1. NAME OF THE MEDICINAL PRODUCT

Poliomyelitis Vaccine (Oral) Bivalent Type 1 and 3

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of 10 (1.20±0.05 mL) / 20 doses (2.25±0.05 mL) contains:

Contents	Quantity per 0.1 ml [Each dose of 2 drops]	Active / Non-active	Specification	Reason for inclusion
Polio virus (Sabin)* Type 1	$10^{6.0}$ $CCID_{50}$	Active	WHO TRS 904, Annex 1, 2002	Immunizing agent
Polio virus (Sabin)* Type 3	$10^{5.8}$ $CCID_{50}$			
Neomycin Sulphate	15 mcg	Non-active	In-house/ IP/BP/Ph. Eur	Preservative (Anti-microbial agent)
Tween 80	10 mcg	Non-active	Ph. Eur	Surfactant
Magnesium Chloride	1 M	Non-active	IP/BP/Ph. Eur	Stabilizer

* grown on primary Monkey Kidney Culture.

3. PHARMACEUTICAL FORM

Solution for Oral administration. Pale pink to pink clear liquid in clear glass vial.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bivalent OPV (Type 1 and 3) is indicated for active Immunization against Type 1 & 3 Polioviruses.

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.

4.2 Posology and method of administration

Bivalent OPV must only be administered orally. Two drops are delivered directly into the mouth from the multi dose vial by dropper. For older children it may be preferred to avoid possible bitter

taste by first placing the drops on a sugar lump or in syrup. Care should be taken not to contaminate a multi dose dropper with saliva of the vaccine. Overdose if any, will not result in ill effect.

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 upto a maximum of 28 days, provided that all of the following conditions are met (as described by WHO policy statement. The use of opened multidose vials in subsequent immunization sessions WHO/IV B/14.07):

- The vaccine is currently prequalified by WHO;
- The vaccine is approved for use for upto 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 or manufacturer recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

4.3 Contraindications

No adverse effects are produced by giving bOPV to a sick child. In case of diarrhoea or vomiting (including gastrointestinal infection), the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

4.4 Special warnings and precautions for use

The possibility of allergic reactions in individuals sensitive to the components of the vaccine should be evaluated.

4.5 Interaction with other medicinal products and other forms of interaction

OPV can be administered at the same time as Haemophilus influenzae type b, hepatitis B, diphtheria, pertussis and/or tetanus, pneumococcal, BCG or rotavirus vaccines according to the vaccination schedule.

Immunosuppressive therapies including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than minimal doses), may reduce the immune response to vaccines.

4.6 Pregnancy and lactation

According to WHO, all available evidence indicates that OPV is non-teratogenic and safe to administer to pregnant women. However, during pregnancy and in an epidemic context, the risk benefit of the use of the vaccine should be evaluated in comparison to the use of inactivated vaccines.

There is no information on use of OPV during lactation.

4.7 Effects on the ability to drive and use machines
Effect of OPV on the ability to drive and operate machines is not known.

4.8 Undesirable effects

In the vast majority of cases there are no side effects. Very rarely, there may be vaccine associated paralysis (one case per one million doses administered). Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine associated paralytic poliomyelitis.

4.9 Overdose
No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Viral Vaccines
Poliomyelitis oral, bivalent, live attenuated. ATC code J07BF04

Immunological Data:
In a clinical study in 270 infants, following 3-dose vaccination schedule at 6, 10 and 14 weeks, the seroprotection (poliovirus neutralizing antibody titre of ≥1:8) was 100% and 97.3%, while seroconversion was observed in 99.6% and 97% infants against type 1 and 3 polioviruses, respectively.

5.2 Pharmacokinetic properties
Pharmacokinetic studies are not required for vaccines.

5.3 Preclinical safety data
No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Name	Specification	Used for
Magnesium Chloride	IP/BP/Ph. Eur	Stabilizer preparation
Tween 80 (Polysorbate 80)	IP/BP/Ph. Eur	To avoid aggregation of virus particles
Neomycin sulphate	USP	Preservative
Water for Injections q.s.	IP/BP/Ph. Eur/ USP	Solvent

6.2 Incompatibilities

Stability studies have demonstrated compatibility of the container closure system with the drug product. No decrease in potency of the final vaccine as a result of sorption to the primary packaging materials during storage has been found.

6.3 Shelf-life

Shelf life of the medicinal product as packages for sale:

24 Months. 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 6 months between +2°C and +8°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 6 months between +2°C and +8°C.

6.5 Nature and contents of container

4 ml clear tubular USP type I European Blow back vial, body diameter 16.5 mm and height 40 mm.

6.6 Special precautions for disposal and other handling

The vaccine may present a colour varying from light yellow to dark pink due to a slight variation of pH, however this does not affect the quality of vaccine.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

Manufacturing License No – 10.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07-01-2013 (for Exports only)

Date: 31 December 2022