SUMMARY PRODUCT CHARECTERISTICS

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

DESCRIPTION	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. Magnesium chloride is used as a stabilizer. Polio Sabin ™ One and Three (oral) contains trace amounts of neomycin sulphate and polymyxin B sulphate.
POTENCY	Each dose (0.1 ml) contains not less than 106.0 CCID50 of Type 1 and 105.8 CCID50 of Type 3.
THERAPEUTIC INDICATIONS	Polio Sabin ™ One and Three (oral) is indicated for active immunization 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 recognized as poliomyelitis Types 1 and 3 free.
DOSAGE & 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 vaccine.
CONTRAINDICATONS	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 oral poliomyelitis vaccines.
SPECIAL WARNINGS & PRECAUTION 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. 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 vaccines 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 vaccines. 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).
INTERACTION WITH OTHER MEDICAL PRODUCTS & OTHER FORM 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. 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 & 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.
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 Biologicalsí trivalent oral poliomyelitis vaccine.
OVERDOSE	Occasional reports of overdose with GlaxoSmithKline Biologicalsí 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
STORAGE OF VACCINES	The vaccine is potent if stored at not higher than ñ20°C until the expiry date indicated on the vial. It can be stored for up to six months between +2°C and +8°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.
PRESENTATION	Oral suspension. The vaccine is presented as clear liquid, yellowish-pink suspension for oral administration.
MARKETING AUTHORIZATON HOLDER	GlaxoSmithKline Biologicals s.a. Rue de líInstitut 89, B-1330 Rixensart, Belgium
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02793