BIO FARMA BIVALENT ORAL POLIOMYELITIS VACCINE

Reg. No.: MAL20041126AZ

DESCRIPTION
The live types 1 & 3 oral polio vaccine (bOPV) is a bivalent vaccine containing suspensions of types 1 and 3 attenuated poliomyelitis viruses (Sabin strains) prepared in primary monkey kidney cell.
The vaccine may present a color varying from yellowish to pink, due to a slight variation of pH; however this does not affect the quality of the vaccine.

COMPOSITION:
Each dose (2 drops = 0.1 mL) contains :
Active Ingredients:
Poliomyelitis virus Type 1 (Sabin strain).....not less than $10^{6.0}$ $CCID_{50}$
Poliomyelitis virus Type 3 (Sabin strain).....not less than $10^{5.8}$ $CCID_{50}$
Inactive Ingredients:
SUCROSE (stabilizer).....35 % v/v.
Erythromycin.....no more than 2 mcg.
Kanamycin.....no more than 10 mcg.

ACTION AND MODE OF MECHANISMS OF ACTION:
Bivalent Oral Poliomyelitis Vaccine (bOPV) stimulates active immunity of human body to promote the development of antibodies against Poliomyelitis Virus Type 1 and 3.

PHARMACOLOGY (SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS)
Not applicable.

TOXICOLOGY (brief):
Specific toxicity tests were conducted on adult mice, guinea pigs and rabbits. The results showed no sign of abnormality and death.

INDICATIONS:
Active immunization against poliomyelitis virus type 1 and 3.

CONTRAINDICATIONS
- Bivalent Oral Poliomyelitis Vaccine is contraindicated in individuals with a history of anaphylactic reaction to the vaccine.
- Bivalent Oral Poliomyelitis Vaccine may contain trace amounts of kanamycin and erythromycin ; should be used with caution in patients with severe hypersensitivity to these antibacterials.
- Acute or developing infectious diseases.
- Leukemia, lymphoma or generalized malignancy.
- Acquired or congenital immunodepression.
- Acute intestinal diseases.

SIDE EFFECTS / ADVERSE REACTIONS:
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.

PRECAUTIONS / WARNINGS:
Human Immunodeficiency Virus (HIV) infected infants, both asymptomatic and symptomatic, should be immunized with Bivalent Oral Poliomyelitis Vaccine according to standard schedules. Simultaneous vaccination with another live vaccine should be administered separately with an interval of 2 weeks.

DRUG INTERACTION:
With Immunosuppressive medications.

PREGNANCY AND LACTATION:
In principle, a live viral vaccine constitutes a contraindication. In such cases the use of an inactivated vaccine is advisable. However, accidental vaccination at the commencement of an unknown pregnancy does not justify termination of the pregnancy. Information on the safety of the vaccine when used during lactation is not available.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION
Bivalent Oral Poliomyelitis Vaccine must only be administered orally. Shake well before use. Two drops (0.1 ml) are delivered directly into the mouth of the vaccinee from the multi-dose vial through a 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 the multi-dose dropper with the saliva of the vaccinated child.
Primary vaccination : 1 dose taken at 3, 4 , 5 months of age.
Boosters : at 1 to 4 years old and at 7 years old.
As Vaccination Schemes vary from country to country, the advised schedule for each country must be in accordance with the National Recommendation.
OPV can be given safely and effectively at the same time as measles, rubella, mump, DTP, DT, TT, Td, BCG, Hepatitis B, *Haemophillus influenzae type b*, yellow fever vaccine and Vitamin A supplement.

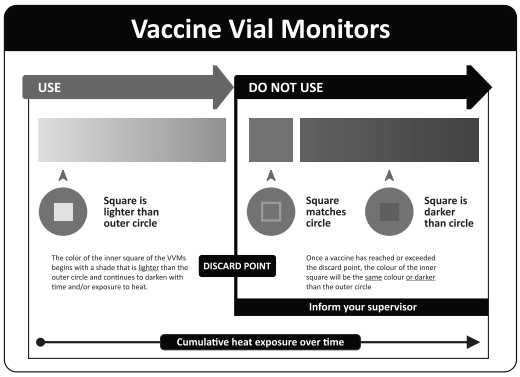
IMMUNE DEFICIENCY
Individuals infected with Human Immunodeficiency Virus (HIV), both asymptomatic and symptomatic, should be immunized with OP Vaccine according to standard schedules.

INFORMATION ON USAGE OF MULTI-DOSE VIALS OF OPV
Once opened, multi-dose vials should be kept between +2ºC and +8ºC. Multi-dose vials of bOPV from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization session for up to a maximum of 4 weeks, provided that all of the following conditions are met (as described in the WHO policy statement: Multi-Dose Vial Policy (MDVP), WHO/IVB/14.07):
- The vaccine is currently prequalified by WHO;
- The vaccine is approved for use up to 28 days after opening the vial, as determined by WHO;
- The expiry date of the vaccine has not passed;
- The vaccine vial has been, and will continue to be stored at WHO or manufacturer's recommended temperature; furthermore, the vaccine vial monitor (VVM), if attached, is not past its discard point (see figure).

SYMPTOMS AND TREATMENT FOR OVERDOSAGE, AND ANTIDOTE(S):
No cases of overdose have been reported.

PACKING / PACK SIZES:
The vaccine comes in vials of 10 doses (1 mL) and 20 doses (2 mL). Each vial is provided with a calibrated dropper which can be fitted to the vial. Every 10 vials is packed within an inner box which is enclosed with a package insert.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS :
Store at -20ºC. It can be stored up to 6 months at temperature between +2ºC and +8ºC. Protect from light.
In order to preserve optimal potency of bivalent oral poliomyelitis vaccine, exposure of the vaccine to ambient (non-refrigerated) temperatures should be kept to minimum and exposure to sunlight should be avoided. Shelf life: 2 years



Vaccine Vial Monitor (VVM) is part of the label on Oral Poliomyelitis Vaccine. 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, 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.

NAME AND ADDRESS OF DISTRIBUTOR IN MALAYSIA:
PROPHARM (M) SDN.BHD
8, Jalan Udang Harimau 2,
Medan Niaga Kepong,
51200 Kuala Lumpur.
Tel: 03-62436389
Fax: 03-62436385
Email: enquiry@propharm.com.my
Revision Date
011219

NAME AND ADDRESS OF MANUFACTURER:
biofarma
PT. Bio Farma (Persero)
Jl. Pasteur no. 28 - Bandung 40161 - Indonesia
PO Box 1136, Tel. +62 22 2033755, Fax. +62 22 2041306

biofarma	Manufactured	: PT Bio Farma (Persero)	Dimensi akhir pelipatan	: 120 x 37.5 mm
	Alamat	: Jl. Pasteur No 28 Bandung 40161	Pelipatan leaflet	: 3x lipatan
	Nama Produk	: Leaflet BOPV (Malaysia)	Warna	: 2 Warna
	Material	: HVS 70 gsm	PMS Red 032 U PMS Black U	
	Dimensi	: 120 x 300 mm, ± 2 mm	Akhir pelipatan	
	Skala	: 100 %		
	Edisi	: 011219		
	Keterangan	: -		