the very slight possibility of vaccine associated polio in adult vaccinees.

For full details regarding recommended immunisation schedule for poliomyelitis vaccines, refer to the Australian Immunisation Handbook of NH&MRC in Australia or the New Zealand Ministry of Health Immunisation Handbook in New Zealand .

Presentation

IPOL is available in a single dose package containing one 0.5 mL syringe.

Storage Conditions

Store at 2°-8°C. Refrigerate. Do not freeze.

Medicine Classification

Prescription Medicine

Name and Address

Manufacturer

Sanofi Pasteur SA
Lyon, France

Distributor

Australia:
Sanofi Pasteur Pty Ltd
ABN 79 085 258 797
Talavera Corporate Centre – Building D
12 – 24 Talavera Road
Macquarie Park NSW 2113
Australia
Tel: 1800 829 468

New Zealand:
sanofi-aventis new zealand limited
Level 8, James & Wells Tower
56 Cawley St
Ellerslie
Auckland
New Zealand
Tel: 0800 727 838

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