

LG Chem, Ltd.

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1. Trade Name of the Drug Product

Eupolio Inj. (Sabin Inactivated Polio Vaccine)

2. Qualitative and Quantitative Composition

A single human dose (0.5 mL) of Sabin Inactivated Polio Vaccine contains 5 D-antigen units, 8 D-antigen units and 16 D-antigen units of inactivated poliovirus types 1, 2 and 3(Sabin strain), respectively as active ingredients.

3. Pharmaceutical Form

Colorless and clear solution for injection

4. Clinical Particulars

4.1 Therapeutic Indications

For active primary immunization against poliomyelitis caused by poliovirus in infants from 6 weeks of age.

4.2 Dosage and Administration

The vaccine should be injected intramuscularly. Do not administer by other route of injection. One pediatric dose is 0.5mL. The first dose should be given at least at the age of 6 weeks, and two subsequent doses should be given at minimum intervals of 4 weeks. The advised vaccination schedule should be in accordance with the national or WHO recommendations. A sterile syringe and sterile needle must be used for each injection.

4.3 Contraindications

Vaccination of persons with an acute, febrile illness should be deferred until after recovery.

The vaccine should be contraindicated in persons with a history of hypersensitivity to any component of the vaccine, including 2-phenoxyethanol and formaldehyde.

Immune deficiency

HIV seropositivity does not represent a contraindication to vaccination. Patients with an

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immunodeficiency disorder or receiving immunosuppressive therapy may have a reduced immunological response. Individuals infected with immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with sIPV according to standard schedules.

4.4 Special Warnings and Special Precautions for Use

As with any injectable vaccine, appropriate medical supervision and treatment should always be readily available in case of immediate allergic reactions, such as anaphylactic shock or anaphylactic reaction, following administration of the vaccine. Before administering the vaccine, precautions should be taken to avoid undesirable reactions.

These precautions include: review of the individual's medical history, particularly regarding hypersensitivity reactions to previous administration of any type of vaccine, as well as the individual's history of recent health disorders and any previous vaccinations.

2-phenoxyethanol and formaldehyde are present in the final product. Therefore, sensitization reactions may occur.

The vaccine must not be injected into a blood vessel.

Eupolio Inj. should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. A fine needle should be used for the vaccination and firm pressure applied to the site (without rubbing) for at least two minutes following administration.

The potential risk of apnoea and the need for respiratory monitoring for 48 -72 hours 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 Medicaments and Other Forms of Interaction

There are no known risks of administering Sabin Inactivated Polio Vaccine with other usual vaccines. From historical data on immunological responses, no clinically relevant interferences have been observed when Sabin Inactivated Polio Vaccine was used at the same time as diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenzae* type b vaccines. If Sabin Inactivated Polio Vaccine is given at the same time as other vaccines, it should be administered at a separate site. It should not be mixed in the vial or syringe with any other vaccine.

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4.6 Pregnancy and Lactation

Reproduction study on animals has not been conducted and there is no evidence that Sabin Inactivated Polio Vaccine is harmful to pregnant women and lactating women. It should only be given when benefits outweigh risks.

4.7 Undesirable Effects

Data from clinical studies:

In the clinical trial, Eupolio Inj. has been administered as a primary vaccination in 968 infants from 6 to 14 weeks of age. Reported adverse reactions are listed below. Frequencies are based on: Very common: $\geq 1/10$, Common: $\geq 1/100$ and $< 1/10$, Uncommon: $\geq 1/1000$ and $< 1/100$, Rare: $\geq 1/10000$ and $< 1/1000$, Very rare: $< 1/10000$, Not known: cannot be estimated from the available data

Solicited adverse events for 7 days after the vaccination

Local events

Very common: Pain/tenderness

Common: Erythema/redness, Induration/swelling

Systemic events

Very common: Irritability/restlessness, Drowsiness/sleepiness, Diarrhea, Vomiting, Loss of appetite

Common: Rash, Fever

Unsolicited adverse drug reactions for 28 days after the vaccination

Uncommon: Infantile colic

Serious adverse events for 28 days after the vaccination

All of the serious adverse events were considered not related to Eupolio Inj.

Infections and infestations

Common: Pneumonia

Uncommon: Gastroenteritis, Urinary tract infection, Pneumonia respiratory syncytial viral, Upper respiratory tract infection, Bronchitis, Bronchiolitis, Gastroenteritis rotavirus, Gastroenteritis salmonella, Meningitis bacterial, Pneumonia measles, Viral infection, Viral myocarditis

General disorders and administration site conditions

Uncommon: Pyrexia, Sudden infant death syndrome

Skin and subcutaneous tissue disorders

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Uncommon: Urticaria

Blood and lymphatic system disorders

Uncommon: Thrombocytopenia

Congenital familial and genetic disorders

Uncommon: Congenital central nervous system anomaly

Nervous system disorders

Uncommon: Epilepsy

Serious adverse events from 28 days to 6 months after the last vaccination

All of the serious adverse events were considered not related to Eupolio Inj.

Infections and infestations

Uncommon: Pneumonia, Gastroenteritis, Pneumonia measles, Bronchitis, Exanthema subitum, Abscess, Infectious diarrhea, Hand-foot-and-mouth disease, Influenza, Measles, Urinary tract infection bacterial

Gastrointestinal disorders

Uncommon: Diarrhea, Gastritis

Metabolism and nutrition disorders

Uncommon: Dehydration

General disorders and administration site conditions

Uncommon: Pyrexia

Surgical and medical procedures

Uncommon: Orchidopexy

4.8 Overdose

Not applicable

5. Pharmacological Properties

5.1 Pharmacodynamic Properties (Immunological Data)

In the Stage II (phase 3) of study, 3 lots of Eupolio Inj. or Imovax Polio® Inj.(conventional Inactivated Polio Vaccine) as a control were administered in 1,084 healthy infants by intramuscular injection 3 times at 6, 10 and 14 weeks of age and the immunogenicity was evaluated.

The seroconversion rate of the combined group of 3 Eupolio Inj. lots was 95.8 to 99.2% for each serotype, and the lower limits of 95% CI for the difference in seroconversion rate for each serotype between the combined Eupolio Inj. group and the Imovax Polio® Inj. group proved greater than the

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non-inferiority margin of -10%, demonstrating the non-inferiority of Eupolio Inj. to conventional Inactivated Polio Vaccine (Table 1).

Table 1. Seroconversion rate of Eupolio Inj.

Seroconversion rate ¹⁾	Per-Protocol Set (PPS)		% Difference (95% CI)
	Control (N=194)	Eupolio Inj. (N=852)	
Sabin 1, n(%)	187 (96.4%)	830 (97.4%)	1.0 (-1.2, 4.8)
Sabin 2, n(%)	184 (94.8%)	830 (97.4%)	2.6 (-0.1, 6.7)
Sabin 3, n(%)	190 (97.9%)	816 (95.8%)	-2.2 (-4.2, 1.2)
Wild 1 (Mahoney), n(%)	194 (100%)	825 (96.8%)	-3.2 (-4.6, -1.0)
Wild 2 (MEF-1), n(%)	193 (99.5%)	838 (98.4%)	-1.1 (-2.3, 1.3)
Wild 3 (Saukett), n(%)	193 (99.5%)	845 (99.2%)	-0.3 (-1.3, 2.1)

¹⁾ Seroconversion criteria

- for subjects seronegative at the pre-vaccination time point (antibody titer < 8 (3 log₂)), the post-vaccination antibody titers of ≥ 8 (3 log₂)
- for subjects seropositive at the pre-vaccination time point (antibody titer ≥ 8 (3 log₂)), a ≥4-fold (2 log₂) rise in the post-vaccination antibody titres

5.2 Pharmacokinetic Properties

Not applicable

6. **Pharmaceutical Particulars**

6.1 List of Excipient(s)

Buffering agent	: Monobasic sodium phosphate dihydrate -----	0.3 mg
	: Dibasic sodium phosphate heptahydrate -----	0.82 mg
Stabilizing agent	: Polysorbate 80 -----	50 µg
	: Medium 199 -----	q.s.
Preservative	: Formalin(as formaldehyde)-----	17.5 µg
	: 2-Phenoxyethanol-----	2.5 mg
Solvent	: Water for injection -----	q.s.

6.2 Incompatibilities

Not known

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6.3 Shelf-life

36 months

6.4 Special precautions for storage

Eupolio Inj. is stable for 36 months at 2-8°C. It can be used safely for 36 months when stored at 2-8°C [36-46°F] in a refrigerator. It should not be frozen.

6.5 Nature and Contents of Container

Elastomeric closures and glass container (vial) for injections
The containers are colorless and transparent, and have no bubbles.

Packs contain ;

0.5 mL (1 pediatric dose) × 10 vials / box

2.5 mL (5 pediatric doses) × 10 vials / box

6.6 Instruction for Use/Handling

It must be administered by intramuscular injection.

7. Marketing Authorization Holder

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8. Marketing Authorization Number

N/A

9. Date of First Authorization / Renewal of Authorization

Registration Number and Date of First Authorization : 5158 / April 02, 2020

Number and Date of Renewal : N/A



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10. Date of (Partial) Revision of the Texts

September 28, 2021