

Poliomyelitis Vaccine, Live (Oral) I.P. For Children **BIOPOLIO**[®]

DESCRIPTION

The live oral polio vaccine (OPV) is a trivalent vaccine containing suspensions of types 1, 2 and 3 attenuated poliomyelitis viruses (Sabin strains) prepared in Primary Monkey Kidney Cells. Each dose contains not less than $10^{6.0}$ CCID₅₀ virus concentration of type 1, $10^{5.0}$ CCID₅₀ virus concentration of type 2, and $10^{5.8}$ CCID₅₀ virus concentration of type 3. MgCl₂ 1M is used as a stabilizer. OPV contains Kanamycin and Neomycin sulphate as antibiotics.

ADMINISTRATION

OPV must only be administered orally. Two drops are delivered directly into the mouth from the multidose vial by dropper or dispenser. 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 multidose dropper with saliva of the vaccinee.

Once opened, multi-dose vials should be kept between +2°C and +8°C.

Multi-dose vials of OPV 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 4 weeks, provided that all of the following conditions are met (as described in the *WHO policy statement: The use of opened multi dose vials in subsequent immunization sessions. WHO/N&B/00.09*):

- The expiry date has not passed;
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water;
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point (see figure).

IMMUNIZATION SCHEDULE

Infants should receive at least three doses of OPV at minimum intervals of 4 weeks. WHO recommends the following schedule in endemic countries: Birth, 6, 10, 14 weeks. In non-endemic areas the first dose can be given from 6 weeks with the first dose of DTP.

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

SIDE EFFECTS

In the vast majority of cases there are no side effects. Very rarely, there may be 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

No adverse effects are produced by giving OPV to a sick child. In case of diarrhoea, 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 OPV 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.

STORAGE

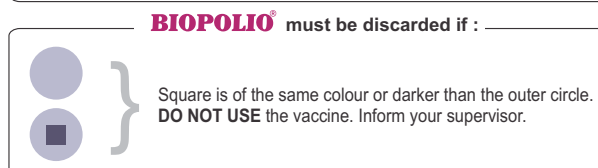
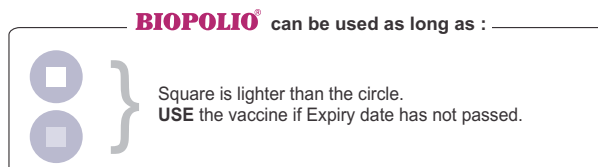
Vaccine is potent if stored at not higher than -20°C until the expiry date indicated on the vial. It can be stored for up to six months between +2°C and +8°C.

The vaccine supplied in plastic tubes may change colour due to storage with dry ice; however this does not affect the quality of the vaccine.

PRESENTATION

The vaccine comes in 10 doses per vial and 20 doses per vial.

Fig. The Vaccine Vial Monitor



Vaccine Vial Monitors (VVMs) are part of the label on all Oral Polio Vaccine supplied by TEMPTIME Corporation, U.S.A. The colour dot which appears on the label of the vial is a VVM. 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 VVM 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, then 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, then the vial should be discarded.

Manufactured & Marketed by:



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Insert Front: 90 mm x 200 mm

Insert Back : 90 mm x 200 mm