BIOPOLIO® B1/3

DESCRIPTION
BIOPOLIO® B1/3 contains suspension of live attenuated poliovirus type 1 and type 3 viruses (Sabin strain) pre-prepared in Primary Monkey Kidney Cells. Each dose contains not less than 10⁷ 50% CPE (50% CPE: Virus concentration of type 1 strain and 10⁴ 50% CPE virus concentration of type 3 strain). BIOPOLIO® B1/3 contains Magnesium Chloride (MgCl₂), Motor as stabilizer; both Karahim Acid Sulfate and Neomycin Sulfate as antibiotics. The vaccine fullfills WHO requirements for Bivalent Poliovirus Vaccine type 1 & 3, Live (oral).

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 dispencer. 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, multidose vials should be kept between -2°C and +4°C.

- The vaccine is currently pre-qualified 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/MVQ_vaccine_1st_edition).
- The expiry date of the vial 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.

IMMUNIZATION SCHEDULE
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. It is also indicated for poliomyelitis supplementary immunization activities (SIAs) in all age groups, to interrupt type 1 & type 3 polio viruses transmission in India and also in the remaining polio endemic areas.

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

ADVERSE EFFECTS
Millions of BIOPOLIO® B1/3 doses have been dispenses, and no major adverse effects have been observed, except for vaccine-associated paralytic poliomyelitis.

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 death, 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.

STORAGE
The recommended storage temperature for BIOPOLIO® B1/3 is at: 2-8°C or below until the expiry date indicated on the vial. It can be stored at +2°C and +8°C at any time during the shelf-life and the expiry of VMV.

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

Customer Name: Bharat Biotech Intl. Ltd.
Product Name : BIOPOLIO B1/3 PACKINSERT for Domestic
Size : 90 X 200 mm
Paper : News print Paper
Gsm : 45±10
Printing : Front/ Back
Colour : 90% Black,
Folding : V-2 50mm
Note: 1. This approval will be considered for final printing
2. Kindly re-check thoroughly before approval.

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