

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

IMOVAX POLIO, suspension for injection in multidose vial
Poliomyelitis vaccine (inactivated)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.5 mL) contains:

Poliomyelitis virus (inactivated)

Type 1 (Mahoney strain)# 29 DU**

Type 2 (MEF-1 strain)# 7 DU**

Type 3 (Saukett strain)# 26 DU**

This vaccine complies with the specifications of the European Pharmacopoeia and the recommendations of the WHO.

Cultivated on VERO cells

* DU: D-antigen unit

+ These antigen quantities are strictly the same as those previously expressed as 40-8-32 D-antigen units, for type 1, 2, and 3 viruses respectively, when measured by another suitable immunochemical method.

IMOVAX POLIO may contain traces of neomycin, streptomycin and polymyxin B (see section 4.3).

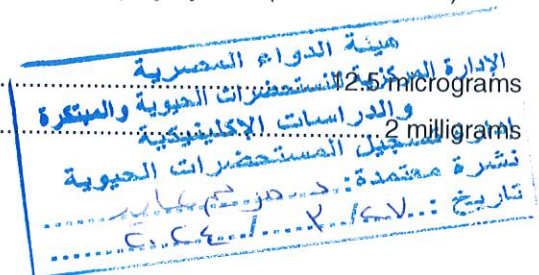
Excipients with known effect:

Phenylalanine 2.5 micrograms

Ethanol 2 milligrams

(See section 4.4).

For the full list of excipients, see section 6.1.



3. PHARMACEUTICAL FORM

Suspension for injection in multidose vial.

IMOVAX POLIO is a clear and colourless suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

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

IMOVAX POLIO must be used according to current official recommendations.

4.2. Posology and method of administration

Posology

Paediatric population

Dosage regimen compliant with French recommendations:

- 2 injections at an interval of two months, one at the age of 2 months and one at the age of 4 months (primary vaccination) followed by a first booster at the age of 11 months.

Other dosing regimens compliant with current national recommendations and to be used according to WHO recommendations as appropriate:

- From the age of 6 weeks or 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 6 to 12 months after the last dose.
- In countries where a live oral poliomyelitis vaccine (trivalent, bivalent or monovalent OPV) is used in the routine vaccination programme, IMOVAX POLIO may be used in combination (co-administration) or sequentially with OPV, compliant with official WHO recommendations and in accordance with the current national recommendations.

Any additional boosters (in childhood, adolescence and adulthood) should be administered in accordance with the current national recommendations.

Adult population

Dosage regimen compliant with French recommendations:

- In unvaccinated adults, 2 successive doses of 0.5 mL should be administered at an interval of two months, followed by a first booster 8 to 12 months after the first dose.

Other dosing regimens compliant with current national recommendations and to be used according to WHO recommendations as appropriate:

- In unvaccinated adults, 2 successive doses of 0.5 mL should be administered at an interval of one, or preferably, two months, followed by a first booster 6 to 12 months after the first dose.

Any additional boosters should be administered in accordance with current national recommendations.

Method of administration

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

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

For special instructions on handling and disposal, see section 6.6.

4.3. 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 and polymyxin B.

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

4.4. Special warnings and precautions for use

Traceability:

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

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

As with any injectable vaccine, IMOVAX POLIO should be administered with caution in subjects with thrombocytopenia or coagulation disorders, as an intramuscular injection may cause bleeding in these subjects.

As with any injectable vaccine, appropriate medical treatment should be readily available and close supervision should be carried out for the rare cases where an anaphylactic reaction occurs following administration of the vaccine.

Immunosuppressive therapy or an immunodeficiency condition may induce a decreased immune response to the vaccine. It is therefore recommended to wait until the end of treatment before vaccinating or to make sure that the subject is well protected. Nevertheless, the 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 in subjects for 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 48-72 hours should be carefully considered when administering the primary vaccination doses in very premature infants (born ≤ 28 weeks of pregnancy) and particularly for those with a history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, administration should not be withheld or delayed.

A syncope attack (fainting) can occur following, or even before, a vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent any injury due to fainting and to manage syncopal reactions.

IMOVAX POLIO contains phenylalanine, ethanol and sodium

IMOVAX POLIO contains 12.5 micrograms of phenylalanine in each 0.5 mL dose. 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 of alcohol (ethanol) per 0.5 mL dose. The low quantity of alcohol in this medicinal product is unlikely to cause a notable effect.

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

4.5. **Interaction with other medicinal products and other forms of interaction**

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

4.6. **Fertility, pregnancy and lactation**

Pregnancy

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

Breast-feeding

The vaccine can be used while breastfeeding.

Fertility

No fertility studies have been performed.

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**

Undesirable effects are ranked according to the MedDRA terminology (by system organ) and by frequency using the following convention:

Very common: $\geq 10\%$

Common: $\geq 1\%$ and $< 10\%$

Uncommon: $\geq 0.1\%$ and $< 1\%$

Rare: $\geq 0.01\%$ 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. As 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 in 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 resolving rapidly.

Nervous system disorders

Not known: convulsions (isolated or associated with fever) in the days following vaccination, headache, moderate and transient paresthesia (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: moderate and transient arthralgia and myalgia 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 last one or two days.

Additional information concerning particular populations

Apnoea in very premature infants (born ≤ 28 weeks pregnancy) (see section 4.4).

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: Agence nationale de sécurité du médicament et des produits de santé [French National Agency for Medicines and Health Products Safety] (ANSM) and Réseau des Centres Régionaux de Pharmacovigilance [French Regional Pharmacovigilance Centres Network] - Website: <https://signalement.medicaments.fr>

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Poliomyelitis vaccine, ATC code: J07BF03.

The vaccine is prepared from poliomyelitis virus types 1, 2 and 3 cultured on VERO cells, purified and inactivated by formaldehyde.

One month after primary vaccination (3 doses), seroprotection rates were at 100% for poliomyelitis virus types 1 and 3 and 99% to 100% for type 2.

In infants, the booster dose (4th dose) led to a large increase in titres with seroprotection rates of 97.5% to 100% for the 3 types of poliomyelitis virus.

Four to five years after the booster dose, 94 to 99% of subjects had protective titres.

In primary-vaccinated adults, a booster injection is followed by an anamnestic response.

For the most part, these data come from studies conducted with combined vaccines containing poliomyelitis vaccines.

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

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of acute toxicity, repeated dose toxicity and local tolerability.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

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

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

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

6.2. Incompatibilities

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

6.3. Shelf life

3 years

After first being opened, the vaccine can be used for 28 days provided it is stored between 2°C and 8°C.

6.4. Special precautions for storage

Store in a refrigerator (2°C to 8°C) and protected from light. Do not freeze.

For storage conditions after first opening of the vaccine, see section 6.3.

6.5. Nature and contents of container

5 mL (10 doses) of suspension for injection in a vial (type I glass) with a stopper (chlorobutyl or bromobutyl) - box of 1 or 10.

Not all pack sizes may be marketed.

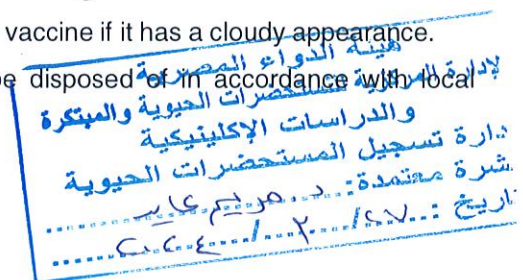
6.6. Special precautions for disposal and other handling

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

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

7. MARKETING AUTHORISATION HOLDER

SANOFI PASTEUR
14 ESPACE HENRY VALLÉE
69007 LYON
FRANCE



8. MARKETING AUTHORISATION NUMBER(S)

- 34009 325 757 3 2: 5 mL (10 doses) of suspension for injection in a vial (type I glass) with a stopper (chlorobutyl or bromobutyl) - box of 1 vial.
- 34009 361 220 6 2: 5 mL (10 doses) of suspension for injection in a vial (type I glass) with a stopper (chlorobutyl or bromobutyl) - box of 10 vials.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed at a later date by the Marketing Authorisation Holder]

10. DATE OF REVISION OF THE TEXT

March 2023

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.



GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription