

## IMOVAX POLIO

### POLIOMYELITIS VACCINE (INACTIVATED) Suspension for injection

**Read all of this leaflet carefully before you are vaccinated or before you have your child vaccinated.**

- Keep this leaflet. You may need to read it again.
- if you have any further questions, if you have a doubt, ask your doctor or pharmacist for more information.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See Section 4.

#### **What is in this leaflet:**

1. What IMOVAX POLIO is and what it is used for
2. What you need to know before you use IMOVAX POLIO
3. How to use IMOVAX POLIO
4. Possible side effects
5. How to store IMOVAX POLIO
6. Further information

#### **1. WHAT IMOVAX POLIO IS AND WHAT IT IS USED FOR**

IMOVAX POLIO is a vaccine. Vaccines are used to protect against infectious diseases. When IMOVAX POLIO is injected, the body's natural defences develop a protection against those diseases. This vaccine is indicated for the prevention of poliomyelitis in infants, children and adults, for primary vaccination (series of first vaccinations) and as a booster. IMOVAX POLIO must be used according to effective official recommendations.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE IMOVAX POLIO**

##### **Do not use IMOVAX POLIO if you or your child:**

- are allergic (hypersensitive) to the active substances or to any of the other components of IMOVAX POLIO, to neomycin, to streptomycin or to polymyxin B. had an allergic reaction after a previous injection of IMOVAX POLIO or a vaccine containing the same substances. had fever or a disease which occurred suddenly, without warning (acute disease). Vaccination will have to be postponed.

##### **Warnings and precautions**

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

- have blood disorders such as a decrease in platelets (thrombocytopenia) or clotting disorders because of the risk of bleeding which may occur during intramuscular administration of the vaccine.
- are taking a treatment that suppresses your immune defences (corticosteroid drugs, cytotoxic drugs, radiotherapy or any other treatments likely to weaken your immune defences) or if you present with immune deficiency (immunosuppression), 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.
- Present with chronic immunodeficiency such as an infection with the AIDS virus (HIV). Vaccination is recommended even if the immune response may be limited.

Vaccination 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.

If you have doubts, talk to your doctor or pharmacist.

### **Other medicines and IMOVAX POLIO**

There are no known risks of administering IMOVAX POLIO with other usual vaccines during the same vaccination session.

If you or your child are taking or have recently taken any other medicines, including those obtained without a prescription, tell your doctor or pharmacist.

### **Pregnancy and breastfeeding**

This vaccine can be used during pregnancy, in high risk situations.

Breast feeding is not a contraindication.

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

**Driving and using machines** This vaccine is unlikely to have any effects on the ability to drive or to use machines. However, no studies on this topic were performed.

## **3. HOW TO USE IMOVAX POLIO**

### **Dosage**

#### **Dosage regimen compliant with French recommendations**

**Pediatric population** One dose at the age of 2 months and one dose at the age of 4 months, followed by a booster dose at the age of 11 months.

#### **Non vaccinated adults**

Two successive doses of 0.5 ml at an interval of two months, followed by a booster dose 8 to 12 months after the first injection.

Please refer to official recommendations for any further boosters.

#### **Other dosage regimens:**

This vaccine must be used according to effective official recommendations.

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 official recommendations.

### **Method of administration**

This vaccine will be administered by a healthcare professional, preferably into a muscle (intramuscular route) or under the skin (subcutaneous route).

This vaccine must never be administered into a blood vessel.

Injection into a muscle will be preferably performed in the upper side of the thigh in young children and in the upper part of the arm in children, adolescents and adults.

**If you forget to use IMOVAX POLIO:** If you forget to take a dose of vaccine, your doctor will decide when to administer this dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. **Serious allergic reactions:**

Serious allergic reactions (hypersensitivity reactions), although very rare, may occur after vaccination. Usually you or your child are still at the vaccination place.

If any of the symptoms described below occurs after you have left the place where you or your child were vaccinated, you must contact your doctor or the emergency services IMMEDIATELY:

- 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:**

If you or your child experiences any of the side effects described below, if it persists or if it worsens, you must contact your doctor or pharmacist.

Very common (may affect more than one in 10 people):

- Injection-site pain
- Fever over than 38.1°C

Common (may affect less than one in 10 people but more than one in 100 people):

- Injection-site redness

Uncommon (may affect less than one in 100 people but more than one in 1000 people):

- Injection-site hardening (induration)

Reactions with a Not Known frequency (frequency which cannot be estimated because these reactions are reported very rarely):

- 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 lower limbs) occurring in the 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 one or two days.

#### **Complementary information concerning 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

#### **Reporting of side effects**

If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE IMOVAX POLIO

Keep this medicine out of the sight and reach of children.

Do not use IMOVAX POLIO after the expiry day stated on the box and on the label after EXP. The expiry date refers to the last day of that month.

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

For multidose vial: After first opening, the vaccine can be used for up to 28 days provided it is stored between 2°C - 8°C.

Do not use IMOVAX POLIO if you notice that the product has a cloudy appearance.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What IMOVAX POLIO contains

- The active substances are:

For one dose (0.5 ml):

Poliovirus (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.

- The other ingredients are:

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

### What IMOVAX POLIO looks like and contents of the pack

IMOVAX POLIO is a clear and colourless suspension for injection.

- 0.5 ml in a prefilled syringe with an attached needle or with two separate needles – box of 1 or of 20.
- Multidose vial of ten 0.5 ml-doses – box of 10.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

SANOFI PASTEUR SA – 2, Avenue Pont Pasteur – 69007 LYON – FRANCE

This leaflet was last revised in 06/2015.

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The following information is intended for healthcare professionals only: **Method of administration**

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

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

Administer preferably via the intramuscular (IM) route, or via the subcutaneous (SC) route.

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