BIO-MED
PRIVATE LIMITED

PREVENT DISEASES BY VACCINATION

In Service Since 1974

POLIOMYELITIS VACCINE, LIVE (ORAL) I.P.
Di-Valent (bivalent/b-OPV)
(Type 1 and Type 3)

DESCRIPTION

The Live Oral Polio Vaccine is a Di-valent (bivalent/b-OPV) vaccine containing mixture of type 1 and type 3 attenuated poliomyelitis viruses (Sabin strains) propagated in primary monkey kidney cells. Each dose contains an estimated mean virus titre of not less than $10^{6.0}$ $CCID_{50}$ for Type 1, $10^{5.8}$ $CCID_{50}$ for Type 3. 1M $MgCl_2$ is used as a stabilizer, Kanamycin 20 mcg per dose is added as preservative. Oral Polio Vaccine is a clear liquid which have a faint yellowish to reddish colour. The colour is due to presence of phenol red indicator. The vaccine tends to shift towards yellowish colour at lower temperatures & frozen state, however this does not affect the quality of vaccine. Oral Polio Vaccine bulk used in manufacture is imported from W.H.O prequalified supplier. Di-Valent (bivalent/b-OPV) (Type 1 and Type 3) is indicated for active immunization against Type 1 and Type 3 Polio viruses.

INSTRUCTIONS FOR USE

1. Thaw the frozen vaccine, mix contents by gentle shaking. Check the vial for any suspended particulate matter, in case of presence of suspended particulate matter discard the vial.
2. Remove the tear down aluminium seal and rubber stopper.
3. Open the sterilized plastic dropper and immediately fit on top of the glass vial.
4. Remove the cap of plastic dropper, invert the dropper vial assembly and gently squeeze 2 drops of vaccine directly into the mouth. Care should be taken not to contaminate the dropper nozzle with saliva.
5. Replace the cap of dropper.

ADMINISTRATION

Vaccine must only be administered orally. Once opened, multi-dose vials should be kept between +2°C to +8°C.

Multi-dose vials of vaccine 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/V&B/00.9) :

- 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), has not reached the discard point (see figure).

IMMUNIZATION SCHEDULE

Poliomyelitis Vaccine is indicated for prevention of poliomyelitis against Type 1 and Type 3 Polio viruses, pulse polio program and in supplementary immunization activities (SIAs) in children from 0 to 5 years of age. The doses and interval of Poliomyelitis vaccination should be according to national policy. Vaccine can be given safely and effectively at the same time as measles, rubella, mumps, DTP and Vitamin A supplementation.

SIDE EFFECTS

In the vast majority of cases there are no side effects reported with the vaccine. 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.

ADDITIONAL INFORMATION ON STABILITY

Vaccine is stable for at least 2 years when stored at or below -20°C and for at least 6 months when kept at +2°C to +8°C

CONTRAINDICATIONS

- **Immune deficiency -** Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with the vaccine according to standard schedules. However, the vaccine is contraindicated in those with primary immune deficiency diseases or suppressed immune response from medication, leukaemia, lymphoma or generalized malignancy.

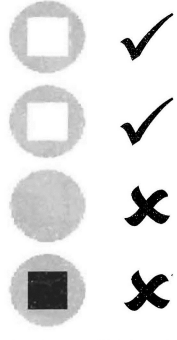
- Administration of vaccine should be delayed in children suffering from acute febrile illness, infection, diarrhoea, dysentery, debilitating ailment and abdominal pain.

STORAGE

Vaccine is potent if stored at or below -20°C until the expiry date indicated on the label.

VACCINE VIAL MONITOR (VVM)

The VVM is a small square, made of heat sensitive material placed in an outer coloured circle. Combined effects of time and temperature cause the VVM to change colour gradually, from white at the starting point to grey colour to dark grey with exposure to heat. The darkening process is irreversible. The outer coloured circle is used as reference to compare the colour of the VVM. Vaccine can be used if colour of inside square has lighter shade than the colour of reference circle.



If the Square is lighter than the circle & if the expiry date is not passed, USE the vaccine

If the Square is lighter than the circle & the expiry date is not passed, USE the vaccine.

If the Square matches the circle, DO NOT USE the vaccine. Inform your supervisor.

If the Square is darker than the circle, DO NOT USE the vaccine. Inform your supervisor.

Manufactured & Marketed by :

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AN ISO 9001, 14001
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