SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Bivalent Poliomyelitis Vaccine Type1 and Type 3, Live (Oral)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of two drops (0.1 ml) of Bivalent Oral Polio Vaccine (Type1 & Type3) contains:

Active ingredients

- Not less than $10^{6.0}$ $CCID_{50}$ of Type 1 Poliomyelitis virus Sabin strain
- Not less than $10^{5.8}$ $CCID_{50}$ of Type 3 Poliomyelitis virus Sabin strain

Excipients

- Earle's based Lactalbumin hydrolysate solution (ELH) as diluent
- 1M $MgCl_2$ as stabilizer
- Phenol red as indicator

  Kanamycin & Neomycin acid sulphate not more than 20μg each as preservative.

3. PHARMACEUTICAL FORM

Oral vaccine

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.

SUMMARY OF PRODUCT CHARACTERISTICS

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.

SUMMARY OF PRODUCT CHARACTERISTICS

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

Not Applicable

5.2 Pharmacokinetic properties

Not Applicable

5.3 Preclinical safety data

Panacea Biotec Ltd. had successfully completed the following animal toxicity studies to establish the Safety and tolerability of bOPV Type 1 & Type 3 (Bulk Source: Sanofi Pasteur, France) carried out in accordance with WHO and schedule Y guidelines.

1. Single dose toxicity study of bivalent poliomyelitis vaccine (Type 1 and Type 3) (bOPV) in New Zealand white rabbits by oral route).

SUMMARY OF PRODUCT CHARACTERISTICS

2. Single dose toxicity study of bivalent poliomyelitis vaccine (Type 1 and Type 3) (bOPV) in Swiss mice by oral route.

The studies were conducted to assess the acute toxic potential of Bivalent Poliomyelitis Vaccine (Type 1 and Type 3) (bOPV), when administered by oral route to Swiss mice and NZW rabbits. There were no clinical signs observed in control and treatment groups of both animals. No treatment related mortality or morbidity throughout the treatment period, no changes in terminal body weight, hematology and clinical chemistry and no gross pathological lesions were observed in terminal sacrifice on day 15.

Based on these results, it is concluded that the bOPV was well tolerated up to the dose level of 0.1 mL (equivalent to intended clinical dose i.e., two drops) when administered orally to mice and NZW Rabbits.

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^{o}C.

6.4 Special precautions for storage

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

SUMMARY OF PRODUCT CHARACTERISTICS

6.5 Nature and contents of container

Glass Vials: They are colorless, transparent glass free from any ting and visual defect made from USP Type-1 glass (molded, borosilicate 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: Aluminium Seals are 13mm circular aluminium seal 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 AUTHORISATION> <PREQUALIFICATION> HOLDER

Panacea Biotec Ltd.
A-241, Okhla Industrial Area
Phase I, New Delhi - 110020, India
Phone : +91-11- 41899000
Fax : +91-11- 26811140, 41613711
E-mail : corporate@panaceabiotec.com
Website: www.panacea-biotec.com

8. <MARKETING> AUTHORISATION NUMBER(S)

Manufacturing Licence No. 1259 (India)

9. DATE OF FIRST < AUTHORISATION> / RENEWAL OF THE <AUTHORISATION>

First authorization date: 26/05/2011