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**Size: 195x168 mm**

*For the use of Registered Medical Practitioner or Hospital or Laboratory only*

# POLIOMYELITIS VACCINE (INACTIVATED) I.P.

# ShanIPV®

## Suspension for injection in multidose vial

### COMPOSITION

One dose (0.5 mL) contains:
Active substances:
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
Other excipients:
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.

### DOSAGE FORM/S, INDICATIONS

Suspension for Injection in multidose vial.
ShanIPV is clear and colourless suspension.
This vaccine is indicated for the prevention of poliomyelitis in infants, children and adults, for primary vaccination (series of first vaccinations) and as booster.

### DOSAGE AND ADMINISTRATION

**Dosage**

**Pediatric population**

- 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:

- 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.
- 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.

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

**Adult population**

- 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:

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

### USE IN SPECIAL POPULATION

**Pregnancy**

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.

### CONTRAINDICATION

Hypersensitivity to the active substances or to any of the excipients of the ShanIPV, to neomycin, streptomycin or polymyxin B. Hypersensitivity (allergic reaction) after a previous injection of ShanIPV or vaccine containing the same substances.
Common transient contraindications to any vaccination: in case of fever or acute illness, it is best to postpone vaccination.

### WARNINGS AND PRECAUTIONS

Do not inject via the intravascular route: make sure the needle does not penetrate a blood vessel.
As with all injectable vaccines, ShanIPV 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.
ShanIPV 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.

### DRUG INTERACTIONS

There are no known risks of administering ShanIPV with other usual vaccines during the same vaccination session. In case of concomitant administration, different syringes and separate injection sites should be used.

### ADVERSE REACTIONS

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 ShanIPV. 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.
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.

**Immune system disorders**

Not known: type 1 hypersensitivity reaction to one of the components of the vaccine, such as urticaria, angioedema, anaphylactic reaction or anaphylactic shock.

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**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).
**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

## OVERDOSE

Not Applicable.

## PHARMACOLOGICAL PROPERTIES

**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.
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.

**Pharmacokinetic properties**

Not Applicable

## INCOMPATIBILITIES

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

## SHELF-LIFE

The expiry date of the vaccine is indicated on the label and packaging.
After first opening, the vaccine can be used for up to 28 days provided it is stored between +2°C to +8°C.

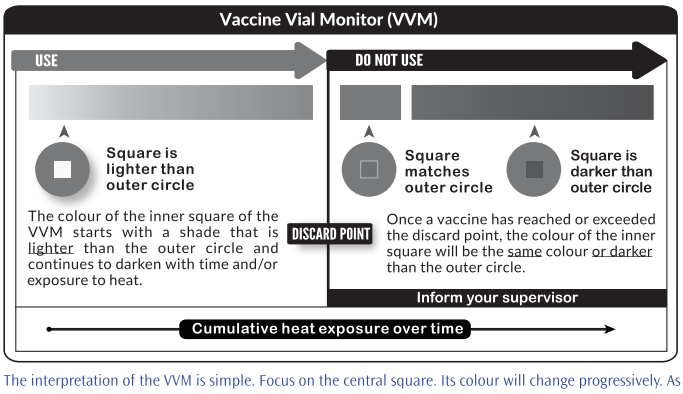
## PACKAGING INFORMATION

2.5 mL (5 doses), 5.0 mL (10 doses) of suspension for injection in a vial (type 1 glass) with a stopper (elastomer) – box of 50.

## STORAGE AND HANDLING INSTRUCTIONS

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 to +8°C). Protect from light. Do not freeze.
Verify that the vaccine is clear and colourless. Do not use the vaccine if it has a cloudy appearance.
After first opening, the vaccine can be used for up to 28 days provided it is stored between +2°C to +8°C.

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.

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Manufactured & Marketed by:
**Sanofi Healthcare India Private Limited**
Survey No. 274, Athvelli Village, Medchal Mandal-501 401,
Medchal-Malkajgiri District, Telangana, India.
Tel +91-40-66301000, 23234104, 23234105, 23234136;
Fax +91-40-2323103, 23234133
Any general enquiry of this product please contact: shipl@sanofi.com
For reporting adverse events please contact: PV.india@sanofi.com

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