SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medical Product: OPVERO, Oral trivalent Poliomyelitis Vaccine, Oral suspension in multidose container

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 0.1 ml dose (2 drops) contains:

Active substances:
- Type 1 Poliovirus* (LS - c 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\(_{50}\)**

* Live attenuated strains produced in Vero cells.

**CCID\(_{50}\): 50 per cent cell culture infective doses (viral infectious units)
The vaccine fulfills W.H.O. requirements.
For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Oral suspension in multidose container

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 non-endemic areas the first dose can be given from 6 weeks with the first dose of DTP.

Booster:
1 oral dose 1 year after 3rd dose.
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 epidemic: 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.

The vaccine should be administered exclusively by the oral route.
The container must first be shaken gently, to avoid foaming, but sufficiently to obtain a homogenous mixture of the contents.
Successful extraction operation for one or more vaccine doses from a multidose container depends essentially on the care of the handling.
The vaccination dose is 2 drops (0.1 ml) which, using the dropper provided with the vaccine, can be administered either directly into the mouth, or on a lump of sugar.
Care should be taken not to contaminate the multidose dropper with saliva of the vaccine.

4.3 Contraindication

Known hypersensitivity to any component of the vaccine, to neomycin, streptomycin and polymyxin B or serious reaction after previous administration of an OPV vaccine.

Primary immune deficiency disease or suppressed immune response from medication, leukaemia, lymphoma or advanced malignancy.

4.4 Special warnings and precautions for use

In the event of vomiting or diarrhea at the time of or immediately after administration, a second dose may be given after the symptoms have disappeared.

In the event of fever or acute disease, it may be recommended to postpone vaccination according to national policy.

This vaccine should not be injected.

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 influenzae 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

Teratogenicity has not been sufficiently documented in animals.

Studies performed following mass immunization activities during epidemics have not showed congenital malformations or foetotoxicity linked to the use of oral polio vaccine.

Consequently, this vaccine could only be prescribed during pregnancy if necessary, particularly in case of epidemic.

4.7 Effects on the ability to drive and use machines

4.8 Undesirable effects

General symptoms: fever, rigors, asthenia (tiredness), myalgia (muscular pains), arthralgia (articual pains)

Rare cases of neurological disorders: parasthesia (tingling sensations, pins and needles), 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 in the vaccine or persons in close contact with a recently vaccinated subject. 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.

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2 -3 days after vaccinations
4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

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 for pH adjustment.

6.2 Incompatibilities

6.3 Shelf life
    2 years

6.4 Special precautions for storage
    Store at -20°C (in freezer)
    After thawing the product can be stored 6 months in a refrigerator (between +2°C to +8°C).

6.5 Nature and contents of container
    Oral suspension in multidose vial or tube:
    - 10 doses (1 ml)
    - 20 doses (2 ml)

6.6 Special precautions for disposal and other handling

*Vaccine Vial Monitor (VVM)*

- ✓ Inner square is lighter than outer ring. If the expiry date is not passed, *USE* the vaccine
- ✓ As time passes: Inner square is still lighter than outer ring. If the expiry date is not passed, *USE* the vaccine.
Discard point:

- Inner square matches the colour of outer ring. **DO NOT USE** the vaccine.

- Beyond the discard point: Inner square is darker than outer ring. **DO NOT USE** the vaccine.

Vaccine vial monitors (VVMs) are part of the label on all OPVERO vaccine supplied by WHO. The colour dot that appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. 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 the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

7. **MARKETING AUTHORISATION HOLDER**
   Sanofi Pasteur Ltd., Bangkok, Thailand

8. **MARKETING AUTHORISATION NUMBER(S)**
   2C 72/49

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
   10 November 2006

10. **DATE OF REVISION OF THE TEXT**
    April 2009
    Date of local approval: 10 March 2010

    (The above information is based on the currently approved leaflet)