SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Poliomyelitis vaccine (inactivated), suspension for injection
Poliomyelitis vaccine (inactivated) multidose, suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.5 mL poliomyelitis vaccine contains the following active components:

Inactivated poliomyelitis virus type 1 (Mahoney)*	40 D-antigen units
Inactivated poliomyelitis virus type 2 (MEF 1)*	8 D-antigen units
Inactivated poliomyelitis virus type 3 (Saukett)*	32 D-antigen units

For the full list of excipients, see section 6.1.

*) Cultivated on Vero-cells.

3. PHARMACEUTICAL FORM

Suspension for injection. The product is a suspension of formaldehyde inactivated and purified virus filled in vials.
The vaccine colour is faint orange-red..

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Active immunisation against poliomyelitis.

4.2 Posology and method of administration

Posology

One dose consists of 0.5 mL for both children and adults. The vaccine is given subcutaneously or intramuscularly.
Primary immunization consists of three vaccinations, administered with a minimum interval of 4 weeks.

Persons fully immunized against poliomyelitis and leaving to areas with a high incidence of poliomyelitis are advised to re-vaccinate with a single-dose of polio vaccine approx. 1 month before departure, particularly when their last immunization was more than 15 years ago.

Paediatric population
Children should receive the primary series within the first 6 months after birth.

After completion of the first series of vaccinations, a booster dose can be administered after an interval of at least six months. If local authorities recommend a vaccination schedule that starts before the age of 2 months and/or if the interval between doses is less than 8 weeks, a booster dose should be administered, however not before the age of 9 months.

In the Netherlands children are preferable vaccinated with the combination vaccine diphtheria (pertussis) tetanus poliomyelitis vaccine in line with the National Vaccination Program.

Method of administration

The vaccine is administered subcutaneously or intramuscularly.

4.3 Contra-indications

The general contra-indications that apply for every vaccine:
- Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Do not administer if the vaccinee is suffering from a severe infection, with fever.

Older children and adults can faint after vaccination. This generally occurs shortly after vaccination and can occur simultaneously with nausea and vomiting. If fainting at earlier vaccinations has occurred or symptoms indicating fainting have been observed the person should be vaccinated when sitting or lying.

Under no circumstances administer poliomyelitis vaccine intravascular.

As for any injectable vaccine, adequate treatment provisions need to be present, in case any anaphylactic reactions should occur following vaccination. If required, injections of epinephrine or corticosteroids can be given, dosed according to age and or body weight.

If poliomyelitis vaccine is administered to individuals with an immune deficiency or undergoing any type of immunosuppressive therapy, the expected immune response can fail to occur.

The potential risk of apnoea and the need for respiratory monitoring for 48 -72 h 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.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

4.5 Interaction with other medicinal products and other forms of interaction

Poliomyelitis vaccine can be administered simultaneously with other vaccines, if administered on different injection locations.

4.6 Fertility, pregnancy and lactation

Fertility
No fertility studies were performed.

Pregnancy
Data on a large number of exposed pregnancies indicate no adverse effects of poliomyelitis vaccine on pregnancy or on the health of the foetus/new-born child. However, poliomyelitis vaccine should only be used during pregnancy when there is a clear risk of infection.

Breastfeeding
Poliomyelitis vaccine can be used during lactation.

4.7 Effects on ability to drive and use machines

It is not likely that Poliomyelitis vaccine has an effect on driving skills or the capability to operate machines.

4.8 Undesirable effects

Based on post marketing information (voluntary reporting) it has been established that the following adverse reactions could occur. The reported adverse reactions following vaccination with poliomyelitis vaccine mostly occurred within the first three days following vaccination and were temporary of nature.

Neural disorders
Very Seldom (< 1/10.000): (Poly-) Neuropathy

Respiratory, thoracic and mediastinal disorders
Apnoea in very premature infants (≤ 28 weeks of gestation) (see section 4.4).

General disorders and reactions:
Local reactions
Seldom (>1/10.000, <1/1.000): Swelling, redness and pain on injection site.
Systematic reactions
Seldom (>1/10.000, <1/1.000)): Fever, discomfort.

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 listed in Appendix V.

4.9 Overdose

No cases of overdosing have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Viral Vaccines, ATC-code: J07BF03
In animals (monkeys or rats) the administration of the vaccine results in the formation of neutralizing antibodies.

Immunogenicity in humans
Administration of the vaccine in humans results in the formation of antibodies and immunological memory. Administration of a second dose of the vaccine results in a secondary response characterized by a rapid increase of antibody levels that indicates the existence of immunological memory.
In general, the antibody level is indicative for protection. For poliomyelitis a titer (reciprocal dilution in neutralisation assay) of ≥ 8 is protective. A complete vaccination series in general results in protective titers against poliomyelitis type 1, 2 and 3.
The percentage seroprotection in the general Dutch population has been studied s in 1995 – 1996 (Immunity to poliomyelitis in the Netherlands, Am.J.Epid., 2001:153,3). During the decade prior to this investigation, the vaccination level for the primary immunization of DTP-IPV (3 doses at 3, 4 and 5 months) in the Dutch national immunization program was 97%. The age of the investigated persons was in the range of 1 to 79 year. The level of seroprotection can be dependent of the moment of collecting blood samples after vaccination, which was not as in most clinical studies 1 month after

vaccination. The interval of blood sampling after vaccination varied depending on the age of the person. Furthermore it needs to be mentioned that the data is obtained using plain poliomyelitis vaccine or a combination vaccine with a poliomyelitis vaccine component. The percentage of seroprotection measured in this study is shown in the following table.

	percentage seroprotection (%)	95 % confidence interval
Polio type 1	96.6 %	95.9 – 97.2
Polio type 2	93.4 %	92.3 – 94.5
Polio type 3	89.7 %	88.3 – 91.0

5.2 Pharmacokinetic properties

Not applicable for vaccines.

5.3 Preclinical safety data

Pre-clinical studies do not show any special risk for humans. These results are obtained of conventional studies in the area of pharmacological safety and toxicology by repeated administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde (12.5 µg) (E240)
2-phenoxyethanol (2.5 mg)
Medium 199 primarily consisting of amino acids, minerals and vitamins (0.1 mL)
Disodium hydrogenphosphate dihydrate (E339)
Sodium dihydrogen phosphate monohydrate (E339)
Sodium chloride, potassium chloride (E508)
Magnesium sulphate heptahydrate (E518)
Calcium chloride dihydrate (E509)
Potassium dihydrogen phosphate (E340)
Polysorbate 80 (E433)
Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at 2 - 8 ºC. Do not freeze.
After opening a multidose vial (containing 5 or 10 doses) store at 2 – 8°C and use within 28 days.

6.5 Nature and contents of container

The vaccine is filled in:

- vials (type 1 hydrolytic glass) sealed with a rubber stopper (free of latex) and an aluminium flip-off cap that contain 0.5 mL vaccine (1 dose), 2.5 mL (5 doses) or 5.0 mL (10 doses).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No specific requirements.

7. MARKETING AUTHORISATION HOLDER

Bilthoven Biologicals B.V.
Antonie van Leeuwenhoeklaan 9
3721 MA Bilthoven
The Netherlands
Telephone: +31 (0)30 8004800

8. MARKETING AUTHORISATION NUMBER

Poliomyelitis vaccine, suspension for injection 0.5 mL	RVG 17642
Poliomyelitis vaccine multidose, suspension for injection	RVG 114720

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation of the monodose: December 2nd, 1993
Date of latest renewal of the monodose: December 2nd, 2013
Date of first authorisation of the multidose: November 12th, 2014
Date of latest renewal of the multidose: November 12th, 2019

10. DATE OF REVISION OF THE TEXT

Latest partial revision concerns the sections: 3, 4.4, 6.1: 14 January 2025