

**WHO PACKAGE INSERT**

## 1. NAME OF THE MEDICINAL PRODUCT

Poliorix™, solution for injection  
Poliomyelitis vaccine (inactivated) (IPV)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A 0.5 ml dose of vaccine contains:

Inactivated polio virus type 1 (Mahoney) <sup>1</sup>	40 D antigen units
Inactivated polio virus type 2 (MEF-1) <sup>1</sup>	8 D antigen units
Inactivated polio virus type 3 (Saukett) <sup>1</sup>	32 D antigen units

<sup>1</sup>Propagated in VERO cells

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection.  
Poliorix™ is a clear liquid solution.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Poliorix™ is indicated for active immunisation from the age of 2 months against poliomyelitis (*see also section 4.2*).

### 4.2 Posology and method of administration

#### Posology

Infants should receive at least three doses of IPV at minimum intervals of 4 weeks in the first six months of life. Most countries give IPV using the same schedule as DTP.

IPV given as part of a combined vaccine was also administered to subjects from the age of 6 weeks onwards. When Poliorix™ is given earlier than 2 months of age and/or if the interval between doses is less than 8 weeks, a booster dose is recommended at 9 months of age or in the second year of life in order to provide optimal protection.

#### Method of administration

Poliorix™ is for deep intramuscular injection  
Infants: anterolateral aspect of the thigh  
Older children and adults: deltoid

### 4.3 Contraindications

Poliorix™ should not be administered to subjects with known hypersensitivity to any component of the vaccine, or to subjects having shown signs of hypersensitivity after previous administration of inactivated polio vaccines (*see sections 2 and 6.1*).

#### **4.4 Special warnings and precautions for use**

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable events) and a clinical examination.

As with other vaccines, the administration of Poliorix™ should be postponed in subjects suffering from acute severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Although there exist limited data in individuals infected with immunodeficiency virus (HIV), both asymptomatic and symptomatic, these individuals should be immunized with IPV according to standard schedules.

Subjects with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic effect, HIV infection, or other causes, may have reduced antibody response to active immunisation.

Poliorix™ should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Poliorix™ should under no circumstances be administered intravenously. No data are available on subcutaneous administration of Poliorix™.

The potential risk of apnoea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunization series to very premature infants (born  $\leq$  28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

It is current practice in vaccination to coadminister different vaccines during the same session. If Poliorix is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.

In clinical studies, Poliorix™ has been administered concomitantly with D, T, P, HBV and Hib antigens. IPV can be given safely and effectively at the same time as measles, mumps, rubella, BCG and yellow fever vaccines and vitamin A supplementation.

#### **4.6 Pregnancy and lactation**

Adequate human data on use during pregnancy and lactation and adequate animal reproduction studies are not available.

#### **4.7 Effects on ability to drive and use machines**

Poliorix™ has no or negligible influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

#### **Clinical trials**

The safety profile presented below is based on data from clinical trials in infants and children. However, as other vaccines were administered concomitantly, the causal relationship of these symptoms to Poliorix™ cannot be established.

Adverse reactions considered by the investigator as being at least possibly related to vaccination have been categorised by frequency as follows.

Very common ( $\geq 1/10$ )

Common ( $\geq 1/100$  to  $< 1/10$ )

Uncommon ( $\geq 1/1,000$  to  $< 1/100$ )

Rare ( $\geq 1/10,000$  to  $< 1/1,000$ )

Very rare ( $< 1/10,000$ )

#### Nervous system disorders

Very common: drowsiness

#### Gastrointestinal disorders

Common: diarrhoea, vomiting

#### Metabolism and nutrition disorders

Very common: appetite lost

#### General disorders and administration site conditions

Very common: pain, redness and swelling at the injection site, fever

#### Psychiatric disorders

Very common: irritability, restlessness, crying abnormal

### **Post-marketing surveillance**

#### Respiratory, thoracic and mediastinal disorders:

Apnoea in very premature infants ( $\leq 28$  weeks of gestation) (see section 4.4)

#### Immune system disorders

Allergic reactions, including anaphylactic and anaphylactoid reactions

### **4.9 Overdose**

No case of overdose has been reported.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmaco-therapeutic group: viral vaccines, ATC code: J07BF03

Poliorix has been administered either according to a two-dose (2-4; 3-4 ½; 3-5; 4-6 months) or a three-dose schedule (3-4-5; 3-4 ½-6 months).

Following a two-dose primary course, 97 to 100% of all vaccinees have neutralising antibodies against all three polio serotypes. All subjects had neutralising antibodies after a three dose primary course.

### **5.2 Pharmacokinetic properties**

Evaluation of pharmacokinetic properties is not required for vaccines.

### **5.3 Preclinical safety data**

Preclinical data reveal no special hazard for humans based on general safety studies.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

2-phenoxyethanol  
Medium 199 including amino acids.  
Formaldehyde  
Polysorbate 80  
Water for injections  
Neomycin (traces)  
Polymyxin (traces)

### **6.2 Incompatibilities**

In the absence of compatibility studies, 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**

Store in a refrigerator (2°C – 8°C).  
Do not freeze.

After first opening of the multidose vial, immediate use is recommended.  
If not used immediately, the multidose vial must be discarded at the end of each immunization session or after 6 hours from first opening, whichever comes first.

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

### **6.5 Nature and contents of container**

0.5 ml of solution in a vial (type I glass) for 1 dose with a grey butyl rubber stopper – pack sizes of 1, 10 or 100

1 ml of solution in a vial (type I glass) for 2 doses with a grey butyl rubber stopper – pack sizes of 1, 10 or 100

Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal and other handling**

Poliorix™ should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the vaccine.

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

The Vaccine Vial Monitor (VVM) is either part of the label or the vial cap used for all Poliorix™ batches supplied by GlaxoSmithKline Biologicals. The colour dot that appears on the label of the vial for 1 dose (0.5 ml) or on the vial cap for 2 doses (1 ml) of vaccine 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 Poliorix™ has not been stored in compliance with those 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.

**Poliorix is a trademark of the GlaxoSmithKline group of companies.**

**WHO Package Insert**

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