

For use by a Registered Medical Practitioner or Hospital or Laboratory only

पोलियोमाइलिटिस वैक्सिन, लईव (ओरल) आई.पी.

Poliomyelitis Vaccine, Live (Oral) I.P.

BIOPOLIO

बायोपोलियो®

DESCRIPTION

Poliomyelitis is primarily a disease of infancy and childhood. However it can be contracted at any age. The paralysis and mortality is highest in the first 5 years of age. Therefore immunization should be completed early in life for efficient prophylaxis against Poliomyelitis. The Poliomyelitis Vaccine Live, (oral) is for active immunization of infants and children against Poliomyelitis.

Composition: The Live Oral Poliomyelitis Vaccine (OPV) is a trivalent vaccine containing aqueous suspension of types 1,2 and 3 attenuated Poliomyelitis viruses (Sabin Strains), derived from PMKCC. Each dose contains not less than $10^{6.0}$ CCID₅₀ infectious units of type 1, $10^{5.0}$ CCID₅₀ infectious units of type 2 and $10^{5.0}$ CCID₅₀ infectious units of type 3. Magnesium chloride is used as a stabilizer. Kanamycin and neomycin at a concentration of 15 mcg each per dose are used as antibiotics.

BIOPOLIO is manufactured from the WHO pre qualified monovalent Type1, Type2 and Type3 bulks.

The Vaccine fulfils the requirements of Indian Pharmacopoeia for Poliomyelitis Vaccine, Live (Oral) 1996 and WHO Requirements for Poliomyelitis Vaccine, Live (Oral) TRS 800-1990.

Instructions for use: Shake the vial well. Remove the aluminium seal and the rubber cap, fix the pre sterilized plastic dropper supplied along with the vial. Hold the vial inverted vertically and gently squeeze the plastic dropper to expel the vaccine drop by drop

DOSAGE AND ADMINISTRATION

The recommended dose for OPV is 0.1 ml (2 drops). The drops are administered directly into the mouth from the multi dose vial through dropper.

WARNING: BIOPOLIO is a clear liquid with a light pink or red colour which may change to pale yellow in frozen condition. The vaccine should not be used if turbidity is noticed on thawing or standing.

TWO DROPS CONSTITUTE THE RECOMMENDED ONE DOSE

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.

THIS VACCINE IS FOR ORAL ROUTE ONLY AND SHOULD NOT BE GIVEN PARENTERALLY

IMMUNIZATION SCHEDULE

The primary course of immunization consists of 3 doses given at an interval of 4-6 weeks. In non endemic areas the first dose can be given from 6th week, with the first dose of DTP. In endemic areas, an extra dose should be given as soon as possible after birth.

OPV can be given safely and effectively at the same time as measles, DTP, DT, Td, TT, BCG, Hepatitis B and Yellow Fever Vaccine.

CONTRA INDICATIONS

Administration of **BIOPOLIO**™ should be delayed in children suffering from acute febrile illnesses, diarrhoea and dysentery, debilitating ailment, abdominal pain and in patients undergoing steroid therapy. However, if in doubt for instance during diarrhoea a repeat dose can be given after recovery. Vaccination should be avoided in patients with leukemia, lymphoma, malignancy and dysgammaglobulinemias.

Human Immune Deficiency Virus (HIV) infected infants: HIV infected infants both asymptomatic and symptomatic, should be immunized with OPV according to standard schedules.

STORAGE

The OPV is highly sensitive to heat and rapidly loses the potency when exposed to higher temperatures. Hence the vaccine is stored at or below - 20° C and transported in frozen conditions.

When stored under prescribed conditions the vaccine retains its potency for 24 months.

When thawed it should be kept at a temperature of 2° C to 8° C and should be used within four months.

PRESENTATION - 20 dose vial
10 dose vial
(Presterilized plastic dropper with each vial)

VACCINE VIAL MONITOR (VVM)

Each vial has vaccine vial monitor-vvm

VVMs are time-temperature sensitive indicators in the form of small (dot) adhesive labels that are applied to individual vial of vaccine. It is a circle of colour with a square indicator positioned in the center of the circle. The circle of the VVM acts as a static reference colour and the sequence is an active colour change in the square. At the start point the colour of the square is lighter than the circle. The end point is indicated when the colour of the square matches the circle. The end point is exceeded when the colour of the square is darker than the circle. Once registered, the change in the colour of the indicator is irreversible.

BIOPOLIO® can be used as long as :



Square is lighter than the circle.
USE the vaccine if Expiry date has not passed.

BIOPOLIO® must be discarded if :



Square is of the same colour or darker than the circle.
DO NOT USE the vaccine. Inform your supervisor.



Manufactured & Marketed By

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