English

BIVALENT ORAL POLIOMYELITIS VACCINE TYPES 1 & 3

drops

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. Each dose (2 drops = 0.1 ml) contains not less than $10^{6.0}$ infective units of type 1 and $10^{5.8}$ of type 3. Sucrose is used as a stabilizer. bOPV may contain trace amounts of not more than 2 mcg erythromycin and not more than 10 mcg kanamycin.

ADMINISTRATION

bOPV must only be administered orally. Two drops are delivered directly into the mouth from the multidose vial by dropper. 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: Multi-dose Vial Policy (MDVP), WHO/IVB/14.07):

- The vaccine is currently prequalified by WHO;
- The vaccine 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 or manufacturer's recommended temperatures; furthermore, the vaccine vial monitor (VVM), if attached, is not past its discard point (see figure).

IMMUNIZATION SCHEDULE

bOPV is indicated for active immunization in all age groups against infection caused by poliomyelitis viruses of Type 1 and 3.

The immunization schedule must be in accordance with the national recommendations.

bOPV can be given safely and effectively at the same time as measles, rubella , mumps, DTP, DT, TT, Td, BCG, hepatitis B, Haemophillus influenzae type b, yellow fever vaccine, IPV (inactivated Polio 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.

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

No adverse effects are produced by giving bOPV to a sick child.

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

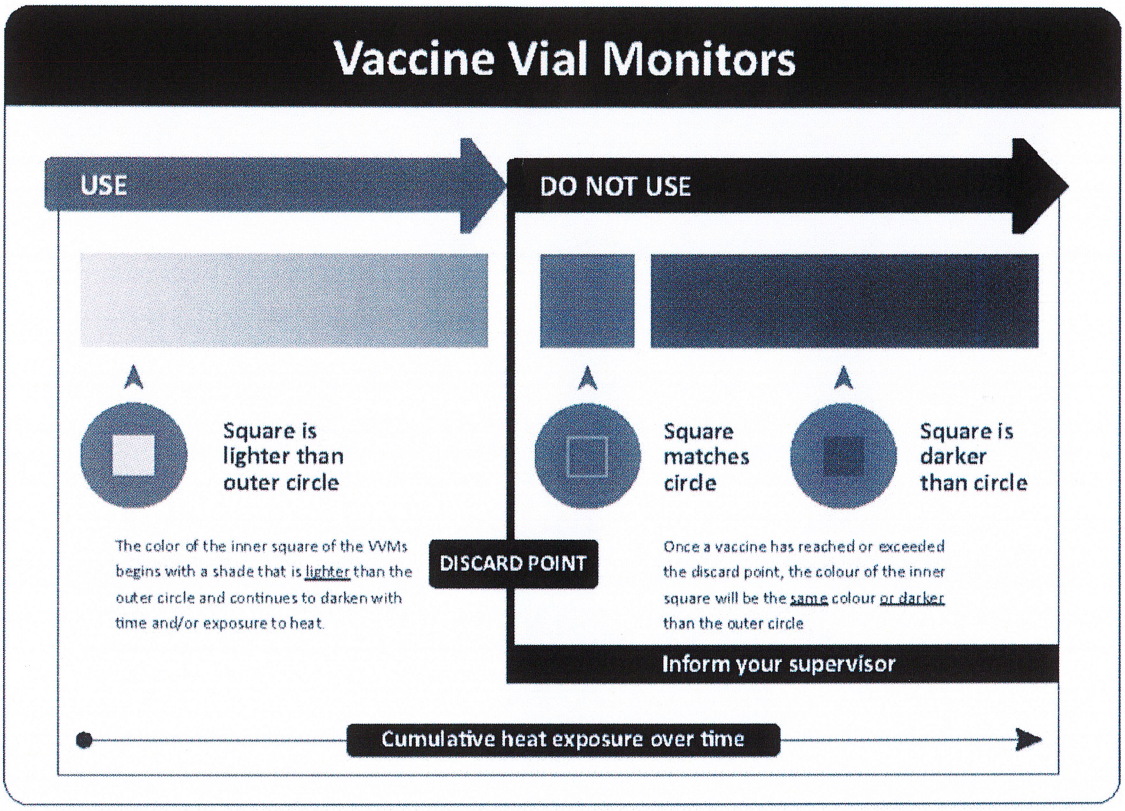
Vaccine is potent if stored at not higher than -20°C until the expiry date indicated on the vial.

It can be stored for up to six months between +2°C and +8°C.

The vaccine may present a colour varying from light yellow to light red, due to a slight variation of pH; however this does not affect the quality of the vaccine.

PRESENTATION

The vaccine comes in vials of 10 and 20 doses.



Vaccine Vial Monitors (VVMs) are part of the label on all bOPV supply through Temp Time. 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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