EUVICHOL-PLUS (ORAL CHOLERA VACCINE)

The vaccine is a liquid formulation of Oral Cholera Vaccine containing O1 and 139 of *Vibrio cholerae* inactivated by heat or formalin. The vaccine was developed by EuBiologics Co., Ltd with the help of International Vaccine Institute (IVI). The vaccine fulfils WHO requirements for cholera.

[COMPOSITION]

One dose (1.5 mL) contains:

Active Ingredients:

- *V. cholerae* O1 Inaba Cairo 48 classical biotype, Heat inactivated ..... 300 L.E.U*
- *V. cholerae* O1 Inaba Phil 6973 El Tor biotype, Formalin inactivated ..... 600 L.E.U
- *V. cholerae* O1 Ogawa Cairo 50 classical biotype, Formalin inactivated ..... 300 L.E.U
- *V. cholerae* O1 Ogawa Cairo 50 classical biotype, Heat inactivated ..... 300 L.E.U
- *V. cholerae* O139 4260B, Formalin inactivated ..... 600 L.E.U

Excipients:

- Sodium phosphate dibasic dihydrate 4.68mg
- Sodium phosphate monobasic dihydrate 0.97mg
- Sodium chloride 12.75mg
- Water for injection ..... q.s. to 1.5mL

*L.E.U.: Lipopolysaccharide ELISA Units

[INDICATION]

For prevention of Cholera for the age of 1 year and above caused by *Vibrio cholerae*.

[INSTRUCTION FOR USE]

1. The vaccine should be administered to anyone above the age of 1 year.
2. Two doses of vaccine should be given at an interval of two weeks.
3. The vaccine is presented as a suspension. Therefore, after shaking the vaccine container rigorously, 1.5mL of the vaccine should be squirted into the mouth. Take a sip of water if necessary.
4. The frozen vaccines should not be taken.
5. The vaccine should not be administered parenterally (intramuscularly, subcutaneously or intravenously). The vaccine is only recommended for oral administration.

[CONTRA-INDICATIONS]

1. The vaccine should not be administered to persons with either known hypersensitivity to any component of the vaccine, or having shown signs of severe reaction due to the previously taken dose.
2. Immunization with Euvichol-Plus should be delayed in the presence of any acute illness, including acute gastrointestinal illness or acute febrile illness.

[ADVERSE DRUG REACTIONS]

2,999 healthy children and adults (1-40 years) were participated in the clinical study for evaluating the safety.

1. After taking the vaccines, during first 7 days, the most frequently reported adverse drug reactions in the clinical trial were headache, fever, diarrhea, Nausea/Vomiting and Myalgia and 102 subjects (3.40%) among 2,999 subjects were reported. The incidence rate for children and adults is described on the table below.

	Total (N=2,999)	1 ~ 17 years (N=1,118)	18~40 years (N=1,881)
Total	3.40%	3.04%	3.62%
Headache	1.83%	0.81%	2.45%
Fever	1.00%	1.97%	0.43%
Diarrhea	0.67%	0.54%	0.74%
Nausea/Vomiting	0.37%	0.63%	0.21%
Myalgia	0.10%	0.00%	0.16%

2. After taking the vaccines, adverse drug reactions were examined for a period of 28 days.
   69 subjects (2.30%) among 2,999 subjects were reported with the adverse effects, and Gastrointestinal disorders were reported the highest numbers i.e., 35 subjects (1.17%). The adverse drug reactions during the study (28 days) were described on the table below.
   (Uncommon: 0~1.5%, Rare: less than 0.1%)

	Incidence	
	Uncommon	Rare
Gastrointestinal disorders	Abdominal pain, toothache, Diarrhea	Vomiting, Abdominal pain upper
General disorders and administration site condition	Pyrexia	Thirst
Infection and infestations	Nasopharyngitis	Gastroenteritis
Nervous systems disorders	Headache	Dizziness
Respiratory, thoracic and meditational disorders	Cough	Oropharyngeal pain
Skin and subcutaneous disorders	Pruritus	Rash macular
Musculoskeletal and connective tissue disorders	-	Arthralgia, Neck pain, Pain in extremity
Vascular disorders	-	Flushing

3. Serious adverse event did not occur during the clinical trial period.

[WARNINGS AND SPECIAL PRECAUTION]

1. As with any vaccine, immunization with the Euvichol-Plus may not protect 100% of susceptible persons.
2. As with all vaccines, appropriate medical treatment should always be readily available in case of a rare event of anaphylactic reactions following the administration of the vaccine. For this reason, it is recommended that the person should remain under medical supervision for at least 30 minutes after vaccination.
3. This vaccine contains residual formaldehyde. Caution should be taken in subjects with known hypersensitivity to formaldehyde.
4. The safety and immune response of Euvichol-Plus has not been clinically evaluated in individual with HIV/ AIDS.
5. No specific clinical studies have been conducted to evaluate the efficacy and safety of Euvichol-Plus in pregnant and lactation women. Therefore, the vaccine is not recommended for use in pregnancy.
6. No clinical studies have been performed to evaluate the efficacy and safety of Euvichol-Plus in infants (less than 1 year of age). Therefore, the vaccine is not recommended for use in infants.

[STORAGE AND SHELF-LIFE]

The vaccine should be stored at 2℃~8℃. Do not freeze. The expiry date of the vaccine is 24 months from the date of manufacture.

[MANUFACTURER]

EuBiologics Co., Ltd., Basement, 1F, 2-4~6 and 3-1~4 of 4-dong, 56 Soyanggang-ro, Chuncheon - si, Gang -wondo, South Korea.
Tel. No.: 18008902590

[IMPORTED AND MARKETED BY]

TechInvention Lifecare Pvt. Ltd.
#1004, The Summit Business Bay, Off WEH Metro Station, Andheri Kurla Road, Andheri (E), Mumbai – 400093. INDIA
Tel. No.: 18008902590
Email address: feedback@techinvention.biz

Euvichol-Plus

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