Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Poliomyelitis Vaccine (Oral) Bivalent Type 1 and 3 - 10 and 20 dose

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 drops (0.1 ml) contains Polio virus (Sabin), grown on Primary Monkey Kidney Culture:

Contents	Quantity per 0.1 ml [Each dose of 2 drops]	Active / Non active	Specification	Reason for inclusion
Polio virus (Sabin) Type 1	$\geq 10^{6.0}$ $CCID_{50}$	Active	WHO TRS 980, Annex 2, 2014	Immunizing agent
Polio virus (Sabin) Type 3	$\geq 10^{5.8}$ $CCID_{50}$			
Neomycin Sulphate	15 mcg	Non active	USP	Preservative
Magnesium Chloride	1M	Non active	IP/BP/Ph. Eur	Stabilizer

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Bivalent OPV (Type 1 and 3) is indicated for active Immunization against Type 1 & 3 Polioviruses.

4.2 Posology and 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 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 saliva of the vaccinee. Overdose if any, will not result in ill effect.

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 immunization session may be used in subsequent immunization sessions for upto a maximum of 28 days, provided that all of the following conditions are met (as described by WHO policy statement. The use of opened multidose vials in subsequent immunization sessions WHO/IV B/14.07):

- The vaccine is currently prequalified by WHO;

- The vaccine is approved for use for upto 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; furthermore, 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 OPV to a sick child. In case of Diarrhea or vomiting (including gastrointestinal infection) the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

Individuals infected with Human Immune Deficiency Virus (HIV) both symptomatic and asymptomatic 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

Bivalent OPV (Type 1 and 3) can be administered at the same time as Haemophilus influenzae type b, hepatitis B, diphtheria, pertussis and/or tetanus, pneumococcal, BCG or rotavirus vaccines according to the vaccination schedule.

Immunosuppressive therapies including irradiation, antimetabolites, alkylating agents, cytotoxic drugs 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 the Ability to Drive and Use Machines

Effect of Bivalent OPV (Type 1 and 3) on the ability to drive and operate 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.

Following adverse events were observed in 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

How and where to Report Adverse Effects Following Immunization (AEFIs):
AEFIs can be reported to SIIPL Pharmacovigilance division on mail id:
pharmacovigilance@seruminstitute.com

4.9 Overdose
How to handle overdose: No case of overdose has been reported. However, to be on safer side, observation for clinical symptoms may be done for a period of 4 weeks. The common side effects may be exaggerated in case of overdose. As per 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

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

Mechanism of Action:
Bivalent OPV (Type 1 and 3) induces the production of neutralizing antibodies against each type of virus which are related to protective efficacy.

5.2 Pharmacokinetic Properties
Pharmacokinetic studies are not required for vaccines.

5.3 Preclinical Safety Data
No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients
- Magnesium Chloride
- Tween 80 (Polysorbate 80)
- Neomycin Sulfate
- Water for Injections

6.2 Incompatibilities

Stability studies have demonstrated compatibility of the container closure system with the drug product. No decrease in potency of the final vaccine as a result of sorption to the primary packaging materials during storage has been found.

6.3 Shelf-life

Shelf life of the Medicinal Product as Packages for Sale:

24 Months. 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 6 months between +2°C and +8°C.

6.4 Special Precautions for Storage

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 6 months between +2°C and +8°C.

6.5 Nature and Contents of Container

13 mm USP Type I, clear, tubular, European blow back glass vials of 16.5 mm diameter and 40 mm height and 4.0 ml overflow volume. Vials are stoppered with a 13 mm Grey coloured Rubber stopper, 13 mm lime green seals made up of Aluminum seal with flip top tear down mechanism with polypropylene disc on top.

6.6 Special Precautions for Disposal and Other Handling

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7. MARKETING AUTHORISATION HOLDER

SERUM INSTITUTE OF INDIA PVT LTD
REGD OFFICE AND LABORATORIES
212/2, HADAPSAR, PUNE-411028.
INDIA.

8. MARKETING AUTHORISATION NUMBER(S)

SER/IND/018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 21st January 2016

Date of latest renewal: 09th February 2021

10. DATE OF REVISION OF THE TEXT

July 2023