NEW ZEALAND DATA SHEET

1 IPOL (0.5 ML SUSPENSION FOR INJECTION)

IPOL Inactivated Poliomyelitis Vaccine (VERO), poliovirus, 0.5mL suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

IPOL (inactivated poliomyelitis vaccine), 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:

Poliovirus type 1 (Mahoney)……. 40 DAgU
Poliovirus type 2 (MEF-1) …….……8 DAgU
Poliovirus type 3 (Saukett)…….……32 DAgU

Contains phenylalanine.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Suspension for Injection

IPOL is a clear, colourless sterile suspension.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC 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 Section 4.4 Special warnings and precautions for use), 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.

4.2 DOSE AND METHOD OF ADMINISTRATION

Dose

Primary immunisation: (see Section 4.1 Therapeutic 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 Section 4.1 Therapeutic 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 Section 4.1 Therapeutic indications). Adults at risk of exposure (see Section 4.1 Therapeutic 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 current Immunisation Handbook.

Method of 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.

4.3 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.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

As each dose may contain undetectable traces of neomycin, streptomycin sulfate and polymixin B sulfate 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 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 (epinephrine) (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.

The potential risk of apnoea and the need for respiratory monitoring for 48-72 h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

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.

Syncope can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent falling and injury and to manage syncope.

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

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.

4.6 FERTILITY, PREGNANCY AND LACTATION

Use in Pregnancy (Category B2)

There is not enough data on the use of this vaccine in pregnant woman. Animal studies are insufficient with respect to effects on pregnancy and embryo/foetal development, parturition and postnatal development. The potential risk is unknown. IPOL may be given to pregnant women only if clearly needed.

Use in lactation

Breast-feeding is not a contraindication.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No studies on the effects on the ability to drive and use machines have been performed.

4.8 UNDESIRABLE EFFECTS

Adverse events presented in this section are listed using MedDRA terminology (system organ classes and terms). Within each system organ class, the adverse events are ranked under headings of frequency (most frequent reactions first), using the following convention:

Very common: ≥ 10%
Common: ≥ 1% and < 10%
Uncommon: ≥ 0.1% and < 1%
Rare: ≥ 0.01% and < 0.1%
Very rare: < 0.01 %
Not known: cannot be estimated from the available data

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.

Post-Marketing Surveillance

Based on spontaneous reporting, the following adverse events have also been reported after commercial use. These events have been very rarely reported, however exact incidence rates cannot be calculated precisely, their frequency is qualified as “Not known".

IPOL safety profile does not differ significantly between the different age classes taking into account relative reporting rates and the fact that some adverse events are specific to an age class (such as convulsion in infants and children or myalgia/arthralgia in adolescents and adults). In addition, IPOL is rarely administered alone. The frequencies cannot be estimated with certainty from the available data.

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:

- Lymphadenopathy

General Disorders and Administration Site Conditions:

- 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:

- 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:

- Mild and transitory arthralgia and myalgia within a few days after the vaccination

Nervous System Disorders:

- 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:

- Within the first hours or days following the vaccination and shortly resolving:
  - Agitation
  - Somnolence
  - Irritability

Skin and Subcutaneous Tissue Disorders:

- 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 Inactivated Poliomyelitis Vaccine (IPV).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions at https://nzphvc.otago.ac.nz/reporting/.

4.9 OVERDOSE

No case of overdose has been reported.

For information on the management of overdose, contact the National Poisons Centre, 0800 POISON or 0800 764 766.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Viral vaccines, ATC code: J07BF03

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.

5.2 PHARMACOKINETIC PROPERTIES

No pharmacokinetic studies have been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Excipients:

Phenoxyethanol[1]
Formaldehyde
Medium 199 (Hanks)[2]

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

[2]Medium 199 (Hanks) 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 sulfate and polymyxin B sulfate 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.

6.2 INCOMPATIBILITIES

This vaccine must not be mixed with other vaccine or medicinal products.

6.3 SHELF LIFE

36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

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

6.5 NATURE AND CONTENTS OF CONTAINER

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

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644
Freecall: 0800 283 684
Email: medinfo.australia@sanofi.com

9 DATE OF FIRST APPROVAL

17 July 1997

10 DATE OF REVISION OF THE TEXT

20 June 2022

SUMMARY OF CHANGES

Section changed	Summary of new information
4.8	Removal of Australian information
4.9	Removal of Australian information
8	Change of sponsor