Polio Sabin™ (oral)
Trivalent Oral Polio vaccine (live, attenuated) Sabin strains

1. NAME OF THE MEDICINAL PRODUCT
Polio Sabin™ (oral)
Poliomyelitis vaccine, live (oral)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Polio Sabin™ (oral) vaccine is a stabilised preparation of live attenuated poliomyelitis viruses of the Sabin™ strains type 1 (LSc, 2 ab), type 2 (P712 ch, 2ab) and type 3 (Leon, 12a, 1b), propagated in MRC5 human diploid cells.

Polio Sabin™ (oral) meets the World Health Organisation requirements for biological substances and for poliomyelitis vaccine (oral).

The appropriate formulation should be chosen in accordance with national recommendations.

For example:
- WHO/EPI recommends that each immunising dose of vaccine contains not less than: \(10^{6.0}\) CCID50 for type 1, \(10^{5.0}\) CCID50 for type 2 and \(10^{5.8}\) CCID50 for type 3 live attenuated Sabin™ strains of polioviruses.
- European Pharmacopoeia recommends that each immunising dose of vaccine contains not less than: \(10^{6.0}\) CCID50 for type 1, \(10^{5.0}\) CCID50 for type 2 and \(10^{5.5}\) CCID50 for type 3 live attenuated Sabin™ strains of polioviruses.

Each dose of Polio Sabin™ (oral) contains not less than \(10^6\) TCID50 for type 1, \(10^5\) TCID50 for type 2 and \(10^{5.8}\) TCID50 for type 3 live attenuated Sabin™ strains of poliomyelitis viruses.

3. PHARMACEUTICAL FORM
Oral suspension.
The vaccine is presented as clear liquid, yellowish-pink suspension for oral administration.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
Polio Sabin™ (oral) is indicated for active immunisation of infants and susceptible children and adults against infection caused by polioviruses of type 1, 2 and 3.

4.2 Posology and Method of Administration
Posology
In a multidose container, one immunising dose (0.1 ml) is contained in two drops.
As vaccination schemes vary from country to country, the advised schedule for each country must be in accordance with the national recommendations.

**Infants:** The primary immunisation course is three doses of Polio Sabin™ (oral) vaccine. The vaccine should be administered with an interval of at least one month between doses.

Polio Sabin™ (oral) may be given at birth provided it is realised that the response is likely to be sub-optimal, and that three additional doses will be required later in life to give adequate protection.

**Children and adults:** In order to maintain the level of protection against polio virus infection, it is recommended to give a booster dose at the time of school entry and again on leaving school and occasionally in adult life when a person is likely to be exposed to a high risk of infection, such as when travelling to endemic areas.

**Method of administration**

Polio Sabin™ (oral) is for oral use only.

Polio Sabin™ (oral) should under no circumstances be injected. One dose of vaccine (0.1 ml) is delivered in 2 drops from the polyethylene dropper supplied with the glass vial or directly from the plastic tube.

The vaccine may be administered alone or mixed with beverages or foods provided that these do not contain substances that may inactivate polioviruses, such as preservatives. Suitable vehicles are simple syrup, milk, bread and a lump of sugar. Since the vaccine has a bitter salty taste, it may be given in syrup or on a lump of sugar, particularly when it is to be given to young children.

The vaccine should be administered to breastfed infants, preferably two hours before or after breastfeeding in order to avoid contact with the antibodies present in the breast milk.

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

**4.3 Contra-indications**

Polio Sabin™ (oral) is contra-indicated in subjects with known hypersensitivity to neomycin or polymyxin or to any other component of the vaccine. A history of contact dermatitis to neomycin or polymyxin is not a contra-indication.

Polio Sabin™ (oral) is contraindicated in subjects having shown signs of hypersensitivity after previous administration of GlaxoSmithKline Biologicals’ oral poliomyelitis vaccines.

In general, Polio Sabin™ (oral) should not be administered to subjects suffering from primary and secondary immunodeficiencies. For those persons it is recommended to use an inactivated polio vaccine (IPV).

However, according to the Expanded Programme on Immunisation (EPI) recommendations, symptomatic and asymptomatic infection with human immunodeficiency virus (HIV) does not contra-indicate immunisation with Polio Sabin™ (oral).

**4.4 Special Warnings and Special Precautions for Use**

Polio Sabin™ (oral) should under no circumstances be injected.
Polio Sabin™ (oral) is recommended for routine immunization and epidemic control. Polio Sabin™ (oral) may not prevent or modify the course of the disease in subjects already infected with a wild type poliovirus.

The administration of Polio Sabin™ (oral) should be postponed in subjects suffering from acute severe febrile illness, or persistent diarrhoea or vomiting. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Episodes of diarrhoea and/or vomiting (as well as any gastro-intestinal infection) may hinder the administration of Polio Sabin™ (oral). In case of diarrhoea, the dose received will not be counted as part of the immunisation schedule and should be repeated after recovery.

The attenuated poliomyelitis viruses multiply in the gut. The faecal excretion of the vaccine viruses may persist for several weeks and may also be transmitted to the contacts of the vaccinees; contacts of vaccinees should therefore be warned about the need for strict personal hygiene.

Non-immune persons in close contact with a recently vaccinated subject may very rarely be at risk of vaccine-associated paralytic poliomyelitis.

Whenever Polio Sabin™ (oral) is administered to an individual, it is good clinical practice to offer immunisation to presumably susceptible close contacts (such as unvaccinated parents) at the same time.

As with any vaccine, a protective immune response may not be elicited in all vaccinees. In immunocompetent recipients previous vaccination with inactivated poliomyelitis vaccine is not a contra-indication for the use of Polio Sabin™ (oral).

HIV-positive asymptomatic individuals may receive live polio vaccine but excretion of the vaccine virus in the stools may continue for longer than in normal individuals. Household contacts should be warned of this and for the need for strict personal hygiene, including handwashing after nappy changes for an HIV-positive infant.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Polio Sabin™ (oral) can be administered at the same time as Haemophilus influenzae Type b vaccine, hepatitis B vaccine, diphtheria, pertussis and/or tetanus vaccine, measles, rubella and/or mumps vaccine, or BCG vaccine if this fits into the vaccination schedule.

Concomitant administration of oral poliomyelitis vaccine (OPV) and rotavirus vaccine does not affect the immune response to the polio antigens but may slightly reduce the immune response to rotavirus vaccine. A clinical study in which OPV was co-administered with GlaxoSmithKline Biologicals’ rotavirus vaccine (Rotarix™) showed that clinical protection against severe rotavirus gastro-enteritis was maintained.

If Polio Sabin™ (oral) cannot be given at the same time as other live attenuated vaccines, an interval of at least one month should be left between both vaccinations.

Immunosuppressive treatment may reduce the immune response, may favour the multiplication of the vaccine viruses and may increase the length of excretion of the vaccine viruses in the stools (see 4.4 Special Warnings and Special Precautions for Use).

4.6 Use During Pregnancy and Lactation
Use in Pregnancy
Although there is no evidence that live attenuated polioviruses have an adverse effect on the foetus, in accordance with general principles, the vaccine should not be given to pregnant women unless they are exposed to a definite risk of infection with wild polioviruses. Non immune woman of child-bearing age should use contraception during 3 months following vaccination.

Use in Lactation
The effect on breastfed infants of the administration of Polio Sabin™ (oral) to their mothers has not been evaluated in clinical studies. No known contra-indication has been established. The vaccine may be administered to a lactating mother.

4.7 Effect on Ability to Drive and Use Machines
There have been no studies to investigate the effect of Polio Sabin™ (oral) on driving performance or the ability to operate machinery. Nevertheless, considering the adverse event profile of Polio Sabin™ (oral) it is unlikely that the vaccine has an effect on the ability to drive and use machines.

4.8 Undesirable Effects
Non-specific signs and symptoms such as fever, vomiting and diarrhea have been described after immunisation but none have been recognised as caused by the vaccine.

Temporal association between immunisation with Polio Sabin™ (oral) and the development of signs and symptoms of paralytic poliomyelitis has been observed in vaccinees and susceptible close contacts. The frequency of this association is however extremely low (less than one case per 1 million doses administered). The majority of post vaccinal paralytic poliomyelitis occurred after the administration of the first dose.

Very rarely allergic reactions, including anaphylactoid reactions, have been reported.

4.9 Overdose
Occasional reports of overdose have been received. Overdose has not resulted in ill-effects.

5. PHARMACOLOGICAL PARTICULARS
5.1 Pharmacodynamic Properties
After administration of the three doses, ≥ 98% of subjects were seroprotected for the three serotypes.

5.2 Pharmacokinetic Properties
Evaluation of pharmacokinetics is not required for vaccines.

5.3 Preclinical Safety Data
Non-clinical data reveal no special hazard for humans based on routine quality control tests performed in animals.
6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients
Magnesium Chloride, L-arginine, polysorbate 80, purified water.
Residues: neomycin sulphate (traces), polymyxin B sulphate (traces).

6.2 Incompatibilities
This medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life
The expiry date of the vaccine is indicated on the label and packaging.

6.4 Special Precautions for Storage
The storage conditions are indicated on the packaging.
The vaccine should be stored in a refrigerator between +2°C and +8 °C or in a freezer at -20 °C, following the recommendations indicated on the label and packaging.
The vaccine which is indicated for storage at –20°C can be temporarily stored between + 2°C and + 8°C for a maximum of 6 months.
In order to preserve optimal potency of Polio Sabin™ (oral), exposure of the vaccine to ambient (non-refrigerated) temperatures should be kept to a minimum and exposure to sunlight should be avoided.

Shipment should be done under refrigerated conditions, particularly in hot climates.
Freezing and thawing does not affect the titre of the vaccine.
When distribution or administration is not imminent, it is advisable to store the vaccine, if possible, at temperatures of -20 °C or less since this halts deterioration in vaccine potency.
If the vaccine has been accidentally exposed to high environmental temperatures, it is recommended that the vaccine be used immediately or stored at -20 °C until administration.
After opening, multidose containers should be kept in a refrigerator and used ideally within eight hours because of the possibility of contamination of the vaccine. If these conditions are not fulfilled, the vaccine should be discarded.
Store in the original package in order to protect from light.

6.5 Nature and Contents of Container
The vaccine is presented in plastic tubes or glass vials.

6.6 Instructions for Use/Handling
Vaccines should be inspected visually for any particulate matter prior to administration.
Due to minor variation of its pH, Polio Sabin™ (oral) may vary in colour from light yellow to light red.
Changes of the colour of the vaccine within these ranges do not signify deterioration of the vaccine.
7. MARKETING AUTHORISATION HOLDER
GlaxoSmithKline (Thailand) Ltd.

8. MARKETING AUTHORISATION NUMBER
2C 51/48

9. DATE OF FIRST AUTHORISATION
25 July 2005

Manufacturer:
GlaxoSmithKline Biologicals s.a., Rixensart, Belgium.

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Polio Sabin is a trademark of the GlaxoSmithKline group of companies.