1. NAME OF THE MEDICAL PRODUCT

ORAL POLIOMYELITIS VACCINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vaccine dose is represented by:
- 2 drops of the multidose presentation (0.1 ml)

Each 0.1 ml dose contains:

Active substances:
- Type 1 Poliovirus* (LS – 2 ab strain) at least $10^{6.0}$ CCID$_{50}$**
- Type 2 Poliovirus* (P 712, Ch, 2 ab strain) at least $10^{5.0}$ CCID$_{50}$**
- Type 3 Poliovirus* (Leon 12 a 1 b strain) at least $10^{5.8}$ CCID$_{50}$**

* produced on Vero cells

** CCID$_{50}$: 50 per cent cell culture infective doses (viral infectious units)

3. PHARMACEUTICAL FORM

Vaccine: Oral solution 20 – dose vial

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Prevention of poliomyelitis

4.2 Posology and method of administration

Primary vaccination

A minimum of 3 oral doses, with an interval which should not be less than four weeks, depending on the vaccination schedule in force in the country. WHO recommends the following schedule in endemic countries: birth, 6, 10, 14 weeks. In nonendemic areas the first dose can be given from 6 weeks with the first doses of DTP.

Booster

1 oral dose 1 year after 3rd dose, then every 5 years.

For subsequent booster doses, an oral dose is recommended every 5 years for children and adolescents and every 10 years for adults.

In the event of an endemic: at least one dose of oral poliomyelitis vaccine must be given to all subjects living in a close contact with a declared case, irrespective of previous vaccinations.

Mode and route of administration

The vaccine should be administered exclusively by the oral route.

The vaccination dose is 2 drops which, with the aid of a dropper provided with the vaccine, can be administered either directly into the mouth, or on a lump of sugar, or with syrup.

Care should be taken not to contaminate a multidose dropper with saliva of the vaccinee.

Any bottle or tube which is opened should be kept between +2 °C and +8 °C. Thereafter, follow the WHO recommendations which may be found in UNICEF or PAHO brochures.

A successful extraction operation for one or more vaccine doses form a multi – dose vial depends essentially on the quality of the handling.

The vial must first of all be shaken gently, to avoid forming, but sufficiently to obtain a homogeneous mixture of the contents.

Between the different withdrawn operations and in any case, within not more than five minutes after the last dose withdrawn, the vial should be replaced in a refrigerator to keep the product at its normal storage temperature, i.e. between +2°C and +8°C (never place it in a freezer).
4.3 Contraindication

This medicinal product must not be used in the following cases:

- Known hypersensitivity to any component of the vaccine or serious reaction after previous administration of an OPV vaccine.

- Vaccination should be postponed in case of fever or acute disease.

- Pregnancy: Although no teratogenic effects have been demonstrated, it is not recommended to vaccinate pregnant women, particularly during the first trimester. However, accidental vaccination in the early stages of pregnancy does not justify termination of pregnancy.

If vaccination is necessary, it is advisable to use inactivated poliomyelitis vaccine except in the event of an epidemic where it is recommended to use oral live vaccine.

- Congenital or acquired immune deficiency in the subject to be vaccinated or those in close contact with the subject. Immune deficiencies include, in particular, infection with human immunodeficiency virus (HIV) and immuno-depressant treatments.

However, in some countries WHO and local Health Authorities recommendations may require vaccinating all persons infected with HIV, whether symptomatic or asymptomatic, with the oral vaccine according to the standard immunization schedule.

- Progressive malignant diseases.

4.4 Special warnings and precautions for use

As each dose may contain undetectable traces of neomycin, streptomycin and polymyxin B which are used during vaccine production, caution should be exercised when the vaccine is administered to subjects with hypersensitivity to these antibiotics.

4.5 Interaction with other medical products and forms of interaction

According to the WHO recommendations, OPV 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 your doctor or to your pharmacist.

4.6 Pregnancy and lactation
Although no teratogenic effects have been demonstrated, it is not recommended to vaccinate pregnant women, particularly during the first trimester. However, accidental vaccination in the early stages of pregnancy does not justify termination of pregnancy.

If vaccination is necessary, it is advisable to use inactivated poliomyelitis vaccine except in the event of an epidemic where it is recommended to use oral live vaccine.

4.7 Effects on the ability to drive and use machines

NA

4.8 Undesirable effects

- General symptoms: fever, rigors, asthenia (tiredness), myalgia (muscular pains), arthralgia (articular pains).

- Rare cases of neurological disorders: paraesthesia (tingling sensations, numbness), paresis (low paralysis), neuritis (nerve inflammation), myelitis (spinal cord inflammation) have been reported.

- In exceptional cases, post–vaccination paralysis due to the reversion of the vaccine virus to neurovirulence may be observed. These cases occur within 4 to 8 weeks following the vaccination.

- According to ACIP data, the overall risk is approximately 1 case in 2.4 million distributed doses. However after the first dose the risk is higher, and is estimated at 1 case in 750,000 distributed doses.

- No side effect has been observed after administration of OPV in a sick child.

Report to your doctor or to your pharmacist any unwanted and disturbing effects which might not be mentioned.

4.9 Overdose

NA

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

NA

5.2 Pharmacokinetic properties

NA
5.3 Preclinical safety data

NA

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Human albumin
HEPES Buffer solution
Magnesium chloride solution (containing polysorbate 80 and phenol red)
Hydrochloric acid or sodium hydroxide to adjust pH

6.2 Incompatibilities

NA

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at -20 °C (in freezer). Once defrosted the product must never be frozen again.
The defrosted product can be stored 6 months between +2 °C and +8 °C.
The vaccine supplied in plastic tubes may change color due to storage with dry ice; however this does not affect the quality of the vaccine.

6.5 Nature and contents of container

Vials of vaccine: Type I borosilicate glass.

6.6 Special precautions for disposal and other handling

NA

7. MARKETING AUTHORISATION HOLDER

Government Pharmaceutical Organization – Mérieux Biological Products Co., Ltd.
8. MARKETING AUTHORISATION NUMBER(S)

1B 12/46

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25 December 2003

10. DATE OF REVISION OF THE TEXT

April 2011