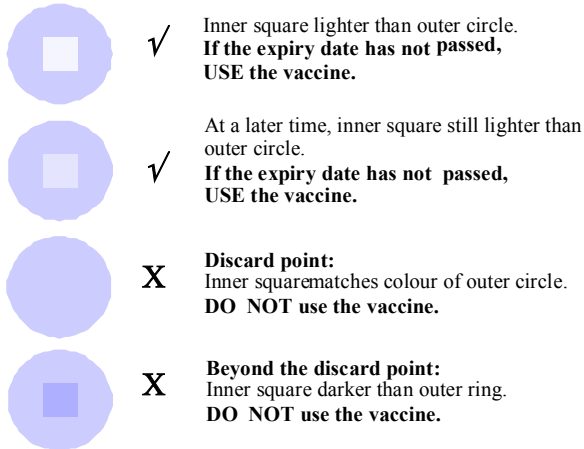


How to read VVM?

The vaccine vial monitor...



Do not use any OPV if the expiry date has passed even if the VVM is lighter than the outer circle.

HAFFKINE BIO-PHARMACEUTICAL CORPORATION LIMITED

(A Govt. of Maharashtra Undertaking)
Acharya Donde Marg, Parel, Mumbai- 400 012.
Tel + 91 22 2412 9320 Fax: + 91 22 24168578
Telegraph Add: HAFFKINE Mumbai
Website : www.vaccinehaffkine.com
e- mail : mkt@vaccinehaffkine.com
qa@vaccinehaffkine.com



Service to Mankind

Instructions for use POLIOMYELITIS VACCINE, (ORAL) IP

DESCRIPTION

The live, Oral Poliomyelitis vaccine (OPV) is a clear, transparent, yellowish orange or light pink coloured solution. The Poliomyelitis Vaccine (oral) is a trivalent vaccine containing suspension of types 1, 2 and 3 attenuated poliomyelitis viruses (Sabin strains) propagated in primary monkey kidney cell cultures (P.M.K.C.C) Each dose of 2 drops (0.1 ml) contains at least Poliovirus (Sabin) Type 1 – 10^6 , Type 2 – 10^5 and Type 3 – $10^{5.8}$ CCID₅₀ [The potency of the vaccine is expressed in the quantity of the virus suspension, that will infect 50% of cell Cultures]. These polioviruses are suspended in Hanks' Balanced Salt Solution with one Molar Magnesium chloride as a stabilizer and phenol red as a pH indicator. OPV may contain trace amounts of Erythromycin and Kanamycin. The vaccine fulfils WHO requirements for Oral Poliomyelitis Vaccine.

INDICATIONS

OPV is indicated for active immunisation of infants, susceptible children and adults against infection caused by polioviruses of Types 1, 2 & 3.

ADMINISTRATION

OPV must only be administered orally. Two drops are delivered directly into the mouth from the multi dose vial by dropper. 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 multi dose dropper with saliva of the vaccinee. Overdose, if any, will not result in ill - effect.

Once opened, multi-dose vials should be kept between +2°C and +8°C. 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 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).

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 six 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.

BOOSTER IMMUNIZATION

Booster doses might be considered every second year till the child is about eight years old. Booster doses may also be considered under the threat of an epidemic. It may also be given occasionally in adult life when a person is likely to be exposed to high risk of infection such as persons working or likely to come in contact with the virus and when travelling to endemic areas.

Although there is no evidence that live, attenuated polio vaccines have an adverse effect on the foetus, in accordance with general principles, the vaccine should not be given to pregnant women unless they are exposed to definite risk of infection with wild polioviruses.

ACTION & USES

Poliomyelitis Vaccine (oral) is administered to stimulate the body mechanism to produce active immunity by simulating the natural infection without producing untoward symptoms of the disease. This is achieved by multiplication of the vaccine virus in the intestinal tract.

SIDE EFFECTS

In the vast majority of cases there are no side effects. Very rarely, there may be vaccine-associated paralysis (one case per one million doses administered). Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine-associated paralytic poliomyelitis.

CONTRAINDICATIONS

No adverse effects are produced by giving OPV to a sick child. In case of diarrhoea or vomiting (including gastro-intestinal infection), the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

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 or below -20°C until the expiry date indicated on the vial i.e. for a period of two years from the date of manufacture. It can be stored for up to six months between +2°C and +8°C. Exposure of the vaccine to sunlight must be avoided. The vaccine may change colour due to storage with dry ice; however this does not affect the quality of the vaccine. Shipment of the vaccine should be done under cold chain and should be immediately stored at -20°C until administration.

PRESENTATION

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

MODE OF USE :

Remove the vaccine vial from cold storage and examine the Vaccine Vial Monitor on the label. Vaccine Vial Monitors (VVMs) are part of the label on all OPV vials. The colour dot 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.

Allow the vaccine to thaw and examine the vial to ensure that the vaccine is clear and transparent. With clean hands, tear off the metal seal, remove the rubber cork and fix the dropper onto the vial. Remove the cap of the dropper and feed two drops of vaccine directly into the mouth of the child by pressing the dropper. Put cap on the dropper and return the vial to cold storage.

CAUTION:

Vaccine, if not handled in an aseptic manner may develop turbidity due to bacterial or fungal contamination. Fingers should never come in contact with the vaccine. The tip of the dropper should never be touched and should always be covered with the cap while in store. Vaccine should be checked carefully for clarity before every use and must be discarded if found turbid.