INACTIVATED POLIOMYELITIS VACCINE
ShanIPV

Suspension for injection in multidose vial

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 ShanIPV IS AND WHAT IT IS USED FOR

ShanIPV is a vaccine. Vaccines are used to protect against infectious diseases.

When ShanIPV 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.

ShanIPV must be used according to effective official recommendations.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ShanIPV

Do not use ShanIPV if you or your child:

- are allergic (hypersensitive) to the active substances or to any of the other components of ShanIPV, to neomycin, to streptomycin or to polymyxin B.
- had an allergic reaction after a previous injection of ShanIPV or a vaccine containing the same substances.

Warnings and precautions

Take special care with ShanIPV 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.
- had fever or a disease which occurred suddenly, without warning (acute disease). Vaccination will have to be postponed.
- 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 ShanIPV

There are no known risks of administering ShanIPV 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.

Pharmacological properties

In a clinical trial where ShanIPV has been administered as a booster vaccine to 15 toddlers aged 15 to 18 months and as a 3-dose primary series vaccine to 50 infants aged 6 to 16 weeks of age, the immune responses against the three poliovirus antigens were robust. All subjects achieved seroprotective levels following booster or primary immunization, and antibody levels were similar to those achieved with other IPV vaccines used in similar conditions.

3. HOW TO USE ShanIPV

Dosage

a. Dosage regimens compliant with national recommendations in effect:

Pediatric population

From the age of 6 weeks or from the age of 2 months, 3 successive doses of 0.5 mL of ShanIPV should be administered at intervals of one or two months, followed by a first booster 6 to 12 months after the last dose.

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

Non vaccinated adults

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.

Please refer to official recommendations for any further boosters.

b. 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, ShanIPV 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 ShanIPV:

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.

In a clinical trial where ShanIPV has been administered as a booster vaccine to 15 toddlers aged 15 to 18 months and as a 3-dose primary series vaccine to 50 infants aged 6 to 16 weeks of age, the solicited local reactions that were observed at the ShanIPV injection site were of similar nature and frequencies to the ones observed with similar vaccines of this class. In particular, tenderness was the most frequent observed solicited adverse reactions (with approximately 30% of vaccinees reporting such event after any of the infant doses) and erythema and swelling were less frequently reported. Solicited systemic adverse events were reported frequently as the vaccine was co-administered with a whole-cell pertussis containing vaccine. They resolved spontaneously and were of no clinical relevance

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 ShanIPV

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

Do not use ShanIPV 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.

Store in a refrigerator (2°C - 8°C).

Protect from light.

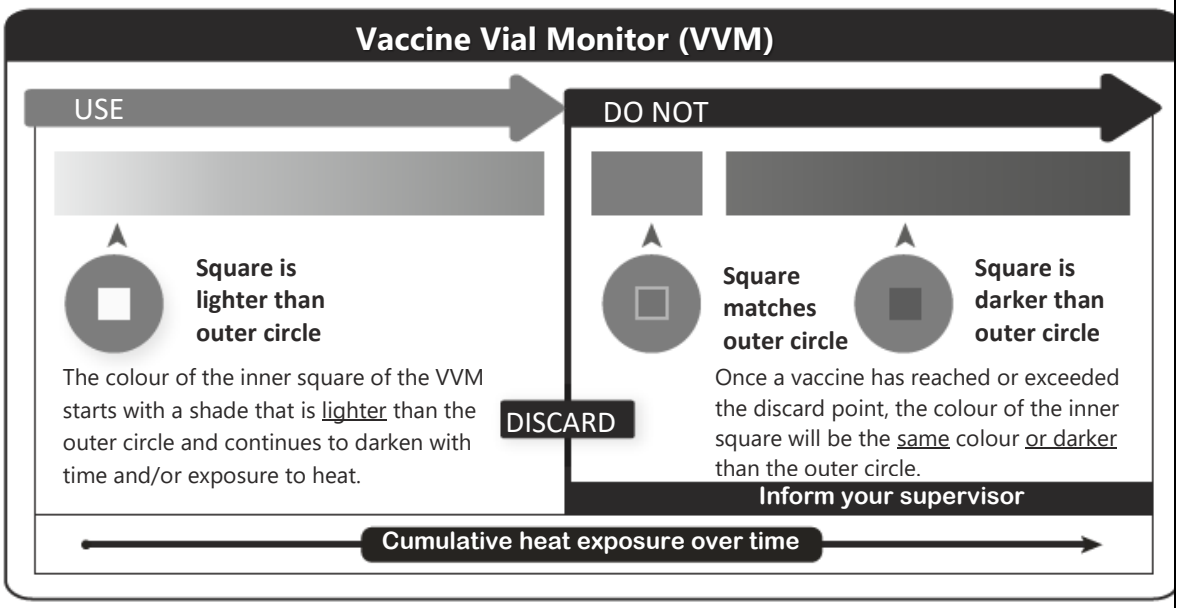
Do not freeze.

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 ShanIPV 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.

The Vaccine Vial Monitors (VVM) are on the label of ShanIPV vaccine supplied through Sanofi Healthcare India Private Limited. 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. FURTHER INFORMATION

What ShanIPV 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*+
produced on VERO cells
* DU: D-antigen Unit
+ or equivalent antigenic quantity determined by a suitable immunochemical method.

- Preservatives:

2-phenoxyethanol..... 2.5 µL
formaldehyde ..... 12.5 µg

The other excipients are: Ethanol, 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.

This vaccine complies with WHO recommendations.

What ShanIPV looks like and contents of the pack

ShanIPV is a clear and colourless suspension for injection (vial of five 0.5 ml-doses – box of 30 vials).

Marketing Authorization Holder

Sanofi Pasteur Ltd., Bangkok, Thailand

This leaflet was prepared in: 10/2020.

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.

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