NAME OF THE MEDICINAL PRODUCT

IMOVAX POLIO, suspension for injection in prefilled syringe

Poliomyelitis vaccine (inactivated)

QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.5 mL) contains:

Poliomyelitis virus (inactivated)

Type 1 (Mahoney strain)#.....40 DU*+

Type 2 (MEF-1 strain)#.....8 DU*+

Type 3 (Saukett strain)# .....32 DU*+

This vaccine complies with European Pharmacopoeia requirements and WHO recommendations.

produced on VERO cells

* DU: D-antigen unit

+ or equivalent antigenic quantity determined by a suitable immunochemical method.

IMOVAX POLIO may contain traces of neomycin, streptomycin and polymyxin B (see section Contraindications).

Excipients with known effect:

Phenylalanine……12.5 micrograms

Ethanol……2 milligrams

(See section Special warnings and precautions for use).

For the full list of excipients, see section List of excipients.

PHARMACEUTICAL FORM

Suspension for injection in prefilled syringe.

IMOVAX POLIO is a clear and colourless suspension.

CLINICAL PARTICULARS

Therapeutic indications

This vaccine is indicated for the prevention of poliomyelitis in infants, children and adults, for primary and booster vaccination.

IMOVAX POLIO must be used according to effective official recommendations.

Posology and method of administration

Posology

- From the age of 2 months, 3 successive doses of 0.5 mL of IMOVAX POLIO should be administered at intervals of one or two months, followed by a first booster 12 months after the last dose.
- *For subsequent boosters, an injection is given every 5 years in children and adolescents and every 10 years in adults.*
- In countries where a live Oral Poliomyelitis vaccine (trivalent, bivalent or monovalent OPV) is used in the routine immunisation programme, IMOVAX POLIO may be used in association (co-administration) or in sequential use with OPV, in accordance with WHO recommendations and in agreement with the national recommendations in effect.

Method of administration

Administration is performed preferably via the intramuscular (IM) route, or via the subcutaneous (SC) route.

Intramuscular injection will be preferably performed in the antero-lateral side of the thigh in young children and in the deltoid muscle in children, adolescents and adults.

For instructions on use, handling and disposal, see section Special precautions for disposal and other handling.

Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1, or to any vaccine containing the same substances, to neomycin, streptomycin or polymyxin B.

Common transient contraindications to any vaccination: in case of fever or acute illness, it is best to postpone vaccination.

Special warnings and precautions for use

Traceability:

In order to improve the traceability of biological products, the name and batch number of the administered product should be clearly recorded.

Do not inject via the intravascular route: make sure the needle does not penetrate a blood vessel.

As with all injectable vaccines, IMOVAX POLIO must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

As with all injectable vaccines, appropriate medical treatment must be readily available and close supervision provided should a rare anaphylactic reaction occur following administration of the vaccine.

Immunosuppressive treatment or an immunodeficiency condition may induce a reduced immune response to the vaccine. It is then recommended to wait until the end of the treatment before vaccinating or to make sure that the subject is well protected. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the immune response may be limited.

IMOVAX POLIO may also be recommended for subjects in whom the oral vaccine is contraindicated, and as a booster for subjects previously vaccinated with the oral vaccine.

The potential risk of apnoea and the need for respiratory monitoring for 48-72h 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.

IMOVAX POLIO contains phenylalanine, ethanol and sodium.

IMOVAX POLIO contains 12.5 micrograms of phenylalanine in each dose of 0.5 mL. Phenylalanine may be dangerous for patients with phenylketonuria (PKU), a rare genetic disorder characterised by the accumulation of phenylalanine that cannot be correctly eliminated.

IMOVAX POLIO contains 2 mg alcohol (ethanol) in a dose of 0.5 mL. The low quantity of alcohol contained in this medicinal product is unlikely to cause a notable effect.

IMOVAX POLIO contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially "sodium-free".

Interaction with other medicinal products and other forms of interaction

There are no known risks of administering IMOVAX POLIO with other usual vaccines during the same vaccination session. In case of concomitant administration, different syringes and separate injection sites should be used.

Fertility, pregnancy and lactation

Pregnancy

Given clinical data, this vaccine may be prescribed during pregnancy in high risk situations.

Breastfeeding

This vaccine can be used during breastfeeding.

Fertility

No fertility studies were performed.

Effects on ability to drive and use machines

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

Undesirable effects

The adverse events are ranked according to the MedDRA terminology (by System Organ Class) and under headings of frequency 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.

Based on spontaneous reporting, certain undesirable events were very rarely reported following the use of IMOVAX POLIO. Because events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. This is why these undesirable events are ranked under the “Not known” frequency.

The events listed below were observed during clinical studies or were spontaneously reported after marketing.

The most common adverse events following administration of this vaccine are local injection-site reactions (pain, redness, induration) and fever over 38.1°C.

Immune system disorders
Not known: type I hypersensitivity reaction to one of the components of the vaccine, such as urticaria, angioedema, anaphylactic reaction or anaphylactic shock.

Psychiatric disorders
Not known: agitation, somnolence and irritability in the first hour or days following vaccination and disappearing rapidly.

Nervous system disorders
Not known: convulsions (isolated or associated with fever) in the days following vaccination, headache, moderate and transient paraesthesia (mainly in the lower limbs) in the two weeks following vaccination.

Skin and subcutaneous tissue disorders
Not known: rash.

Musculoskeletal and connective tissue disorders
Not known: mild and transitory arthralgia, and myalgia have been reported in the days following vaccination.

General disorders and administration site conditions
Very common: injection-site pain, fever over 38.1°C.

Common: injection-site redness.

Uncommon: injection-site induration.

Not known: lymphadenopathy, local injection-site reactions such as oedema that can occur in the 48 hours following vaccination and lasting one or two days.

Complementary information concerning particular populations

Apnoea in very premature infants (born ≤ 28 weeks of gestation) (see section Special warnings and precautions for use).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system

Overdose

Not applicable.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Vaccine against poliomyelitis, ATC code: J07BF03.

The vaccine is prepared from poliovirus types 1, 2 and 3 cultured on Vero cells, purified and inactivated by formaldehyde.

One month after primary vaccination starting at 2 months of age and using 3 doses of Imovax Polio 1 to 2 months apart, seroprotection rates were 99% to 100% for types 1 and 3 polioviruses, and 97% to 100% for type 2 poliovirus.

For infants, the booster dose (4th dose) led to a large increase in titres with seroprotection rates of 97.5% to 100% for the three types of polioviruses.

Children primed with IPV during infancy and boosted in the second year of life maintain high levels (≥ 80%) of seroprotective antibodies at 4–6 years of age, and produce a strong anamnestic response (97-100% seroprotection) following a second IPV booster.

In primed adults, a booster injection is followed by an anamnestic response.

For the most part, these data comes from studies done with combined vaccines containing poliomyelitis vaccine.

Immunity lasts for at least 5 years after the 4th injection.

Pharmacokinetic properties

Not applicable.

Preclinical safety data

Non-clinical data revealed no special hazard for humans based on conventional acute toxicity, repeat dose toxicity and local tolerance studies.

PHARMACEUTICAL PARTICULARS

List of excipients

2-phenoxyethanol, ethanol, formaldehyde, medium 199 Hanks, hydrochloric acid or sodium hydroxide for pH adjustment.

The 2-phenoxyethanol is contained in a solution of 2-phenoxyethanol at 50% in ethanol.

The medium 199 Hanks (without phenol red) is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins, and other components (such as glucose), supplemented with polysorbate 80 and diluted in water for injections.

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Special precautions for storage

Store in a refrigerator (2°C - 8°C) in order to protect from light. Do not freeze.

Nature and contents of container

0.5 mL of suspension for injection in a prefilled syringe (type I glass) with a plunger stopper (bromobutyl or chlorobutyl or chlorobromobutyl) – box of 1 or of 20.

0.5 mL of suspension for injection in a prefilled syringe (type I glass) with a plunger stopper (bromobutyl or chlorobutyl or chlorobromobutyl), a tip-cap and with 1 to 2 separate needles – box of 1.

Not all pack sizes may be marketed.

Special precautions for disposal and other handling

Verify that the vaccine is clear and colourless. Do not use the vaccine if it has a cloudy appearance.

For syringes without attached needles, the needle must be fitted firmly to the syringe, rotating it by a one quarter turn.

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

MARKETING AUTHORISATION HOLDER

SANOFI-AVENTIS SINGAPORE PTE LTD,

38 BEACH ROAD #18-11,

SOUTH BEACH TOWER,

SINGAPORE 189767.

DATE OF REVISION OF THE TEXT

Mar 2023