

POLIOMYELITIS VACCINE, LIVE (ORAL) IP (OPV) ORAL POLIO VACCINE FOR CHILDREN

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 monkey kidney cells. Each dose contains not less than virus concentration per dose $10^{6.0}$ CCID₅₀ of type 1, $10^{5.5}$ CCID₅₀ of type 2 and $10^{5.8}$ CCID₅₀ of type 3. 1M MgCl₂ is used as a stabilizer and phenol red as indicator. During formulation of OPV trace amounts of antibiotics: Kanamycin and Neomycin sulphate are added.

ADMINISTRATION

OPV must only be administered orally. Two drops are delivered directly into the mouth of vaccinee 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 vaccinees.

Once opened, multi-dose vials should be kept at $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ for not more than 4 weeks.

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 period 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/V&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). After opening, immediate use is recommended.

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.

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 OPV to a sick child.

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 minus 20°C or below until the expiry date as indicated on the vaccine vial label. It can be stored up to six months at $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

PRESENTATION

The vaccine comes in vials of 20 doses.

Vaccine Vial Monitors (VVMs) are part of the label on all Oral Polio Vaccine vials. These VVMs are 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, 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 vaccine vial should be discarded.

Figure of the Vaccine Vial Monitor (VVM)

The vaccine vial monitor ...



Inner square is lighter than outer circle.
If the expiry date has not been passed,
USE the vaccine.



At a later time, inner square still lighter than outer circle.
If the expiry date has not been passed,
USE the vaccine.



Discard point :
inner square matches colour of outer circle.
Do not use the vaccine.

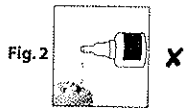


Beyond the discard point :
Inner square darker than outer circle.
Do not use the vaccine.

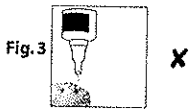
Holding Position of Dropper During Vaccine Delivery



Hold the vial at tilted position
during vaccine delivery into the mouth



Do not hold the vial horizontally
for vaccine delivery into the mouth



Do not hold the vial vertically
for vaccine delivery into the mouth

Directions for use of droppers

1. Use specific droppers supplied by Panacea Biotec Ltd.
2. Dropper should be discarded with vaccine vial as re-use of droppers from one vial to another may lead to crack and leakage.
3. Always hold the vial in tilted position (ref. fig. 1) for vaccine delivery.
4. Press the dropper gently just above the delivery nozzle with soft part of the fingers avoiding nail contact.
5. Bring vial along with dropper back to upright position after delivery of each dose.
6. Put the nozzle cover back on the dropper when there is some time elapsed between two consecutive vaccine deliveries.


Panacea Biotec
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Manufactured by :
Panacea Biotec Ltd,
A-241, Okhla Indl. Area-1,
New Delhi - 110 020, India.

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