POLIORIX®

Poliomyelitis Vaccine (Inactivated) IP

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) of the vaccine cultivated on a continuous VERO cell line contains:

- Inactivated Polio Virus Type 1 (Mahoney strain) 40 antigen D Units
- Inactivated Polio Virus Type 2 (MEF-1 strain) 8 antigen D Units
- Inactivated Polio Virus Type 3 (Saukett strain) 32 antigen D Units

Preservatives:
- 2-phenoxyethanol IP 2.5mg
- Formaldehyde 0.01mg

For a full list of excipients, see section ‘List of Excipients’.

It complies with the requirements of the World Health Organisation concerning biological substances and the polio vaccine.

PHARMACEUTICAL FORM

Solution for injection

CLINICAL PARTICULARS

Therapeutic Indications

POLIORIX is indicated for active immunisation against poliomyelitis as of the age of 6 weeks.

Posology and Method of Administration

Posology

The primary and booster vaccination scheme must be compliant with the official recommendations.

POLIORIX can be administered as of the age of 6 weeks. An interval of 8 weeks between the first and second dose is recommended, and of 8 months between the second and third dose. A fourth dose is administered at the age of 6.
A booster dose is recommended later, as of the age of 16, and as of adult age, every ten years for people who travel in endemic regions.

**Method of administration**

*POLIORIX* is administered with a deep intramuscular injection.

Babies: anterolateral side of the thigh.

Children: deltoid muscle.

**Contraindications**

*POLIORIX* must not be administered to persons with a known hypersensitivity to one of the constituents of the vaccine nor to patients who had shown signs of hypersensitivity during a previous administration of inactivated polio vaccines.

**Special Warnings and Special Precautions for Use**

As for every vaccine for injection, it is recommended that appropriate medical treatment be available in case of anaphylactic reaction to the administration of the vaccine.

The vaccination must be preceded by a review of the patient's anamnesis (especially as regards any undesirable effects that have occurred during previous vaccinations) as well as a clinical examination.

As with other vaccines, the administration of *POLIORIX* will be postponed in patients suffering from high fever. A minor infection, on the other hand, is not a contraindication.

The active immunity response, i.e. the formation of antibodies, may diminish in persons suffering from immunity disorders, whether due to immunosuppressive therapy, a genetic disease, infection with the HIV virus, or any other reason.

*POLIORIX* contains traces of neomycin and polymyxin. The vaccine must be used with precaution in patients who have a known hypersensitivity to these antibiotics.

*POLIORIX* must be administered with precaution to patients suffering from thrombocytopenia or coagulation disorders, as haemorrhage could occur after the intramuscular administration of the vaccine in such patients.

*POLIORIX* must under no circumstances be administered intravascularly.

The potential risk of apnoea with the necessity for respiratory monitoring for 48-72 hours should be carefully taken into account when administering doses of initial vaccination to highly premature infants (born at 28 weeks of pregnancy or less), especially in those with
a history of respiratory immaturity. Due to the high benefit of vaccination in these infants, administration should not be suspended or postponed.

**Interaction with Other Medicaments and Other Forms of Interaction**

It is common practice to administer several vaccines during the same vaccination session.

Injectable vaccines must be administered at different injection sites.

*POLIORIX* may be administered concomitantly with the antigens D, T P, Hepatitis B and Hib, with injections at different injection sites.

**Pregnancy and Lactation**

Appropriate data are not available on the use of *POLIORIX* during pregnancy or the lactation period, and no studies have been conducted on animals relating to toxicity on the reproductive function.

**Effects on Ability to Drive and Use Machines**

*POLIORIX* has little or no influence on the ability to drive a motor vehicle or to use machines.

**Undesirable Effects**

**Clinical Studies**

The safety profile presented below is based on data collected in infants and children. Nevertheless, as other vaccines have been administered concomitantly, the relation of these symptoms to *POLIORIX* cannot be established.

The undesirable effects considered by investigators as at least triggered by the vaccination have been classified by frequency as follows:

- Very common (≥1/10)
- Common (≥1/100 to <1/10)
- Uncommon (≥1/1,000 to <1/100)
- Rare (≥1/10,000 to <1/1,000)
- Very rare (<1/10,000)

**Nervous system disorders**

Very common: somnolence

**Gastrointestinal disorders**

Common: diarrhoea, vomiting
Metabolism and nutrition disorders
Very common: loss of appetite

General disorders and administration site conditions
Very common: pain, redness and swelling at the injection site, fever

Psychiatric disorders
Very common: irritability, nervousness, abnormal crying

Post-marketing surveillance

Immune system disorders
Allergic reactions, including anaphylactic and anaphylactoid reactions

Respiratory, thoracic and mediastinal disorders
Apnoea in highly premature infants (5≤8 weeks of gestation) - See section ‘Special Warnings and Special Precautions for Use’

Overdose
No case of overdose has been reported.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties
Pharmaco-therapeutic group: viral vaccine - Code ATC: J07BF03

After the primary vaccination of 2 doses, 97 to 100% of the vaccinees have neutralising antibodies against the three polio serotypes. All the subjects have neutralising antibodies after a primary vaccination comprising 3 doses.

Pharmacokinetic Properties
An evaluation of pharmacokinetic properties is not required for vaccines.

Preclinical Safety Data
Preclinical data show no risks for human beings, based on general safety studies.

PHARMACEUTICAL PARTICULARS

List of Excipients
Excipients:

2-phenoxyethanol  
Medium 199  
Formaldehyde  
Polysorbate 80  
Water for preparations for injection

Traces:

Neomycin sulphate  
Polymyxin sulphate

Incompatibilities

POLIORIX cannot be mixed in the same syringe with other vaccines.

Shelf Life

36 months  
The expiry date is indicated on the label and packaging.

Special Precautions for Storage

Keep in a refrigerator (between 2°C and 8°C).  
Do not freeze.  
Do not use the vaccine if it has been frozen.  
Keep out of reach of children

Nature and Specification of Container

0.5 ml (I dose) of solution in a type I glass vial (Ph. Eur.) sealed with a grey butyl cap. Packaging of: 1, 10 or 100 vials

1.0 ml (2 doses) of solution in a type I glass vial (Ph. Eur.) sealed with a grey butyl cap. Packaging of: 1, 10 or 100 vials

5.0 ml (10 doses) of solution in a type I glass vial (Ph. Eur.) sealed with a grey butyl cap. Packaging of: 1, 10 or 50 vials
All presentations may not be marketed in India.

**Instructions for Use/Handling**

*POLIORIX* is a transparent aqueous solution.

*POLIORIX* must be visually inspected to detect any foreign particles and/or a variation of unusual appearance before administration. If such is the case, the vaccine must not be used.

**Manufactured by:**

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