

WHO PACKAGE INSERT

1. NAME OF THE MEDICINAL PRODUCT

Polio Sabin™ One and Three (oral)
Bivalent Oral Poliomyelitis vaccine Types 1 and 3 (bOPV)

2. 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.

Each dose (0.1 ml) contains not less than $10^{6.0}$ CCID₅₀ of Type 1 and $10^{5.8}$ CCID₅₀ of Type 3. Magnesium chloride is used as a stabilizer. Polio Sabin™ One and Three (oral) contains trace amounts of neomycin sulphate and polymyxin B sulphate.

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

This vaccine may be used in two instances:

- Eradication of poliomyelitis, to supplement vaccination against poliomyelitis with a trivalent vaccine in areas where the poliomyelitis viruses of Type 1 and Type 3 are circulating.
- Reappearance of Types 1 and 3 poliomyelitis viruses in an area previously recognised as poliomyelitis Types 1 and 3 free.

4.2 Posology and method of administration**Posology**

In a multidose container, one immunising dose (0.1 ml) is contained in two drops.

Polio Sabin™ One and Three (oral) is not intended for routine vaccination.

The advised vaccination schedule for each country must be in accordance with the national recommendations.

According to WHO recommendations, Polio Sabin™ One and Three (oral) is indicated for poliomyelitis Supplementary Immunisation Activities (SIAs) in children from 0 to 5 years of age, to interrupt Type 1 and Type 3 polioviruses transmission in remaining polio endemic areas. The routine poliomyelitis vaccination programme should continue to use trivalent vaccines according to national policy.

Polio Sabin™ One and Three (oral) may also be given to children and adults when it is necessary to maintain or to reinforce the level of protection against infection caused by Type 1 and Type 3 polioviruses. The vaccine may also be administered to persons with a high risk of exposure to infection caused by Type 1 and Type 3 polioviruses. This vaccine does not act as a substitute for the trivalent poliomyelitis vaccine when this later is recommended.

Method of administration

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

POLIO SABIN™ ONE AND THREE (ORAL) SHOULD UNDER NO CIRCUMSTANCES BE INJECTED.

One dose of vaccine (0.1 ml) 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 a multidose dropper with saliva of the vaccinee.

4.3 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. 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.

4.4 Special warnings and special precautions for use

POLIO SABIN™ ONE AND THREE (ORAL) SHOULD UNDER NO CIRCUMSTANCES BE INJECTED.

Polio Sabin™ One and Three (oral) should not be used for routine immunization against poliomyelitis (see section 4.1).

The routine poliomyelitis vaccination programme should continue to use trivalent vaccines according to national policy.

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.

Episodes of diarrhoea and/or vomiting (as well as any gastro-intestinal infection) may hinder the administration of Polio Sabin™ One and Three (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.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

Where the person to be vaccinated or contacts of persons to be vaccinated suffer from spontaneous or iatrogenic immunodeficiency (hereditary immunodeficiency, hypogammaglobulinemia and dysgammaglobulinemia, blood dyscrasia, leukaemia, lymphoma, neoplasia of the bone marrow or of the lymphatic system, generalised malignancy, administration of ACTH, corticosteroids, immunosuppressive drugs, cytostatic drugs or radiation therapy) the risk benefit of the use of the vaccine should, in an epidemic context, be evaluated in comparison to the use of inactivated vaccines. However, individuals with asymptomatic or symptomatic human immunodeficiency virus (HIV) infection may be vaccinated with Polio Sabin™ One and Three (oral).

4.5 Interaction with other medicinal products and other forms of interaction

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, measles, rubella and/or mumps vaccine, yellow fever 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 trial involving more than 4200 subjects who received OPV concomitantly with GlaxoSmithKline Biologicals' rotavirus vaccine (Rotarix™) showed that clinical protection against severe rotavirus gastroenteritis 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 (see section 4.4).

4.6 Pregnancy and lactation

Pregnancy

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.

Lactation

The vaccine may be administered to a lactating mother.

Women of childbearing potential/ Contraception

Non immune woman of child-bearing age should use contraception during 3 months following vaccination.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

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 post vaccinal paralytic poliomyelitis occurred after the administration of the first dose.

Fever, vomiting, diarrhoea and allergic/anaphylactoid reactions have been described after immunisation with GlaxoSmithKline Biologicals' trivalent oral poliomyelitis vaccine.

4.9 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.

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties

On the basis of literature, 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.

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 and purified water.

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. (see also section 6.4)

6.4 Special precautions for storage

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 $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$.

Multidose vials of Polio Sabin™ One and Three (oral) from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met (as described in the WHO policy statement: The use of opened multidose vials in subsequent immunization sessions. WHO/V&B/00.09):

- The expiry date has not passed;

- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water;
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point

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 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.

Store in the original package in order to protect from light.

6.5 Nature and contents of container

The vaccine is presented in glass vials (multidose vials containing 10 doses or 20 doses).

6.6 Instructions for use and handling

Vaccines 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 light peach to light red.

Changes of the colour of the vaccine within these ranges do not signify deterioration of the vaccine.

6.7 Vaccine Vial Monitor (see VVM pictogram at the end of the leaflet)

The Vaccine Vial Monitor (VVM) is part of the label used for all Polio Sabin™ One and Three (oral) batches supplied by GlaxoSmithKline Biologicals. 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.

It is absolutely critical to ensure that the storage conditions specified above (in particular the cold chain) are complied with. GlaxoSmithKline Biologicals will assume no liability in the event Polio Sabin™ One and Three (oral) has not been stored in compliance with that storage instructions. Furthermore GlaxoSmithKline Biologicals assumes no responsibility in case a VVM is defective for any reason.



Inner square lighter than outer circle. **If the expiry date has not been passed, USE the vaccine.**



At a later time, inner square still lighter than outer circle. **If the expiry date has not been passed, USE the vaccine.**



Discard point: Inner square matches colour of outer circle. **DO NOT use the vaccine.**



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

For further information, please contact the manufacturer.

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