PRODUCT INFORMATION

IMOVAX POLIO, suspension for injection in prefilled syringe
Poliomyelitis vaccine (inactivated)

ENGLISH TRANSLATION

French MA updates	Sections of Annex I modified
13 May 2015	Full text
17 June 2015	SmPC: Sections 4.2; 4.3 Leaflet: Section 3

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

IMOVAX POLIO, suspension for injection in prefilled syringe

Poliomyelitis vaccine (inactivated)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.5 ml) contains:

Poliomyelitis virus (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.

IMOVAX POLIO may contain traces of neomycin, streptomycin and polymyxin B (see section 4.3).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection in prefilled syringe.

IMOVAX POLIO is a clear and colourless suspension.

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 vaccination.

IMOVAX POLIO must be used according to effective official recommendations.

4.2 Posology and method of administration

Posology

Pediatric population

Dosage regimen compliant with French recommendations:

- 2 injections at an interval of two months, one at the age of 2 months and one at the age of 4 months (primary vaccination) followed by a first booster at the age of 11 months.

Other dosage regimens compliant with national recommendations in effect to be used according to WHO recommendations as appropriate:

- From the age of 6 weeks or from the age of 2 months, 3 successive doses of 0.5 mL of IMOVAX POLIO should be administered at intervals of one or two months, followed by a first booster 6 to 12 months after the last dose.
- 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 WHO recommendations and in agreement with the national recommendations in effect.

Any further boosters (in childhood, in adolescence and in adulthood) should be administered according to the national recommendations in effect.

Adult population

Dosage regimen compliant with French recommendations:

- In non-vaccinated adults, 2 successive doses of 0.5 mL should be administered at an interval of two months, followed by a first booster 8 to 12 months after the first dose.

Other dosage regimens compliant with national recommendations in effect to be used according to WHO recommendations as appropriate:

- In non-vaccinated adults, 2 successive doses of 0.5 mL should be administered at an interval of one or, preferably, two months, followed by a first booster 6 to 12 months after the last dose.

Any further boosters should be administered according to the national recommendations in effect.

Method of administration

Administration is performed preferably via the intramuscular (IM) route, or via the subcutaneous (SC) route.

Intramuscular injection will be preferably performed in the antero-lateral side of the thigh in young children and in the deltoid muscle in children, adolescents and adults.

For instructions on use, handling and disposal, see Section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients of the vaccine, or to any vaccine containing the same substances, to neomycin, streptomycin or polymyxin B.

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

As with all injectable vaccines, IMOVAX POLIO must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

As with all injectable vaccines, appropriate medical treatment must be readily available and close supervision provided should a rare anaphylactic reaction occur following administration of the vaccine.

Immunosuppressive treatment or an immunodeficiency condition may induce a reduced immune response to the vaccine. It is then recommended to wait until the end of the treatment before vaccinating or to make sure that the subject is well protected. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the immune response may be limited.

IMOVAX POLIO 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.

The potential risk of apnoea and the need for respiratory monitoring for 48-72h 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 are no known risks of administering IMOVAX POLIO with other usual vaccines during the same vaccination session. In case of concomitant administration, different syringes and separate injection sites should be used.

4.6 Pregnancy and lactation

Pregnancy

Given clinical data, this vaccine may be prescribed during pregnancy in high risk situations.

Breastfeeding

This vaccine can be used during breastfeeding.

Fertility

No fertility studies were performed.

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

The adverse events are ranked according to the MedDRA terminology (by System Organ Class) and under headings of frequency using the following convention:

Very common: ≥ 10%
Common: ≥ 1% and < 10%
Uncommon: ≥ 0.1% and < 1%
Rare: ≥ 0.01% and < 0.1%
Very rare: < 0.01%
Not known: cannot be estimated from the available data.

Based on spontaneous reporting, certain undesirable events were very rarely reported following the use of IMOVAX POLIO. Because events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. This is why these undesirable events are ranked under the « Not known » frequency.

The events listed below were observed during clinical studies or were spontaneously reported after marketing.

The most common adverse events following administration of this vaccine are local injection-site reactions (pain, redness, induration) and fever over 38.1°C.

Immune system disorders

Not known: type I hypersensitivity reaction to one of the components of the vaccine, such as urticaria, angioedema, anaphylactic reaction or anaphylactic shock.

Psychiatric disorders

Not known: agitation, somnolence and irritability in the first hour or days following vaccination and disappearing rapidly.

Nervous system disorders

Not known: 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.

Skin and subcutaneous tissue disorders

Not known: rash.

Musculoskeletal and connective tissue disorders

Not known: mild and transitory arthralgia, and myalgia have been reported in the days following vaccination.

General disorders and administration site conditions

Very common: injection-site pain, fever over 38.1°C.

Common: injection-site redness.

Uncommon: injection-site induration.

Not known: lymphadenopathy, local injection-site reactions such as oedema that can occur in the 48 hours following vaccination and lasting one or two days.

Complementary information concerning particular populations

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: « Agence nationale de sécurité du médicament et des produits de santé (Ansm) et réseau des Centres Régionaux de Pharmacovigilance » - Site internet : www.ansm.sante.fr.

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccine against poliomyelitis, ATC code: J07BF03.

The vaccine is prepared from poliovirus types 1, 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 polioviruses and at 99% to 100% for type 2.

For 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 polioviruses.

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

Non-clinical data revealed no special hazard for humans based on conventional acute toxicity, repeat dose toxicity and local tolerance studies.

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

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 (bromobutyl or chlorobutyl or chlorobromobutyl) – box of 1 or of 20.

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

Not all pack sizes may be marketed.

6.6 Instructions for use, handling and disposal

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

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

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

SANOFI PASTEUR
2 AVENUE PONT PASTEUR
69007 LYON
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

- 325 755.0 or 34009 325 755 0 3: 0.5 ml of suspension for injection in a prefilled syringe (type I glass) with a plunger stopper (bromobutyl or chlorobutyl or chlorobromobutyl) – box of 1
- 369 926.5 or 34009 369 926 5 8: 0.5 ml of suspension for injection in a prefilled syringe (type I glass) with a plunger stopper (bromobutyl or chlorobutyl or chlorobromobutyl), a tip-cap and with a separate needle – box of 1
- 369 927.1 or 34009 369 927 1 9: 0.5 ml of suspension for injection in a prefilled syringe (type I glass) with a plunger stopper (bromobutyl or chlorobutyl or chlorobromobutyl), a tip-cap and with 2 separate needles – box of 1
- 325 756.7 or 34009 325 756 7 1: 0.5 ml of suspension for injection in a prefilled syringe (type I glass) with a plunger stopper (bromobutyl or chlorobutyl or chlorobromobutyl) – box of 20

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

- Date of first authorization: 02 July 1982.
- Date of renewal of the authorization: unlimited, starting from 01 March 2012.

10. DATE OF REVISION OF THE TEXT

17 June 2015

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

A.1. Name and address of the manufacturer(s) of the biological active substance(s)

SANOFI PASTEUR
CAMPUS MERIEUX
1541, AVENUE MARCEL MERIEUX
69280 MARCY L'ETOILE
FRANCE

A.2. Name and address of the manufacturer(s) responsible for batch release

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

B. CONDITIONS OF THE MARKETING AUTHORISATION

B.1. Conditions or restrictions regarding supply and use imposed on the marketing authorisation holder

Medicinal product not subject to medical prescription.

B.2. Conditions or restrictions with regard to the safe and effective use of the medicinal product

Not applicable.

B.3. Other conditions

Not applicable.

C. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

Not applicable.

D. QUALITATIVE AND QUANTITATIVE COMPOSITION IN EXCIPIENTS

One dose (0.5 ml) of vaccine contains:

- 2-Phenoxyethanol ..... 2.5 µl
- Formaldehyde ..... 12.5 µg
- Medium 199 Hanks ..... qs 0.5 ml

The 2-phenoxyethanol is contained in a solution of 2-phenoxyethanol at 50% in ethanol.

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, with a pH that has been adjusted with hydrochloric acid or sodium hydroxide.

During manufacture of the active substance, neomycin, streptomycin and polymyxin B are used, and traces of them may exist in the final vaccine.

ANNEX IIIA

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

NATURE/TYPE Outer packaging or immediate packaging

Outer packaging

1. NAME OF THE MEDICINAL PRODUCT

IMOVAX POLIO, suspension for injection in prefilled syringe

Poliomyelitis vaccine (inactivated)

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (0.5 ml) contains:

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.

3. LIST OF EXCIPIENTS

2-phenoxyethanol, formaldehyde, ethanol, 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.

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection in prefilled syringe (0.5 ml) <with> <one> <two> <separate needles> box of 1 or 20.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular route preferred, or subcutaneous route.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet carefully before use.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

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

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Not applicable.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Holder

SANOFI PASTEUR
2 AVENUE PONT PASTEUR
69007 LYON
FRANCE

Distributor

SANOFI PASTEUR MSD SNC
12, RUE JONAS SALK
69007 LYON
FRANCE

Manufacturer

SANOFI PASTEUR
2 AVENUE PONT PASTEUR
69007 LYON
FRANCE

12. MARKETING AUTHORISATION NUMBER(S)

Authorised medicinal product No.:

13. BATCH NUMBER

Batch {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

15. INSTRUCTIONS ON USE

This vaccine is indicated for the prevention of poliomyelitis.

16. INFORMATION IN BRAILLE

In accordance with local requirements.

PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE Small immediate packaging units

Prefilled syringe

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

IMOVAX POLIO, suspension for injection in prefilled syringe

Poliomyelitis vaccine (inactivated)

Intramuscular or subcutaneous route.

2. METHOD OF ADMINISTRATION

Not applicable.

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch {number}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 ml.

6. OTHER

Not applicable.

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

IMOVAX POLIO, suspension for injection in prefilled syringe

Poliomyelitis vaccine (inactivated)

Boxed text

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.

Package leaflet summary

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, suspension for injection in prefilled syringe IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group

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.

Therapeutic indications

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, suspension for injection in prefilled syringe

List of information necessary before taking the medicinal product

Not applicable.

Contraindications

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.

Precautions for use; special warnings

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.

Interactions with other medicinal products

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.

Interactions with food and drinks

Not applicable.

Interactions with phytotherapy or alternative therapies

Not applicable.

Use during pregnancy and breast-feeding

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.

Athletes

Not applicable.

Effects on the ability to drive or to use machines

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.

List of excipients with recognised effect

Not applicable.

3. HOW TO USE IMOVAX POLIO, suspension for injection in prefilled syringe

Instructions for proper use

Not applicable.

Dosage, Method and/or route(s) of administration, Frequency of administration and Duration of treatment

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.

Symptoms and instructions in the case of overdose

Not applicable.

Actions to be taken when one or more doses have been missed

If you forget to use IMOVAX POLIO:

If you forgot to take a dose of vaccine, your doctor will decide when to administer this dose.

Risk of withdrawal syndrome

If you stop using IMOVAX POLIO:

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Description of 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 (œdema) 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. You can also report side effects directly via the national reporting system: « Agence nationale de sécurité du médicament et des produits de santé (Ansm) et réseau des Centres Régionaux de Pharmacovigilance » - Site internet: www.ansm.sante.fr.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE IMOVAX POLIO, suspension for injection in prefilled syringe

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

Expiry date

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

Storage conditions

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

Where appropriate, warning against certain visible signs of deterioration

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

Full statement of the active substances and excipients

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.

Pharmaceutical form and contents

What IMOVAX POLIO looks like and contents of the pack

IMOVAX POLIO is a clear and colourless suspension for injection (0.5 ml in prefilled syringe with or without a needle. Box of 1 or of 20).

Not all pack sizes may be marketed.

Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing Authorisation Holder and Manufacturer

Holder

SANOFI PASTEUR
2 AVENUE PONT PASTEUR
69007 LYON
FRANCE

Distributor

SANOFI PASTEUR MSD SNC
12, RUE JONAS SALK
69007 LYON
FRANCE

Manufacturer

SANOFI PASTEUR
2 AVENUE PONT PASTEUR
69007 LYON
FRANCE

Names of the medicinal product in the Member States of the European Economic Area

Not applicable.

Date of approval of the package leaflet

This leaflet was last revised in: 06/2015.

Marketing authorisation under exceptional circumstances

Not applicable.

Internet information

Detailed information on this medicinal product is available on the website of ANSM (France)

Information intended for healthcare professionals

The following information is intended for healthcare professionals only:

Method of administration

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.

Other

Not applicable.