Polio Sabin™ One and Three (Oral)

Bivalent Oral Poliomyelitis vaccine Types 1 and 3 (live, attenuated)

QUALITATIVE AND QUANTITATIVE COMPOSITION

***Polio Sabin*™** One and Three (oral) is a bivalent, live attenuated poliomyelitis virus vaccine of the Sabin strains Type 1 (LSc, 2ab) and Type 3 (Leon 12a, 1b), propagated in MRC5 human diploid cells.

1 dose (0.1 ml) contains:

Virus Polio Type 1, strain LSc, 2ab	$\geq 10^{6.0}$ $CCID_{50}$
Virus Polio Type 3, strain Leon 12a, 1b	$\geq 10^{5.8}$ $CCID_{50}$

PHARMACEUTICAL FORM

Oral suspension.

The vaccine is presented as a clear liquid, yellowish-to pink suspension for oral administration.

CLINICAL PARTICULARS

Indications

***Polio Sabin*™** One and Three (oral) is indicated for active immunisation in all age groups against infection caused by poliomyelitis viruses of Type 1 and 3.

Dosage and 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*™** One and Three (oral) vaccine. The vaccine should be administered with an interval of at least one month between doses.

***Polio Sabin*™** One and Three (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™ One and Three (oral) is for oral use only.

One dose of vaccine is contained in two drops which are delivered from the polyethylene dropper supplied with the multidose container.

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 the dropper with saliva of the vaccinee.

Contraindications

Polio Sabin™ One and Three (oral) is contraindicated in subjects with known hypersensitivity to neomycin or polymyxin, or to any other component of the vaccine (see *Qualitative and quantitative composition* and *List of excipients*). A history of contact dermatitis to neomycin or to polymyxin is not a contraindication.

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

Polio Sabin™ One and Three (oral) is contraindicated in subjects suffering from primary and secondary immunodeficiencies. For those persons it is recommended to use an inactivated polio vaccine (IPV). However, according to the WHO Expanded Programme on Immunisation (EPI) recommendations symptomatic and asymptomatic infection with human immunodeficiency virus is not a contraindication for immunisation with ***Polio Sabin™*** One and Three (oral).

Warnings and Precautions

Polio Sabin™ One and Three (oral) should under no circumstances be injected.

Polio Sabin™ One and Three (oral) may not prevent or modify the course of the disease in subjects already infected with a wild Type 1 or Type 3 poliovirus.

The administration of ***Polio Sabin™*** One and Three (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.

Since diarrhoea and/or vomiting (as well as gastro-intestinal infection) may interfere with the administration of ***Polio Sabin™*** One and Three (oral), 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™*** One and Three (oral) is administered to an individual, it is good clinical practice to offer immunisation to 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.

Previous vaccination with IPV is not a contraindication for the use of ***Polio Sabin™*** One and Three (oral).

Interactions

Polio Sabin™ One and Three (oral) can be administered at the same time as *Haemophilus influenzae* type b vaccine, hepatitis B vaccine, diphtheria, pertussis and/or tetanus vaccine, inactivated polio vaccine (IPV), 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 trivalent OPV was co-administered with GlaxoSmithKline Biologicals' rotavirus vaccine (***Rotarix™***) showed that clinical protection against severe rotavirus gastro-enteritis was maintained.

If ***Polio Sabin™*** One and Three (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.

Pregnancy and Lactation

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. The risk benefit of the use of the vaccine should be evaluated in comparison to the use of inactivated polio vaccines.

Women of child-bearing age without immunity to polio should use contraception during 3 months following vaccination.

Lactation

The effect on breast-fed infants of the administration of ***Polio Sabin™*** One and Three (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.

Adverse Reactions

Very rarely, vaccine-associated paralysis has been observed with trivalent oral poliomyelitis vaccines (less than one case per 1 million doses administered). The majority of vaccine associated paralytic poliomyelitis (VAPP) occurred after the administration of the first dose.

Fever, vomiting and diarrhoea have been observed after immunisation with ***Polio Sabin™*** One and Three (oral). Allergic/anaphylactoid reactions have been described after immunisation with GlaxoSmithKline Biological's trivalent oral poliomyelitis vaccine.

The frequencies by dose are defined as follows:

Very rare: (<1/10,000)

Organ system classes	**Frequency**	**Undesirable effects**
General disorders and administration site conditions	Very rare[1]	Fever[2]
Gastrointestinal disorders	Very rare[1]	Diarrhoea[2], vomiting[2]
Immune system disorders	Very rare[1]	Allergic/anaphylactoid reactions[3]
Infections and infestations	Very rare[1]	Vaccine-associated paralysis[3]

[1] Frequency based on post-marketing surveillance data on trivalent poliomyelitis vaccines

[2] Undesirable effects reported in the context of a clinical trial conducted in Bangladesh

[3] Undesirable effects based on post-marketing surveillance data on trivalent poliomyelitis vaccines

Overdose

Occasional reports of overdose with GlaxoSmithKline Biologicals' trivalent oral poliomyelitis vaccine have been received. Overdose has not resulted in ill-effects.

Insufficient data on ***Polio Sabin™*** One and Three (oral) are available.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

On the basis of literature and a clinical study conducted in Bangladesh in which more than 370 subjects from 6 weeks of age received ***Polio Sabin™*** One and Three (oral) according to either a 6, 10, 14 weeks or a 6, 8, 10 weeks schedule, it can be estimated that the immune responses against Types 1 and 3 poliomyelitis viruses will be at least equal to those obtained with a trivalent oral poliomyelitis vaccine.

PHARMACEUTICAL PARTICULARS

List of Excipients

Magnesium chloride, L-arginine, polysorbate 80 and water for injections.

Neomycin sulphate and polymxin B sulphate are present as residuals from the manufacturing process.

Incompatibilities

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

Shelf Life

The expiry date is indicated on the label and packaging.

Special Precautions for Storage

Store in a freezer (–20°C).

The 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.

In order to preserve optimal potency of ***Polio Sabin™*** One and Three (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 lower 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.

Nature and Contents of Container

Glass vials (Type I glass) for 10 doses with a separate polyethylene dropper - pack size of 100.

Glass vials (Type I glass) for 20 doses with a separate polyethylene dropper - pack size of 100.

Not all presentations are available in every country.

Instructions for Use/Handling

The vaccine should be inspected visually for any particulate matter prior to administration.

Due to minor variation of its pH, ***Polio Sabin™*** One and Three (oral) may vary in colour from yellow to pink.

Changes of the colour of the vaccine within this range do not signify deterioration of the vaccine.

Polio Sabin and Rotarix are trade marks of the GSK group of companies.

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