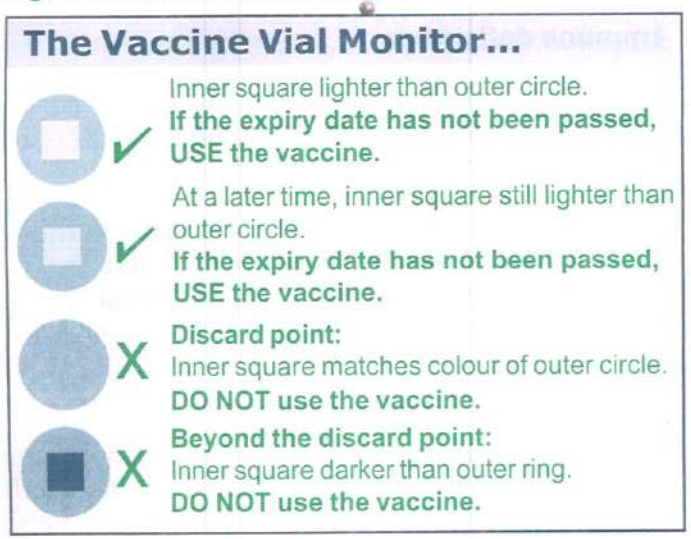
Fig. The Vaccine Vial Monitor



Vaccine Vial Monitors (VVMs) are part of the label on all Bivalent Types 1 & 3 Oral Polio Vaccine supplied by TEMPTIME Corporation, USA. 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.

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Instructions for use

BIVALENT TYPES 1 & 3 ORAL POLIO VACCINE(bOPV) FOR CHILDREN

DESCRIPTION

The live types 1 & 3 oral polio vaccine (bOPV) is a bivalent vaccine containing suspensions of types 1 and 3 attenuated poliomyelitis viruses (Sabin strains) prepared in primary monkey kidney cell cultures (P.M.K.C.C.). Each dose contains 2 drops of infective units of Poliovirus Type 1 10^{6} $CCID_{50}$ and Type 3 $10^{5.8}$ $CCID_{50}$. 1 Molar Magnesium chloride is used as a stabilizer.
bOPV may contain trace amounts of Erythromycin and Kanamycin. **The vaccine fulfils WHO requirements for Bivalent Types 1 & 3 Oral Polio Vaccine.**

ADMINISTRATION

bOPV must only be administered orally. Two drops are delivered directly into the mouth from the multidose vial by dropper or dispenser. 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 bOPV 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 : Handling of Multi-Dose Vaccine Vials After Opening. WHO/IVB/14.07):***

- The vaccine is currently prequalified by WHO;
- The vaccines is approved for use for up to 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/ Manufacturers recommended temperatures (+2°C and +8°C), once opened;
- The vaccine vial monitor (VVM), attached is visible and , has not reached the discard point (see figure).

IMMUNIZATION SCHEDULE

Bivalent Types 1 & 3 Oral Poliomyelitis Vaccine is to be indicated for poliomyelitis routine immunisation in addition to Supplementary Immunisation Activities (SIAs) in children from 0 to 5 years of age, to interrupt types 1 & 3 poliovirus transmission in remaining polio endemic areas. The routine poliomyelitis vaccination programme should continue according to national policy.

bOPV can be given safely and effectively at the same time as IPV, 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 reported with the trivalent OPV, that includes the same bOPV component.
Very rarely, there may be vaccine-associated paralysis. Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine-associated paralytic poliomyelitis.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

In case of diarrhoea, the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

CONTRAINDICATIONS

Immune deficiency

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, 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.

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.

PRESENTATION

The vaccine comes in vials of 20 doses (2ml).
Due to minor variation of its pH, OPV may vary in colour from light yellow to light red.