Bivalent Poliomyelitis Vaccine type 1 & 3, Live (Oral)

For children

BIOPOLIO® B1/3

DESCRIPTION

BIOPOLIO® B1/3 contains suspension of live attenuated poliomyelitis type 1 and type 3 viruses (Sabin strain)prepared in Primary Monkey Kidney Cells. Each dose contains not less than $10^{6.0}$ $CCID_{50}$ virus concentration of type 1 strain and $10^{5.8}$ $CCID_{50}$ virus concentration of type 3 strain. **BIOPOLIO® B1/3** contains Magnesium Chloride ($MgCl_2$) 1Molar as stabilizer; both Kanamycin Acid Sulphate and Neomycin Sulphate as antibiotics. The vaccine ful fills WHO requirements for Bivalent Poliomyelitis 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 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 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/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.

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.

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.

ADVERSE 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.

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.

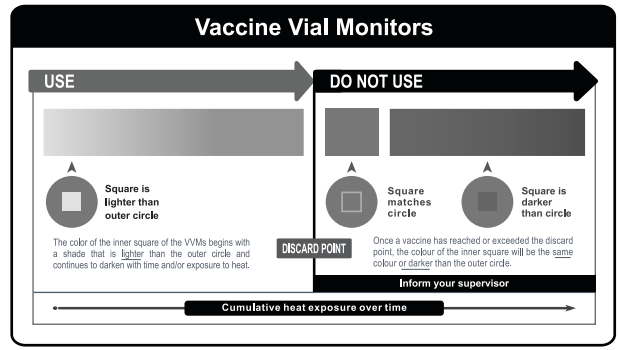
STORAGE

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 at + 2°C and +8°C at any time during the shelf-life until the expiry of VVM2.

PRESENTATION

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

Fig. The Vaccine Vial Monitor



Vaccine Vial Monitors (VVM2) are part of the label on all **BIOPOLIO® B1/3** vials. VVM2s 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 willchange 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.

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