

# IPOL

## *Inactivated Poliomyelitis Vaccine (VERO)*

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### Description

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IPOL (inactivated poliomyelitis vaccine), produced by Aventis Pasteur S.A., is a sterile suspension of three strains of poliovirus: Type 1 (Mahoney), Type 2 (MEF1) 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 immunising dose (0.5 mL) of trivalent vaccine is formulated to contain 40D antigen units of type 1, 8D antigen units of type 2 and 32D antigen units of type 3 poliovirus. A maximum of 20 mcg of formaldehyde per dose is present as preservative. Traces of neomycin, streptomycin and polymyxin B used in vaccine production may be present. Trace amounts of bovine serum albumin may also be present. Phenoxyethanol and Medium 199 reconstituted with water for injections are also present. The vaccine is a clear colourless solution and should be administered as a subcutaneous injection.

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### Pharmacology

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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.

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### Indications

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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 NH&MRC's Immunisation Procedures book.

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;

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- 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.

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### Contraindications

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IPOL is contraindicated in persons with a history of hypersensitivity to any component of the vaccine, including neomycin, streptomycin and polymyxin B.

If anaphylaxis or anaphylactic shock occurs within 24 hours of administration of a dose of vaccine, no further doses should be given.

Vaccination should be postponed in persons with any significant acute febrile illness, including respiratory infections, acute disease or unstable chronic disease.

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### Precautions

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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.

IPV should be used in all patients with immunodeficiency diseases and members of such patients' households when vaccination of such persons is indicated. Patients with immune deficiency diseases, such as HIV infection, combined immunodeficiency, hypogammaglobulinaemia and agammaglobulinaemia, and those with altered immune states due to diseases such as leukaemia, lymphoma or generalised malignancy or with immune systems compromised by therapy with corticosteroids, alkylating drugs, antimetabolites or radiation may or may not develop a protective immune response after administration of IPV.

#### ***Drug Interactions.***

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

#### ***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.

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### Adverse Reactions

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Transient local reactions at the site of injection have been observed during clinical trials. Erythema, induration and pain occurred in 3.2%, 1% and 13%, respectively, of vaccinees within 48 hours post vaccination. Oedema has also been reported. Temperatures of  $\geq 39^{\circ}\text{C}$  ( $\geq 102^{\circ}\text{F}$ ) were reported in 38% of vaccinees. Fever may be isolated or associated with myalgia, headache or lymphadenopathy. Rash or urticaria were reported rarely. Other symptoms included irritability, sleepiness, fussiness, and crying.

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As most of the children in the clinical trials received DTP at the same time as IPV (but at a separate site), it was not possible to attribute reactions to a particular vaccine; however, the reactions observed were not significantly different to when DTP is given alone.

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

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### Dosage and Administration

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IPOL is for subcutaneous or intramuscular 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, followed by a fourth dose of 0.5 mL approximately 12 months after the third dose.

In infancy the primary schedule is usually integrated with DPT (Diphtheria and Tetanus Toxoids and Pertussis Vaccine) immunisation, beginning at 8 to 12 weeks of age.

**Booster doses:** (see INDICATIONS). All children who have received the initial four doses in infancy and in early childhood should be given a booster dose of 0.5 mL IPOL before entering school.

**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.

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.

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### Presentation

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IPOL is available in a single dose package containing one 0.5 mL syringe or in packs containing ten single dose syringes.

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### Storage Conditions

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

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### Medicine Classification

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Prescription Medicine

## **Name and Address**

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### *Manufacturer*

**Sanofi Pasteur SA**  
Lyon, France

### *Distributor*

Australia:  
**Sanofi Pasteur Pty Ltd**  
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## **Date of Preparation**

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1 November 2007