Summary of Product Characteristics for Pharmaceutical Products

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 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 ≤ 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.

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 Effect on Ability to Drive and Operate Machinery

N/. A

4.8 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: ≥ 1/10, Common: ≥ 1/100 and <

1/10, Uncommon: ≥ 1/1000 and < 1/100, Rare: ≥ 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
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
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the PPB website https://pv.pharmacyboardkenya.org.

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 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)		
	Control (N=194)	Eupolio Inj. (N=852)	% Difference (95% CI)
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)] Seroconverstion 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
Dibasic sodium phosphate
Polysorbate 80
Medium 199
Formalin(as formaldehyde
2-Phenoxyethanol

6.2 Incompatibilities
Not known

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
LG Chem, Ltd, Osong plant ,151,
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Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,
Korea

8. Marketing Authorization Number
N/A

9. Date of First Authorization / Renewal of Authorization
01-01-2022

10. Date of (Partial) Revision of the Texts
12/2024