**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE MEDICINAL PRODUCT

**Product Name :** Bivalent Poliomyelitis Vaccine Type 1 and Type 3, Live (Oral)

**Strength :** One dose consists of two drops (0.1 ml)

**Pharmaceutical Dosage Form**: Oral Vaccine

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each dose of two drops (0.1 ml) of Bivalent Poliomyelitis Vaccine Type 1 & Type 3, Live (Oral) contains:

| Component | Concentration Per Dose |
|---|---|
| Poliovirus Type 1 (Sabin strain) | NLT $10^{6.0}$ $CCID_{50}$ |
| Poliovirus Type 3 (Sabin strain) | NLT $10^{5.80}$ $CCID_{50}$ |
| Magnesium Chloride | 1 Molar |
| Kanamycin acid Sulphate | NMT 20 mcg |
| Neomycin Sulphate | NMT 20 mcg |
| Phenol red as indicator | |

## 3. PHARMACEUTICAL FORM

Bivalent Poliomyelitis Vaccine Type 1 and Type 3, Live (Oral) is a sterile suspension of live attenuated Poliomyelitis virus type 1 and type 3 (Sabin strain) propagated in Monkey kidney cells. It is a clear liquid with light reddish color.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications:

The Bivalent Poliomyelitis Vaccine Type 1 & Type 3, Live (Oral) is classified as prophylactic for prevention of poliomyelitis caused by Type 1 and Type 3 strains of poliovirus.

## 4.2 Posology and method of administration:

The vaccine must be administered orally. Two drops are delivered directly into the mouth of the vaccinee from the multi-dose 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.

## 4.3 Contraindications:

The vaccine is contra-indicated in those with primary immune deficiency disease or suppressed immune response from medication, leukemia, lymphoma or generalized malignancy.

## 4.4 Special warnings and precautions for use:

**Warning:**

- Bivalent Poliomyelitis Vaccine Type1 and Type 3, Live (Oral) should not be used for routine immunization against polio.
- Care should be taken not to contaminate a multi dose dropper with saliva of the vaccines.
- After opening the vaccine vial, immediate use is recommended.

**Precautions:**

- Anyone who is moderately ill or severely ill at the time the dose is scheduled, should usually wait until they recover to get vaccinated.
- In case of Diarrhoea, the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.
- Always hold the vial in tilted position for vaccine delivery.
- Focus on the central square on the VVM (Vaccine Vial Monitor). 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 of the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

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

According to the WHO recommendations, Oral Polio Vaccines can be given safely and effectively at the same time as measles, rubella, mumps, DTP, DT, TT, Td, BCG, Hepatitis B, Haemophilus influenza type b, and yellow fever vaccine. In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to doctor or to pharmacist.

### 4.6 Pregnancy and lactation:

Not Applicable

### 4.7 Effects on ability to drive and use machines:

Not Applicable

### 4.8 Undesirable effects:

In the vast majority of cases, there are no side effects reported with trivalent OPV that includes the same Bivalent Poliomyelitis Vaccine Type 1 & Type 3 as its component. Very rarely, there may be vaccine associated paralysis. Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine – associated paralytic poliomyelitis.

### 4.9 Overdose:

Not Applicable

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Prophylactic

ATC code: J07BF04

### 5.2 Pharmacokinetic properties:

Not Applicable.

### 5.3 Preclinical safety data:

No preclinical studies have been performed as Bivalent Oral polio Vaccine Type 1 & 3 (bOPV) is derived from an already established product i.e. Trivalent Oral polio vaccine (tOPV). Trivalent Oral polio vaccine is a conventional product and is used for Polio eradication from past 5 decades worldwide. Similarly all the excipients used in the said product are the established excipients as it is being used in the tOPV also.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients:

- Earle's based Lactalbumin hydrolysate solution (ELH) as diluent
- 1M $MgCl_2$ as stabilizer
- Phenol red as indicator
- Kanamycin & Neomycin acid sulphate are used as preservative

### 6.2 Incompatibilities:

Not applicable

### 6.3 Shelf life:

Assigned shelf life is 24 months when stored at minus 20 °C.

### 6.4 Special precautions for storage:

Vaccine is potent if stored at minus 20 °C or below until the expiry date as indicated on vaccine vial label. Once opened, multi dose vials should be kept at 5±3 °C for not more than 4 weeks.

### 6.5 Nature and contents of container:

**Glass Vials:** Colorless, transparent, free from any ting and visual defect made from USP Type-1 glass.

**Rubber Stopper:** Rubber Stoppers are elastic and opaque having a circle, free from flash and adventitious material such as fibers, foreign particles and adhering rubber pieces.

**Aluminium Seal:** Tear down aluminium seals 13mm and free from foreign particles.

### 6.6 Special precautions for disposal

- Dropper should be discarded with vaccine vial as re-use of droppers of one vial to another may lead to crack and leakage.
- Discard the vaccine vial when the inner square of the VVM (Vaccine Vial Monitor) matches the color of the outer circle or becomes darker than the outer circle.

## 7. MARKETING AUTHORIZATION HOLDER

Panacea Biotec Ltd.
Malpur, Baddi, Distt Solan,
Himachal Pradesh – 173205, India
Tel. : 01795-674000
E-mail : corporate@panaceabiotec.com
Website: https://www.panaceabiotec.com

## 8. MARKETING AUTHORIZATION NUMBER(S)

MF-195/11 dated 29.04.2011
License No. : MB/07/632

## 9. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION

The details of the manufacturing authorization certificates obtained from Licensing Authority, India for Bivalent Poliomyelitis Vaccine Type 1 & 3, Live (Oral) manufactured at Vaccine Formulation Plant (VFP), Baddi, Himachal Pradesh, India are as mentioned below:

- Date of first authorization: June 01, 2017
- Renewal of the authorization on September 29, 2017 to September 28, 2022
- Retained upto September 28, 2027