

Monovalent Type 1 Poliomyelitis Vaccine, Live (Oral)

Monovalent Oral Polio Type 1 Vaccine (mOPV Type 1)

DESCRIPTION

mOPV Type 1 (Substrate - Monkey Kidney Cells)

The live monovalent Oral Polio Type 1 Vaccine (mOPV Type 1) contains suspension of live attenuated poliomyelitis type 1 virus (Sabin strain) prepared in Monkey Kidney cells. Each dose contains not less than $10^{6.0}$ CCID₅₀ virus concentration of type 1. MgCl₂1M is used as a stabilizer and phenol red as an indicator. During formulation of mOPV Type 1 trace amounts of antibiotics: Kanamycin & Neomycin Sulphate are added.

mOPV Type 1 (Substrate - Vero Cells)

The live monovalent Oral Polio Type 1 Vaccine (mOPV Type 1) contains suspension of live attenuated poliomyelitis type 1 virus (Sabin strain) prepared in Vero cells. Each dose contains not less than $10^{6.0}$ CCID₅₀ virus concentration of type 1. MgCl₂1M is used as a stabilizer and phenol red as an indicator. During formulation of mOPV Type 1 trace amounts of antibiotics: Kanamycin & Neomycin Sulphate are added.

ADMINISTRATION

mOPV Type 1 must 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 four weeks. Multi-dose vials of mOPV Type 1 from which one or more doses of vaccine have been removed during 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

The live Monovalent Oral Polio Type 1 Vaccine (mOPV Type 1) is indicated for poliomyelitis Supplementary Immunisation Activities (SIAs) in children from 0 to 5 years of age, to interrupt type 1 poliovirus transmission in remaining polio endemic areas. The routine poliomyelitis vaccination programme should continue to use trivalent vaccines according to national policy.

SIDE EFFECTS

In the vast majority of cases there are no side effects reported with trivalent OPV, that includes the same mOPV Type 1 as one of the component. Very rarely, there may be vaccine associated paralysis (less than 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 mOPV Type 1 to a sick child.

Immune deficiency

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with mOPV Type 1 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°C ± 3°C.

PRESENTATION

The vaccine comes in vials of 20 doses.

Vaccine Vial Monitors (VVMs) are put on all mOPV Type 1 vials 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)



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.