Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Name of the medicinal product: Poliomyelitis Vaccine (Oral) Bivalent Type 1 and 3 – 10 Dose, 20 Dose

2. Qualitative and quantitative composition

Each dose of 2 drops (0.1 mL) contains poliovirus (Sabin), grown on primary monkey kidney cell culture:

Type I … $10^{6.0}$ CCID50

Type III … $10^{5.8}$ CCID50

Neomycin 15 micrograms.

Stabiliser: 1 M MgCl2

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Solution for oral administration.
Light yellow to dark pink clear liquid in a clear glass vial.

4. Clinical particulars

4.1 Therapeutic indications

Bivalent OPV (type 1 and 3) is indicated for active immunisation against type 1 and type 3 polioviruses.

4.2 Posology and method of administration

Posology

Bivalent OPV (type 1 and 3) is indicated for routine and supplementary immunisation activities against type 1 and type 3 poliovirus in all age groups. The use of this vaccine should be in accordance with official recommendations.

Method of administration

Bivalent OPV must only be administered orally. Two drops are delivered directly into the mouth from the multi-dose vial by dropper. For older children it may be preferred to avoid the possible bitter taste by first placing the drops on a sugar lump or in syrup. Care should be taken not to contaminate a multi-dose dropper with the saliva of the vaccinee.

Use of opened multi-dose vials

Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of bOPV from which one or more doses of vaccine have been removed during an immunisation session may be used in subsequent immunisation sessions for up to a maximum of 28 days, provided that all of the following conditions are met, as described in the WHO policy statement on the handling of multi-dose vaccine vials after opening (WHO/IVB/14.07):

The vaccine is currently prequalified by WHO.

The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO.
The expiry date of the vaccine has not passed.
The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer-recommended temperatures; the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

Immunization schedule

Bivalent OPV (type 1 and 3) is indicated for routine and supplementary immunization activities (SIAs) against type 1 and 3 poliovirus in all age groups. The use of this vaccine should be in accordance with official recommendations.

4.3 Contraindications

No adverse effects are produced by giving bOPV to a sick child. In case of diarrhoea or vomiting (including gastro- intestinal infection), the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

Immune deficiency

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with bOPV according to standard schedules. However, the vaccine is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukaemia, lymphoma or generalized malignancy.

4.4 Special warnings and precautions for use

The possibility of allergic reactions in individuals sensitive to the components of the vaccine should be evaluated.

4.5 Interaction with other medicinal products and other forms of interaction

bOPV can be given safely and effectively at the same time as IPV, measles, rubella, mumps, DTP, DT, TT, Td, BCG, hepatitis B, Haemophilus influenzae type b and yellow fever vaccines, and with vitamin A supplementation.

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic medicinal products and corticosteroids used in greater than minimal doses, may reduce the immune response to vaccines.

4.6 Pregnancy and Lactation

Not applicable

4.7 Effects on ability to drive and use machines

The effect of bivalent OPV (type 1 and 3) on the ability to drive and use machines is not known.

4.8 Undesirable effects

In the vast majority of cases there are no side effects. Very rarely, there may be vaccine-associated paralysis (one case per one million doses administered). Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine-associated paralytic poliomyelitis.
The following adverse events were observed in a clinical trial of bivalent OPV, irrespective of causality:

System Organ Class	Frequency	Adverse events
General disorders and administration site conditions	Very common (> 10%)	Fever
	Common (> 1% to < 10%)	Injection site swelling
	Uncommon (> 0.1% to < 1%)	Crying; injection site erythema; injection site induration; injection site pain
Infections and infestations	Common (> 1% to < 10%)	Respiratory tract infection; conjunctivitis; fungal infection; injection site abscess
	Uncommon (> 0.1% to < 1%)	Gastroenteritis; dysentery; conjunctivitis; skin infection
Respiratory, thoracic and mediastinal disorders	Common (> 1% to < 10%)	Cough; rhinorrhoea
	Uncommon (> 0.1% to < 1%)	Nasal obstruction; bronchospasm
Gastrointestinal disorders	Common (> 1% to < 10%)	Vomiting
	Uncommon (> 0.1% to < 1%)	Abdominal pain; constipation; dyspepsia
Eye disorders	Uncommon (> 0.1% to < 1%)	Increased lacrimation
Musculoskeletal and connective tissue disorders	Uncommon (> 0.1% to < 1%)	Pain in extremity
Skin and subcutaneous tissue disorders	Uncommon (> 0.1% to < 1%)	Erythema; rash; dermatitis
Immune system disorders	Uncommon (> 0.1% to < 1%)	Hypersensitivity

Reporting of suspected adverse reactions

Healthcare professionals can also report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS): https://pv.pharmacyboardkenya.org

4.9 Overdose

No case of overdose has been reported. Overdose, if any, will not result in ill effect. As a precaution, observation for clinical symptoms may be carried out for a period of 4 weeks. The common side effects may be exaggerated in cases of overdose. At the physician's discretion, symptomatic treatment may be given.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: viral vaccines; poliomyelitis oral, bivalent, live attenuated. ATC code: J07BF04.

Mechanism of action

Bivalent OPV (type 1 and 3) induces the production of neutralising antibodies against each type of virus, which are related to protective efficacy.

Immunological data

In a clinical study in 270 infants, following a 3-dose vaccination schedule at 6, 10 and 14 weeks, seroprotection (poliovirus neutralising antibody titre ≥ 1:8) was 100% and 97.3%, while seroconversion was observed in 99.6% and 97% of infants against type 1 and type 3 polioviruses respectively.

5.2 Pharmacokinetic properties

Pharmacokinetic studies are not required for vaccines.

5.3 Preclinical safety data

Not available

6. Pharmaceutical Particulars

6.1 List of Excipients

Magnesium chloride
Polysorbate 80
Neomycin sulfate
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

24 months.

6.4 Special Precautions for storage

The vaccine is potent if stored at not higher than −20°C until the expiry date indicated on the vial. It can be stored for up to six months between +2°C and +8°C.

The vaccine may present a colour varying from light yellow to dark pink due to a slight variation of pH; this does not affect the quality of the vaccine.

6.5 Nature and Content of container

Poliomyelitis Vaccine (Oral) Bivalent Type 1 and 3 is filled in USP type I clear tubular glass vials with grey butyl rubber stoppers and an aluminium seal with flip-top tear-down mechanism and a polypropylene disc on top.

1 mL – 10 dose vial
2 mL – 20 dose vial

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Once the vaccine has been administered, the vaccine containers should be disposed of according to the standard procedures for medical waste.

7. Marketing Authorization Holder

Serum Institute of India Pvt. Ltd.
S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110, 113-114, 168-170 (M), Hadapsar, Pune – 411 028, India.
Telephone: +91-20-71946820 Fax: +91-20-26993924 Email: pharmacovigilance@seruminstitute.com

8. Marketing Authorization Number

H2016/CTD4142/857/R1

9. Date of first authorization/renewal of the authorization

2026 June 22

10. Date of revision of the text

2026 June 22