Summary of Product Characteristics of Poliomyelitis Vaccine, Live (Oral) I.P. Di-Valent (bivalent/b-OPV)

Manufactured By:

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Summary of Product Characteristics

(As per Annexure C of Module 1 of Guidance for industry by CDSCO)

1. Name of the Medicinal product :-

Poliomyelitis Vaccine, Live (Oral) I.P. Di-Valent (bivalent/b-OPV)

2. Qualitative & Quantitative Compositions :-

Each dose of 0.1 ml contains:	
Ingredients	**Quanitity**
Monovalent bulk of poliomyelitis Type-1 (Attenuated, Sabin strain)	$\geq 10^6$ $CCID_{50}$
Monovalent bulk of poliomyelitis Type-3 (Attenuated, Sabin strain)	$\geq 10^{5.8}$ $CCID_{50}$
Kanamycin	20mcg/dose
1 M $Mgcl_2$ as Stabilizer	

3. Pharmaceutical Form :-

Liquid Vaccine

4. Clinical Particulars :-

4.1 Therapeutic Indications:

Poliomyelitis Vaccine, Live (Oral) I.P. Di-Valent (bivalent/b-OPV) is indicated for prevention of poliomyelitis, supplementary immunization activities (SIAs) in children from 0 to 5 years of age, to interrupt poliovirus transmission in remaining polio endemic areas. The routine poliomyelitis vaccination programme should continue to use Di-Valent (bivalent/b-OPV) vaccines according to national policy. Infants should receive at least three doses of OPV at minimum intervals of 4 weeks. WHO recommends the following schedule in endemic countries; at birth 6, 10, 14 weeks. OPV can be given safely and effectively at the same time as measles, rubella, mumps, DTP and Vitamin A supplementation.

4.2 Physiology and method of administration:

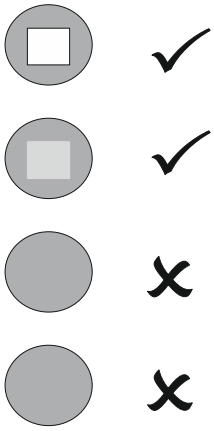
bOPV must only be administered orally. Two drops are delivered directly into the mouth from the multi dose vial by dropper. Care should be taken not to contaminate the multi dose dropper of the vaccine with saliva.

Vaccine must only be administered orally. Once opened, multi-dose vials should be kept between +2^{o}C to +8^{o}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).

- 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

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

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4.3 Contra indication:

- 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.

4.4 Special warnings and precaution 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.

4.5 Interaction with other medicinal products and other forms of interaction:

No interaction studies of Poliomyelitis Vaccine, Live (Oral) I.P. Di-Valent (bivalent/b-OPV) with other vaccine have been performed.

4.6 Pregnancy & Lactation:

The safety of Poliomyelitis Vaccine, Live (Oral) I.P. Di-Valent (bivalent/b-OPV) in pregnant Women has not been established.

4.7 Effects on ability to drive and use machines:

The Poliomyelitis Vaccine, Live (Oral) I.P. Di-Valent (bivalent/b-OPV) has no effects after vaccination on ability to drive and use machines. No separate studies were done.

4.8 Undesirable 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 with a recently vaccinated child may very rarely be at risk of vaccine-associated paralytic poliomyelitis.

4.9 Over dose:-

No cases of over dose have been reported till now.

5. Pharmacological Properties :-

5.1 Pharmacodynamics Properties :

Not applicable.

5.2 Pharmacokinetic Properties:

Not applicable.

5.3 Preclinical Safety Data :

Not applicable.

6. Pharmaceutical Particulars :-

6.1 List of excipients :-

- Magnesium chloride
- Kanamycin

6.2 Incompatibilities:-

- No compatibility studies of poliomyelitis vaccine, live (oral) I.P. Di-Valent (bivalent/b-OPV) vaccine with other vaccine was done.
- In the absence of compatibility studies the medicinal product must not be mixed with other medicinal product.

6.3 Shelf life:-

Use the product within 24 months from the date of manufacture.

6.4 Special precaution for storage:-

Store at or below -20^{o}C.

6.5 Nature & contents of container:-

a). For glass vial

The container used for manufacture of final lot of Poliomyelitis Vaccine, Live (Oral) I.P. Di-Valent (bivalent/b-OPV) is of 13 mm metro flint USP Type 1, glass vial, stoppered sealed with a grey butyl rubber stopper (pre-sterilized by radiation, ready for use) and sealed with 13 mm tear down aluminium seal. The container closure system have been tested and found to be leak proof.

b). For Plastic vial

Vaccine is packed 2 ml L.D.P.E. Repsule with white polystyrene cap.

6.6 Special precautions for disposal:

No special requirements

7. Marketing authorization Holder:-

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pharmacovigilancebm@gmail.com
Website : www.biomed.co.in

8. Marketing authorization number:-

Form 46 Permission No. MF – 269/2014 dated 10/12/2014

9. Date of first authorization/Renewal of the authorization:-

a) Additional item license No. vide Letter No. Drug/837/381 dated 16/01/2015.

b) Additional item license No. vide Letter No. Drug/837/2046 dated 24/02/2016.

c) Renewal of authorization on Form 26-H dated 21/05/2014.

10. Date of Revision of the text:-

January 2024.