

Registration No. : 2C 37/40

Importer / Manufacturer: Sanofi Pasteur Ltd., Thailand/Sanofi Pasteur S.A., France

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT : IMOVAX POLIO, Poliomyelitis Vaccine (Inactivated),

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.5 ml) contains:

Poliovirus [#] type 1, Mahoney strain (inactivated)	40 DU*†
Poliovirus [#] type 2, MEF-1 strain (inactivated)	8 DU*†
Poliovirus [#] type 3, Saukett strain (inactivated)	32 DU*†

This vaccine is in compliance with European Pharmacopoeia requirements and WHO recommendations.

[#] cultured on VERO cells

* DU: D-antigen Unit

† or the equivalent antigenic quantity, determined by suitable immunochemical method.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Dosage:

Primary vaccination:

From 2 months of age, 3 successive injections of 0.5 ml should be administered at intervals of one or two months.

From 6 weeks of age, IMOVAX POLIO may be administered following the 6, 10, 14-week schedule, as per the recommendations of the Expanded Programme on Immunisation of the World Health Organisation.

For nonvaccinated adults, 2 successive injections of 0.5 ml must be given at intervals of one or, preferably, two months.

Booster:

In children in the second year of life, a 4th dose (1st booster) is administered one year after the 3rd injection.

For adults, a 3rd dose (1st booster) is administered 8 to 12 months after the 2nd injection.

A booster is given every 5 years in children and adolescents and every 10 years in adults.

Method of Administration:

The preferred route of administration is intramuscular, though the vaccine may also be given subcutaneously.

The preferred site of intramuscular injection is the mid-lateral aspect of the thigh in infants and toddlers and the deltoid muscle in children, adolescents and adults.

If you use more IMOVAX POLIO than you should have: Not applicable.

If you forget to take IMOVAX POLIO:

Your doctor will decide when to administer the missing dose.

4.3 Contraindication

Do not use IMOVAX POLIO if you or your child:

- Are allergic to the active substances, to one of the excipients, to neomycin, to streptomycin or to polymyxine B or have had an allergic reaction following a previous injection of this vaccine.
- Have a fever or acute illness; in this case, vaccination should be postponed.

4.4 Special warnings and precautions for use

Take special care with IMOVAX POLIO if you or your child:

- Have thrombocytopenia (insufficient blood platelets, which play an important role in coagulation) or a bleeding disorder, because of the bleeding that can occur during intramuscular administration of the vaccine.
- Are taking a treatment that suppresses your immune responses or presenting with an immune deficiency disorder, in which case the immune response to the vaccine may be reduced. In such cases it is recommended to postpone vaccination until the end of the treatment or to make sure the subject is well protected. Vaccination of subjects with chronic immunodeficiency, such as HIV infection, is nevertheless recommended even if the immune response might be limited by the underlying illness.
This vaccine may also be indicated for subjects for whom the oral vaccine is contraindicated and as a booster for subjects previously vaccinated with the oral vaccine.
- Do not inject by the intravascular route: make sure the needle does not penetrate a blood vessel.

List of Excipients with Known Effect: formaldehyde, phenylalanine.

4.5 Interaction with other medical products and forms of interaction

There is no documented evidence against administration of IMOVAX POLIO with other usual vaccines in a single vaccination session.

Please tell your doctor or pharmacist if you are taking or have recently taken another medicine, including medicines obtained without a prescription.

4.6 Pregnancy and lactation

This vaccine may be used during pregnancy, if required. Breast-feeding is not a contraindication.

Ask your doctor or pharmacist for advice before taking any medicine.

4.7 Effects on the ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Like all vaccines, IMOVAX POLIO may cause side effects.

The most frequently reported side effects are:

- Local reactions at the site: pain, erythema (skin redness), induration.
- Moderate, transient fever.

Other side effects, reported very rarely (< 0.01%), are:

- Local reactions at the injection site:
 - oedema that can occur within 48 hours and persist for one or two days
 - lymphadenopathy (increase in the size of lymph nodes)
- Hypersensitivity reaction (allergy): urticaria, Quincke's oedema (facial oedema), anaphylactic shock in response to one of the vaccine components.
- Moderate and transient arthralgia (joint pain) and myalgia (muscular pain) in the days following vaccination.
- Convulsions (isolated or associated with fever) in the days following vaccination, headaches, moderate and transient paresthesia (a tingling sensation, primarily in the lower limbs) occurring in the two weeks following vaccination.
- Agitation, somnolence and irritability in the first hours or days following vaccination and disappearing rapidly.
- Widespread skin rash.
- In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2 -3 days after vaccinations

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

2-phenoxyethanol, ethanol, formaldehyde, medium 199 Hanks (containing in particular amino acids, mineral salts, vitamins, glucose, polysorbate 80 and water for injections), hydrochloric acid or sodium hydroxide for pH adjustment.

6.2 Incompatibilities

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a refrigerator (between +2°C and +8°C), protected from light. Do not freeze.
Keep out of the reach and sight of children

6.5 Nature and contents of container

Suspension for injection (0.5 ml) in a prefilled syringe with an attached needle or with two separate needles – box of 1 or 20.
Multidose vial (vial of 10 doses of 0.5 ml) – box of 10.

6.6 Special precautions for disposal and other handling

For multidose vial: It is best to use the vaccine immediately after opening it.
Do not use IMOVAX POLIO if it has a cloudy appearance.
Do not use after the expiry date listed on the package.

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur Ltd., Bangkok, Thailand

8. MARKETING AUTHORISATION NUMBER(S)

2C 37/40

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 March 1997

10. DATE OF REVISION OF THE TEXT

16 April 2009

Date of local approval: 26 January 2012

(The above information is based on the currently approved leaflet)