BIVALENT TYPE 1&3 ORAL POLIOMYELITIS VACCINE IP bOPV 1&3 . LIVE

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

BIVALENT TYPE 1&3 ORAL POLIOMYELITIS VACCINE IP bOPV 1&3 . LIVE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

BIVALENT TYPE 1&3 ORAL POLIOMYELITIS VACCINE IP bOPV 1&3 . LIVE

The live types 1 & 3 oral polio vaccine (bOPV) is a bivalent vaccine containing suspensions of types 1& 3 attenuated poliomyelitis viruses (Sabin strains) prepared in Primary Monkey Kidney Cells (P.M.K.C.C.)
The vaccine vial of 20 doses (2ml)
Each dose contains 2 drops of infective units of Poliovirus

Type 1 $10^{6.0}$ $CCID_{50}$
Type 3 $10^{5.8}$ $CCID_{50}$

Due to minor variation of its pH, OPV may vary in colour from light yellow to light red.

Excipients

Hanks Balanced Salt solution (HBSS) as diluent
1M $MgCl_2$ as stabilizer
Phenol red as indicator
Trace amounts of erythromycin and kanamycin as per bulk formulation of PT BioFarma

3. PHARMACEUTICAL FORM

Oral Vaccine

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIVALENT TYPE 1& 3 ORAL POLIOMYELITIS VACCINE IP bOPV 1&3 . LIVE 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

bOPV must only be administered orally. Two drops are delivered directly into the mouth from the multidose vial by dropper or dispenser. Care should be taken not to contaminate a multidose dropper with saliva of the vaccinee.

Once opened, multi-dose vials should be kept between +2°C and +8°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 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:. Handling of Multi-Dose Vaccine Vials After Opening. WHO / IVB / 14.07):**

- The vaccine is currently prequalified by WHO.
- The vaccines is approved for use for up to 28 days after opening the vial, as determined by WHO.
- The expiry date of the vaccine has not passed.
- The vaccine vial has been and will continue to be stored at WHO / Manufacturers recommended temperatures (+2^{o}C and +8^{o}C), once opened.
- The vaccine vial monitor (VVM) attached is visible and has not reached the discard point.

4.3 Contraindications

Immune deficiency

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with bOPV according to standard schedules.

However, the vaccine is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukaemia, lymphoma or generalized malignancy.

4.4 Special warnings and precautions 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

bOPV can be given safely and effectively at the same time as IPV, measles, rubella, mumps, DTP, DT, TT, Td, BCG, Hepatitis B, Haemophilus influenza type b, Yellow fever vaccine and Vitamin A supplementation.

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 . 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

HANKS BALANCED SALT SOLUTION WITH MAGNESIUM CHLORIDE (HBSS)

Calcium chloride
Disodium hydrogen orthophosphate
Magnesium Sulphate
Potassium dihydrogen orthophosphate
Potassium Chloride
Dextrose (anhydrous)
Sodium Chloride
Sodium bicarbonate
Water for Injection (WFI)
Phenol Red (water soluble) as indicator
1 M Magnesium Chloride as stabilizer

6.2 Incompatibilities
Not applicable

6.3 Shelf life
Assigned shelf life is 24 months when stored at -22°C± 2°C.

6.4 Special precautions for storage
Vaccine is potent if stored at not higher than -20°C until the expiry date indicated on the vial. It can be stored for up to six months between +2°C and +8°C.

6.5 Nature and contents of container

i) 3 ml 20 mm Glass Vials (USP Type 1)
ii) 20mm grey butyl rubber stoppers RFS (non- popping)
iii) 20 mm Lacquer Coated Green coloured HAFFKINE Embossed Tear Down Aluminium Seals (Gamma Irradiated / Sanitized)
iv) Each OPV vial is supplied along with a sterile plastic dropper (supplied at the time of shipment

6.6 Special precautions for disposal

Vaccine Vial Monitors (VVMs) are part of the label on all Bivalent Type 1 & 3 Oral Poliomyelitis Vaccine. 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. Do not use the vaccine.

7. TRANSPORT INFORMATION

Transportation of bOPV1&3 vaccine is done in cold chain vehicle at temperature 2-8°C. As per current edition of IATA Dangerous Goods Regulation (DGR), these are known to be non-dangerous for transportation.

8. <MARKETING AUTHORISATION> <PREQUALIFICATION> HOLDER

Haffkine Bio-Pharmaceutical Corporation Limited
(A Government of Maharashtra Undertaking)
Address : Acharya Donde Marg, Parel, Mumbai – 400 012, INDIA
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e–mail :md@vaccinehaffkine.com/qa@vaccinehaffkine.com, mkt@vaccinehaffkine.com
Website : www.vaccinehaffkine.com

9. <MARKETING> AUTHORISATION NUMBER(S)

As per Drugs & Cosmetic Act 1940 & Rules 1945, in Form 28D, Licence No.5.

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

Authorization by DCGI on 23rd Feb. 2010

11. REVISION NO. AND DATE OF REVISION

Rev. No. 01, Date 05/08/2024