SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Polio Sabin One and Three (oral), drinkable suspension, multidose.
Bivalent poliomyelitis vaccine Types 1 and 3 (live, attenuated).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.1 ml) contains:

Polio virus type 1 (LSc, 2ab strain) live attenuated*	not less than $10^{6.0}$ $CCID_{50}$
Polio virus type 3 (Leon, 12a, 1b strain) live attenuated*	not less than $10^{5.8}$ $CCID_{50}$

*produced on a culture of human diploid cells

The vaccine is presented in a multidose pack. See section 6.5 for the number of doses per vial.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Drinkable suspension.
Clear, yellowish to pink suspension for oral administration.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Polio Sabin One and Three (oral) is indicated for active immunisation at any age against poliomyelitis infection caused by poliomyelitis viruses Types 1 and 3.

4.2. Posology and method of administration

Posology

In a multidose vial, one immunising dose consists of two drops.

The vaccination schedule must be in accordance with official recommendations.

Method of administration

Polio Sabin One and Three (oral) is presented ready for use and is for oral administration only.

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The vaccine can be administered alone or together with beverages or foods (syrup, milk, bread, a sugar lump), provided that these do not contain substances that may inactivate the virus such as preservatives. Since the vaccine has a slightly bitter, salty taste, it can be given in syrup or on a sugar lump, particularly when it is given to young children.

In breast-fed infants, the vaccine should be administered preferably two hours before or after breast-feeding in order to avoid any interference with the antibodies present in the mother's milk.

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

4.3. Contraindications

Hypersensitivity to the active substances or to any of the excipients referred to in section 6.1 or to neomycin or polymyxin. 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 an oral poliomyelitis vaccine from GlaxoSmithKline Biologicals.

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).

4.4. Special warnings and precautions for use

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

Polio Sabin One and Three (oral) does not prevent the appearance of or modify the course of the disease in subjects already infected with wild Type 1 or Type 3 viruses.

Vaccination with Polio Sabin One and Three (oral) should be postponed in subjects suffering from an acute severe febrile illness, or in the case of persistent diarrhoea or vomiting. However, the presence of a minor infection, such as a cold, is not a contraindication for 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 Types 1 and 3 multiply in the gut. The faecal excretion of the vaccinal virus may persist for several weeks and may also be transmitted to people in contact with the vaccinee; it is therefore prudent to recommend people in contact with the vaccinee to observe strict personal hygiene.

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30.06.16
04.07.16

Non-immune people in close contact with a recently vaccinated subject may very rarely be at risk of paralysis connected with the vaccination of the contact.

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).

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 a *Haemophilus influenzae* type b vaccine, a hepatitis B vaccine, a diphtheria, pertussis and/or tetanus vaccine, an inactivated polio vaccine (IPV), a measles, mumps and rubella vaccine or a BCG vaccine, if the vaccination schedule allows.

Concomitant administration of an oral poliomyelitis vaccine (OPV) and rotavirus vaccine does not affect the immune response to polio antigens but can slightly reduce the immune response to the rotavirus vaccine. A clinical trial involving more than 4,200 subjects who received trivalent OPV at the same time as the 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.

Immunosuppressant treatments can reduce the immune response to the vaccine, favour the multiplication of the vaccinal virus and can increase the length of time that the vaccinal virus is excreted in the stools.

4.6. Fertility, pregnancy and lactation

Pregnancy

There is limited data, and even no data, on the use in the pregnant woman of live attenuated poliomyelitis virus from Sabin strains of Type 1 (LSc, 2ab) and of Type 3 (Leon 12a, 1b). Animal studies are insufficient to allow conclusions to be drawn about the toxicity on reproduction (see section 5.3). Polio Sabin One and Three (oral) is not recommended during pregnancy or in women of childbearing age who do not use contraception.

During pregnancy and if there is an epidemic, the risk/benefit of the use of this vaccine should be evaluated in comparison with the use of inactivated vaccines.

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30.06.16

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10

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 contraindication has been established.

The vaccine can be administered to a mother during the breast-feeding period.

Fertility
Women of childbearing age who have not been immunised against polio should use contraception for 3 months following vaccination.

4.7. Effects on ability to drive and use machines

The effects of the Polio Sabin One and Three vaccine (oral) on the ability to drive and use machines have not been studied.

However, based on the known side effects, 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 cases 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

Reporting suspected undesirable effects
The reporting of suspected undesirable effects after authorisation of the medicinal product is important. It enables continuous surveillance of the risk/benefit relationship of the medicinal product. Healthcare professionals report any suspected undesirable effect via the national reporting system:

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B-1060 Brussels
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4.9 Overdose

Occasional cases of overdose with GlaxoSmithKline Biologicals' trivalent oral poliomyelitis vaccine have been reported but have not resulted in any significant effects.

No case of overdose has been reported with the Polio Sabin One and Three (oral) vaccine.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: Viral vaccine, ATC code: J07BF04.

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 week or a 6, 8, 10 week 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.

5.2. Pharmacokinetic properties

An evaluation of the pharmacokinetic properties is not required for vaccines.

5.3. Preclinical safety data

Non-clinical data have not revealed any particular risk for man, based on quality controls carried out on animals.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Magnesium chloride hexahydrate
Polysorbate 80
L-arginine

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Water for injection

6.2. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3. Shelf-life

2 years

After opening, the multidose vial must be kept in the refrigerator (between 2°C and 8°C) and ideally used within 8 hours.

6.4. Special precautions for storage

Store in the freezer (-20°C).
Store in the original outer packaging, away from light.

The vaccine can be stored for six months in the refrigerator (between 2°C and 8°C).

For storage conditions for the vaccine after first opening, see section 6.3.

6.5. Nature and contents of outer packaging

Vial (of glass type I) containing 10 doses or 20 doses with a stopper (butyl rubber) with an aluminium closure and with a polyethylene dropper supplied separately – box of 100.

Not all of the presentations may be marketed.

6.6. Special precautions for disposal and handling

Before administration, the vaccine must be inspected visually to detect the presence of any foreign particulate.

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.

One dose of vaccine consists of 2 drops which are delivered by the polyethylene dropper supplied with the multidose vial.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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13

7. MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Biologicals s.a.
Rue de l'Institut, 89
1330 Rixensart
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

BE349334

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATAON

Date of first authorisation: 08 October 2009
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

June 2015
Date approved: 06/2015

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