For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory
Abridged Prescribing Information

POLIOMYELITIS VACCINE (INACTIVATED) I.P.

IMOVAX® POLIO

COMPOSITION

The active substances are:

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 Indian Pharmacopoeia requirements, European Pharmacopoeia requirements and WHO recommendations.

The other ingredients are: 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.

THERAPEUTIC INDICATIONS

This vaccine is indicated for the prevention of poliomyelitis in infants, children and adults, for primary vaccination and as a booster. It must be used according to official recommendations

DOSAGE AND ADMINSITRATION

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.

SAFETY RELATED INFORMATION

CONTRAINDICATIONS

Allergy to active substances, any excipient, neomycin, streptomycin or polymyxin B or the person has had an allergic reaction after previous injection of this vaccine. Fever or acute illness (vaccination should be postponed).

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WARNING AND PRECAUTIONS

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

Thrombocytopenia or a bleeding disorder,

Immunosuppression or immunodeficiency (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.

Do not inject by the intravascular route **Pregnancy and lactation**

This vaccine may be used during pregnancy in high risk situation. Breast feeding is not a contraindication.

ADVERSE REACTIONS

Serious allergic reactions:

-Skin eruption with itching (urticaria),

Sudden swelling of the face and neck and breathing difficulty (angioedema, Quincke's oedema), Sudden and serious malaise with drop in blood pressure causing dizziness and loss of consciousness, acceleration of heart rhythm associated with respiratory disorders (anaphylactic reaction and shock)

Other side effects:

Very common: Injection-site pain, Fever over 38.1°C

Common:

Injection site redness

Uncommon:

Injection site hardening (induration)

Reactions with a Not Known frequency:

Agitation, somnolence and irritability in the first hour or days following vaccination, and disappearing rapidly, Convulsions (isolated or associated with fever) in the days following vaccination, headache (cephalalgia), moderated and transient tingling sensations (paraesthesia) mainly in the lower limbs occurring in two weeks following vaccination,Widespread skin eruption (rash), Moderate and transient joint pain (arthralgia) and muscle pain (myalgia) in the days following vaccination.

-Local injection site reaction:

Increase in size of lymph nodes (lymphadenopathy),

Swelling (oedema) that may occur in the 48 hours following vaccination and persisting 1 or 2 days.

Complementary information pertaining particular populations:

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 vaccination.

For full prescribing information, please contact Sanofi Pasteur India Pvt. Ltd., Sanofi House, C.T.S No. - 117-B, L & T Business Park, Saki Vihar Road, Powai, Mumbai 400072.

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