1. NAME OF THE MEDICINAL PRODUCT

Trivalent Poliomyelitis Vaccine Type 1, Type 2 and Type 3, Live (Oral). **tOPV**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Recommended composition per dose of Trivalent Poliomyelitis vaccine, Live (Oral) Type 1, Type 2 and Type 3:

Particulars	Qualitative	Quantitative (per dose of 0.1 mL)
Active ingredients	Poliovirus Type 1	$10^{6.00}$ $CCID_{50}$
	Poliovirus Type 2	$10^{5.00}$ $CCID_{50}$
	Poliovirus Type 3	$10^{5.80}$ $CCID_{50}$
Other ingredients	$MgCl_2$ $6H_2O$	20.33 mg. (1 M)
	Polysorbate (Tween-80)	10 mcg.
	Kanamycin sulphate	15 mcg
	Neomycin sulphate	15 mcg
	Water For Injection	q.s 0.1 Ml
pH range	6.5 - 7.0	

3. PHARMACEUTICAL FORM

Vaccine

Category: Active Immunizing Agent.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For active immunization against polio infection by oral route.

4.2 Posology and method of administration

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

Care should be taken not to contaminate a multi-dose dropper with saliva of the vaccine.

4.3 Contraindications

Administration of Trivalent OPV should be avoided in,

a. Children who have experienced an anaphylatic or allergic reaction to previous dose of OPV.
b. Diagnosed cases of Leukemia, Lymphoma, Malignancies and any Immuno deficiencies.
c. Steroid therapy of systemic prednisone or equivalent at dose ≥ 2mg/kg/day or ≥ 20mg/day.

HIV infected: Children with acquired immuno deficiency syndrome should not be immunized with Trivalent OPV. But children, who are asymptomatic through HIV infected, may be carefully considered for vaccination.

4.4 Special warnings and precautions for use

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 two drops.

4.5 Interaction with other medicinal products and other forms of interaction

Trivalent OPV should be delayed in children suffering from acute febrile illnesses, diarrhoea and dysentry, debilitating ailment and abdominal pain. However, if in doubt, for instance during diarrhoea a repeat dose can be given after recovery.

4.6 Pregnancy and lactation

There is no evidence to suggest that a pregnant women or her fetus is at greater risk from OPV than other persons and therefore OPV should be used for pregnant women during control of an outbreak.

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. Very rarely, there may be vaccine-associated paralysis (less than one case per 3 million doses administered)

4.9 Overdose

Not Recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Clinical trials in Healthy individuals provided/ demonstrated safety and immunogenicity of **TRIVALENT ORAL POLIO VACCINE** by oral route of administration. The antibody titres were significantly greater than the minimum prescribed protective level. No serious vaccine related adverse reactions were observed in any of the volunteers during the clinical trial. Vaccine elicited adequate homologous antibody titers as compared to comparator vaccine.

5.2 Pharmacokinetic properties

Evaluation of Pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

In accordance with WHO TRS 904 there is no requirement for Non Clinical studies.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Magnesium chloride, Kanamycin and Neomycin sulphate, per dose.

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

Two years (when stored at -20° C or below).

6.4 Special precautions for storage

The **Trivalent** OPV is highly sensitive to heat and rapidly loses the potency when exposed to higher temperatures. Hence the vaccine shall 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 can be stored for six months at a temperature of 2° to 8°C.

6.5 Nature and contents of container

2 mL vial contains 20 doses x 0.1 mL (2 drops)*

1 mL vial contains 10 doses x 0.1 mL (2 drops)*

* A pre-sterilized plastic dropper is provided with each vial.

6.5 Special precautions for disposal

Discard the vaccine if particulate matter observed.

7. MARKETING AUTHORIZATION PREQUALIFICATION HOLDER

Name of the Company: Bharat Biotech International Limited

Address:

Genome Valley, Shameerpet Mandal,

Hyderabad, Andhra Pradesh,

INDIA – 500078.

Phone No.: +91-40-2348 0567.

Fax No.: +91-40-2348 0560.

E. Mail: info@bharatbiotech.com

Web: www.bharatbiotech.com

8. MARKETING AUTHORIZATION NUMBER(S)

4556/M3A/2008 dated 23.05.2008 from Drugs Control Administration

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORIZATION

We got marketing authorization for **Trivalent Oral Polio Vaccine** vide permission number MF-154/2013 dated 24.07.2013