SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

ShaniPV, suspension for injection in multidose vial

Inactivated Poliomyelitis Yaccine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL single dose contains:

S.N o.	Name of the Co:rnp9nept.(s)	Quantjcy per Single-dose
Poliomyelitis virus (inactivated)		
1	Type 1 (Mahoney strain)#	40 DU*+
2	Type 2 (MEF-1 strain)#	8DU*+
3	Type 3 (Saukett strain)#	32 DU*+

#produced on VERO cells.

* DU: D-antigen unit.

+ or equivalent antigenic quantity determined by a suitable immunochemical method.

ShaniPV 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 multidose vial.

ShaniPV is a clear and colourless suspension.

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4 CLINICAL PARTICULARS

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4.1 Therapeutic indications

This vaccine is indicated for the prevention of poliomyelitis in infants, children and adults, for primary and booster vaccination.

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ShaniPV must be used according to effective official recommendations

4.2 Posology and method of administration

Posology

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 frrst 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 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

- 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 v1a the intramuscular (IM) route, or v1a 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 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.

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, 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.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known risks of administering ShanlPV 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 vaccme may be prescribed during pregnancy m high risk situations.

Breastfeeding

This vaccine can be used during breastfeeding.

Fertility

No fertility studies were performed.

4.7 Effect 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 tenninology (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.

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.

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 of97.5% to 100% for the three types ofpolioviruses.

Four to five years after the booster dose, 94 to 99% of subjects had protective titres.

Inprimed 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 Pre-clinical 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

2 years.

After ftrst opening, the vaccine can be used for up to 28 days provided it is stored between 2°C to 8°C.

6.4 Special precautions for storage

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

For storage conditions of the vaccine after fust opening, see Section 6.3

6.5 Nature and contents of container

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 vials.

6.6 Special precautions for disposal

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

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

7 MARKETING AUTHORIZATION HOLDER

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8 MARKETING AUTHORIZATION NUMBER

MF-147/2015

9 DATE OF FIRST AUTHORIZATION/ RENEWAL OF AUTHORIZATION

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Joint Director

16 MAR 2018

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