

**1.3.1.2 SUMMARY OF PRODUCT CHARACTERISTICS**

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**Product Name** : Bivalent Oral Poliomyelitis Vaccine  
Types 1 and 3  
**Pharmaceutical Form** : Oral drops  
**Strength** : 20 doses (0.1 ml/dose)  
**Presentation** : Box of 10, 50 vials @ 2 mL

SUMMARY OF PRODUCT CHARACTERISTICS

**1. NAME OF THE MEDICINAL PRODUCT**

**1.1 Product Name:**

Bivalent Oral Poliomyelitis Vaccine Types 1 and 3

**1.2 Strength:**

20 doses

**1.3 Pharmaceutical dosage form:**

Oral drops

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**Composition :**

Each dose (2 drops = 0.1 ml) contains:

Types 1 attenuated poliomyelitis virus	not less than $10^{6.0}$ CCID <sub>50</sub>
Types 3 attenuated poliomyelitis virus	not less than $10^{5.8}$ CCID <sub>50</sub>
Sucrose	35%v/v
Erythromycin	not more than 2 mcg
Kanamycin	not more than 10 mcg

**3. PHARMACEUTICAL FORM**

Clear, light yellow to light red solution.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications:**

Bivalent Oral Poliomyelitis Vaccine Types 1 & 3 is indicated for active immunization against poliomyelitis type 1 and 3.

**4.2 Posology 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 or dispenser. Care should be taken not to contaminate a multi-dose dropper with saliva of the vaccinee.

Bivalent Types 1 & 3 Oral Poliomyelitis Vaccine is indicated for active immunization against poliomyelitis type 1 and 3. This vaccine can be used simultaneously with IPV. Infants should receive at least three doses of bOPV 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 6 weeks with the first dose of DTP.

**4.3 Contraindications:**

**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, leukemia, lymphoma or generalized malignancy.

**4.4 Special warnings and precautions for use:**

- In case of diarrhea 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:**

None

**4.6 Pregnancy and lactation:**

None

**4.7 Effects on ability to drive and use machine :**

None

**4.8 Undesirable effects:**

In the vast majority of cases there are no side effects reported with the trivalent OPV that includes the same bOPV 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:**

Not applicable

**5.2 Pharmacokinetic Properties:**

Not applicable

**5.3 Preclinical safety data:**

Not applicable

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients:

Sucrose  
Erythromycin  
Kanamycin

### 6.2 Incompatibilities:

Not applicable

### 6.3 Shelf life:

The shelf life of Bivalent Oral Poliomyelitis Vaccine is 2 years stored at  $\leq -20^{\circ}\text{C}$   
The expiry date is shown on the label.

### 6.4 Special precautions for storage:

Vaccine is potent if stored at not higher than  $-20^{\circ}\text{C}$  until the expiry date indicated on the vial. It can be stored for up to six months between  $+2^{\circ}\text{C}$  and  $+8^{\circ}\text{C}$ .  
The vaccine may present a colour varying from yellow to dark pink, due to a slight variation of pH; however this does not affect the quality of the vaccine.

### 6.5 Nature and contents of container:

The Bivalent Oral Poliomyelitis Vaccine comes in 20 doses in clear vials.  
Box of 10 and 50 vials @ 2 ml (20 doses) with 10 and 50 droppers blistered and packed in separate boxes.

### 6.6 Instructions for use, handling and disposal:

Once opened, multi-dose vials should be kept between  $+2^{\circ}\text{C}$  and  $+8^{\circ}\text{C}$ . 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: 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

**7. MARKETING AUTHORIZATION HOLDER**

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**8. MARKETING AUTHORIZATION NUMBERS**

GKE1002906436.VI

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

Date of first authorization:

18<sup>th</sup> February 2011

Date of renewal of the authorization:

21<sup>st</sup> March 2016

**10. DATE OF REVISION OF THE TEXT**

9<sup>th</sup> May 2018