SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT:

Name of the product: Bivalent Poliomyelitis Vaccine Type 1 & Type 3, Live (Oral)
Strength: Each dose of 0.1 mL Contains:
Poliovirus Type 1 (Sabin Strain): NLT $10^{6.0}$ $CCID_{50}$
Poliovirus Type 3 (Sabin Strain): NLT $10^{5.8}$ $CCID_{50}$
Pharmaceutical Form: Vaccine (Liquid)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each dose of 0.1 mL Contains:

Sl. No.	Ingredient	Quantity per dose 0.1mL
1 2	Poliovirus Type 1 (Sabin Strain)	NLT $10^{6.0}$ $CCID_{50}$
3	Poliovirus Type 3 (Sabin Strain)	NLT $10^{5.8}$ $CCID_{50}$
4	$MgCl_26H_2O$ IP/BP	20.33 mg
5	Tween 80 IP/BP	10 mcg
6	Kanamycin Acid Sulphate IP/BP	15 mcg
7	Neomycin Sulphate IP/BP	15 mcg
8	Water for Injection IP/BP	q.s. to 0.1 mL

3. PHARMACEUTICAL FORM
Vaccine (Liquid)

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
For prophylactic use only.
BIOPOLIO® B1/3 is indicated for routine immunization against poliomyelitis in children from birth to 5 years of age, to interrupt transmission of type 1 & type 3 polio viruses.

BIOPOLIO® B1/3 can be administered safely and effectively at the same time as measles, mumps, rubella, inactivated polio vaccine (IPV), DTP, DT, TT, Td, BCG, Haemophilus influenzae type b, yellow fever and hepatitis B vaccines and Vitamin A supplement.

4.2. Posology and method of administration

BIOPOLIO® B1/3 must be administered only orally. Two drops are delivered directly into the mouth of the vaccinee from the multi-dose vial by dropper or dispenser. Care should be taken not to contaminate the multi-dose dropper with saliva of the vaccinee.

Multi-dose vials of **BIOPOLIO® B1/3** from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 28 days after opening, provided that all of the following conditions are met (as described in the WHO Policy Statement: Multi-Dose Vial Policy (MDVP) Revision 2014 WHO/IVB/14.07). Once opened, multi-dose vials should be kept between +2°C and +8°C.

- The vaccine is currently prequalified by WHO.
- The vaccine is approved for use for up to 28 days after opening of the vial, as determined by WHO

(http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/).

- The expiry date of the vaccine has not passed.
- The vaccine vial has been, and will continue to be, stored at the recommended temperature; furthermore, the vaccine vial monitor is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

4.3 Contraindications

BIOPOLIO® B1/3 is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukemia, lymphoma or generalized malignancy. No adverse effects are produced by giving BIOPOLIO® B1/3 to a sick child. In case of diarrhea, 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 BIOPOLIO® B1/3 according to standard schedules.

4.4 Special warning and Precautions for use

Millions of BIOPOLIO® B1/3 doses have been dispensed, and no major adverse effects have been observed, except for vaccine-associated paralysis (one case per 1 million doses

administered). Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine-associated paralytic poliomyelitis.

4.5 Interaction with other medicinal products/active immunising agents and other forms of interaction

No interaction studies have been performed.

4.6. Pregnancy and lactation

No data available

4.7. Effect on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Millions of **BIOPOLIO® B1/3** doses have been dispensed, and no major adverse effects have been observed, except for vaccine-associated paralysis (one case per 1 million doses administered). Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine-associated paralytic poliomyelitis.

BIOPOLIO® B1/3 is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukemia, lymphoma or generalized malignancy. No adverse effects are produced by giving BIOPOLIO® B1/3 to a sick child. In case of diarrhea, 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 BIOPOLIO® B1/3 according to standard schedules.

4.9. Overdose

No data available

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not Applicable

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Pre-clinical safety data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

BIOPOLIO® B1/3 contains Magnesium Chloride ($MgCl_2$)1 Molar and Tween 80 as stabilizer; both Kanamycin Acid Sulphate and Neomycin Sulphate as antibiotics.

6.2 Incompatibilities

The vaccine should not be mixed with any other medicinal products or active immunizing agents.

BIOPOLIO® B1/3 can be administered safely and effectively at the same time as measles, mumps, rubella, inactivated polio vaccine (IPV), DTP, DT, TT, Td, BCG, Haemophilus influenzae type b, yellow fever and hepatitis B vaccines and Vitamin A supplement.

6.3 Shelf life

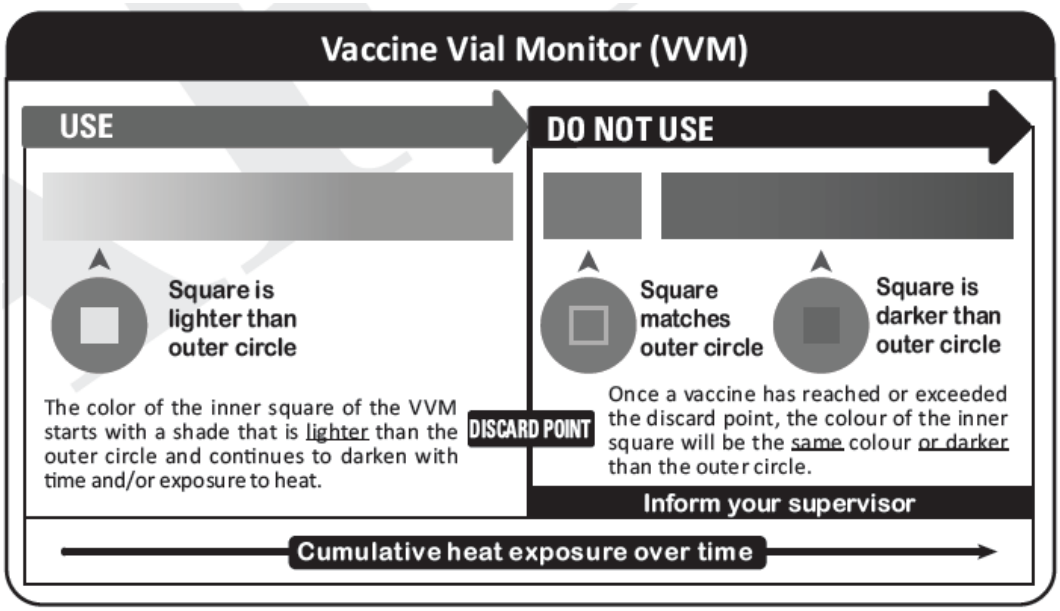
The expiry date of BIOPOLIO® B1/3 is indicated on the label and carton of the vaccine.

6.4 Special Precautions for Storage

The recommended storage temperature for BIOPOLIO® B1/3 is at -20°C or below until the expiry date indicated on the vial. It can be stored up to six months between 2°C and 8°C during its shelf -life.

Multi-dose vials of BIOPOLIO® B1/3 from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 28 days after opening, provided that all of the following conditions are met (as described in the WHO Policy Statement: Multi-Dose Vial Policy (MDVP) Revision 2014 WHO/IVB/14.07). Once opened, multi-dose vials should be kept between +2°C and +8°C.

Figure: The Vaccine Vial Monitor



The Vaccine Vial Monitor

Vaccine Vial Monitors (VVM2) are part of the label on all BIOPOLIO® B1/3 vials. VVM2 are supplied by TEMPTIME Corporation, U.S.A. The colour dot which appears on the label of the vial is a VVM2. 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 VVM2 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 ring, the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, the vial should be discarded.

6.5 Nature and contents of container

BIOPOLIO® B1/3 vaccine is presented as 10 doses per vial and 20 doses per vial.

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

Bharat Biotech International Limited situated
Sy. No. 230, 231 & 235, Genome Valley,
Turkapally, Shamirpet Mandal,
Medchal, Malkajgiri District, Telangana State, India, Pin: 500078.

8. MARKETING AUTHORISATION NUMBER

MF-224/10

9. DATE OF FIRST MARKETING AUTHORISATION

12 MAR 2010

10. DATE OF REVISION

April 2021