NAME OF THE MEDICINAL PRODUCT

IMOVAX POLIO, suspension for injection in a prefilled syringe or multidose
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 a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection in a prefilled syringe or multidose.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

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

4.2. Posology and method of administration

Posology

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 should be given at intervals of one or, preferably, two months.

Booster

For children older than 12 months , a 4th dose (1st booster) is administered 6-12 months after the 3rd injection.

For adults, a 3rd dose (1st booster) is administered 6 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, although 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.

4.3. Contraindications

Known severe hypersensitivity to any component of the vaccine or a vaccine containing the same substances, or to one of the excipients.

Known severe hypersensitivity to neomycin, streptomycin or polymyxine B (each dose may contain undetectable traces of these antibiotics which are used during vaccine production).

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

4.4. Special warnings and precautions for use

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

Like any injectable vaccine, IMOVAX POLIO should be administered with caution to subjects with thrombocytopenia or a bleeding disorder, because bleeding may occur following an intramuscular administration to these subjects.

As with all injectable vaccines, there is a possibility (though rare) of an anaphylactic event. For this reason, appropriate medical treatment should be readily available, and the subject should be kept under surveillance following administration.

The immune response to the vaccine may be reduced in subjects who are immunodeficient or who are taking an immunosuppressive treatment. In such cases it is recommended to postpone vaccination until the end of the treatment or to make sure that 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.

IMOVAX POLIO may also be indicated for subjects for whom oral vaccination 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 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.

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

There is no documented evidence against administration of IMOVAX POLIO during a single vaccination session with other usual vaccines. Different syringes and separate injection sites should be used in case of concomitant administration.

4.6. Pregnancy and lactation

Clinical data indicate that this vaccine may be prescribed during pregnancy, only if required.

This vaccine may be used during breast feeding.

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

Clinical Trial Experience

Local reactogenicity was evaluated in two multicenter, randomised clinical trials involving a total of 395 patients. Local reactions at the injection site were commonly to very commonly reported: redness (in 0.7% to 2.4% of subjects in each trial), pain (0.7% to 34%) and induration (0.4%).

The incidence and severity of local reactions may be affected by the site, route and method of injection and by the number of previous injections.

In a multicenter, randomised, 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.)

Data from Post-Marketing Surveillance

Data from spontaneous reporting shows that the following post-marketing events have been reported very rarely (<0.01%). However, the exact frequency cannot be precisely calculated.

Given the childhood immunisation schedule, IMOVAX POLIO is rarely injected alone.

General Disorders and Local Reactions:

Local reactions at the injection site, such as oedema, can occur in the 48 hours following vaccination and persist for one or two days.

Lymphadenopathy.

Immune System Disorders:

Type I hypersensitivity reaction to one of the components of the vaccine, such as urticaria, angioedema, anaphylactic reaction or anaphylactic shock.

Musculoskeletal and Connective Tissue Disorders:

Myalgia and moderate and transient arthralgia have been reported in the days following vaccination.

Nervous System Disorders:

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.

Psychiatric Disorders:

Agitation, somnolence and irritability in the first hours or days following vaccination and disappearing rapidly.

Skin and Subcutaneous Tissue Disorders:

Rash.

Apnoea in very premature infants (born ≤ 28 weeks of gestation) (see section 4.4)

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

POLIOMYELITIS VACCINE

(J: Anti-infectious)

ATC code: J07 BF

5.1. Pharmacodynamic properties

The vaccine is prepared from poliovirus types I, 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 types 1 and 3 poliovirus vaccines and at 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 three types of poliovirus vaccine.

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

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.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

2-phenoxyethanol, 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.

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.

6.4. Special precautions for storage

Store in the refrigerator (between +2°C and +8°C), protected from light. Do not freeze.

It is best to use the product immediately after opening it.

6.5. Nature and contents of container

0.5 ml of suspension for injection in a prefilled syringe (type I glass) with a plunger stopper (elastomer) – box of 1 or of 20.

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

5 ml (10 doses) of suspension for injection in a vial (type I glass) with a stopper (elastomer) – box of 1.

6.6. Instructions for use and handling

Verify that the vaccine is clear and colourless. Do not use the vaccine if it has a cloudy appearance. For syringes without an attached needle, the needle should be mounted firmly on the syringe by rotating it 90°.

Manufacturer:
SANOFI PASTEUR SA
2, avenue Pont Pasteur
69007 Lyon

License Holder:
Medici Medical Ltd.,
2 Hapnina St., Ra'anana 43000.

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