W.H.O PACKAGE INSERT TEXT

IMOVAX POLIO

Suspension for injection in multidose vial

Poliomyelitis vaccine (inactivated)

Read all of this leaflet carefully before you or your child are vaccinated because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, or pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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. See section 4.

What is in this leaflet:

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

Talk to your doctor, pharmacist or nurse before using IMOVAX POLIO.

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.

Fainting can occur following, or even before, any needle injection. Also, talk to your doctor or nurse if you or your child has fainted during a previous injection.

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.

Tell your doctor or pharmacist if your or your child are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

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.

IMOVAX POLIO contains phenylalanine, ethanol and sodium

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

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

3. HOW TO USE IMOVAX POLIO

Dosage

Dosage regimen compliant with French recommendations:

Paediatric 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 or your child forget to use IMOVAX POLIO

If you forgot 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 experience 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 this medicine after the expiry date which is stated on the box and on the label after EXP. The expiry date refers to the last day of that month.

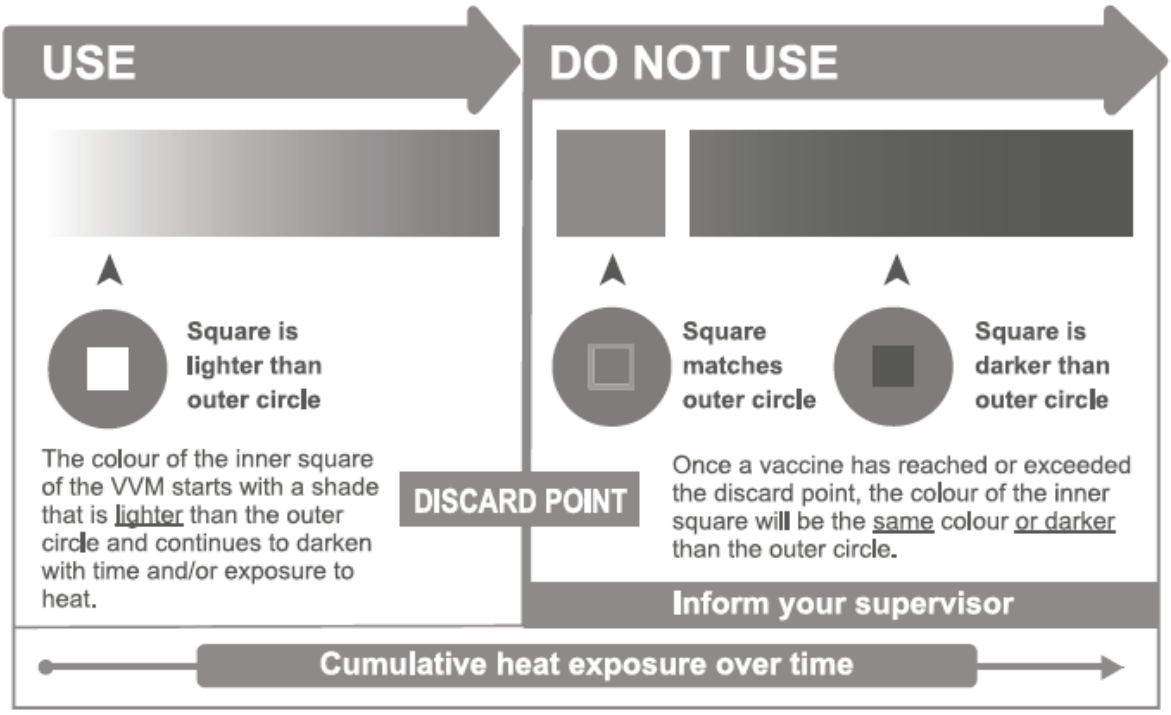
Store in a refrigerator (2°C - 8°C) and protect from light. Do not freeze.

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 this medicine if you notice that the product has a cloudy appearance.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

The Vaccine Vial Monitors (VVM) are on the label of MenQuadfi vaccine supplied through SANOFI PASTEUR. The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.



The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, then the vaccine can be used. As soon as the colour of the central square is the same colour as the circle or of a darker colour than the circle, then the vial should be discarded.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What IMOVAX POLIO contains

- The active substances are:

For one dose (0.5 mL):

Poliovirus (inactivated)

Type 1 (Mahoney strain)# ..... 29 DU*+

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

Type 3 (Saukett strain)# ..... 26 DU*+

This vaccine complies with European Pharmacopoeia requirements and WHO recommendations.

produced 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 virus type 1, 2 and 3 respectively, when measured by another 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 is and contents of the pack

IMOVAX POLIO is a clear and colourless suspension for injection (vial of ten 0.5 mL-doses – box of 1 or 10 vials).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

SANOFI PASTEUR - 14 Espace Henry Vallée - 69007 LYON - FRANCE

This leaflet was last revised in: 05/2023.

The following information is intended for healthcare professionals only:

Method of administration

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.