EUVICHOL-S (ORAL CHOLERA VACCINE)

The vaccine is a liquid formulation of Oral Cholera Vaccine containing O1 of Vibrio cholerae inactivated by formalin. The vaccine was developed by EuBiologics Co., Ltd with the support of International Vaccine Institute (IVI). The vaccine fulfills WHO requirements for cholera.

[COMPOSITION]

One dose (1.5 mL) contains:

Active ingredients:	*V. cholerae* O1 Inaba Phil 6973 El Tor biotype, Formalin inactivated	900 L.E.U.*
	V. cholerae O1 Ogawa Cairo 50 classical biotype, Formalin inactivated	600 L.E.U.*
Excipients:	Sodium phosphate dibasic dihydrate	4.68 MG
	Sodium phosphate monobasic dihydrate	0.97 MG
	Sodium chloride	12.75 MG
	Water for injection	q.s to 1.5 mL
***L.E.U.: Lipopolysaccharide ELISA Unit**		

[INDICATION]

Prevention of Cholera caused by Vibrio cholerae.

[INSTRUCTIONS 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, 1.5 mL 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-S should be delayed in the presence of any acute illness, including acute gastrointestinal illness or acute febrile illness.

[ADVERSE DRUG REACTIONS]

1,595 healthy children, adolescents, and adults (1-40 years) were participated in the clinical study for evaluating the safety.

1. After the first vaccination of this vaccine, during the first 7 days, the most frequently reported adverse drug reactions in the clinical trial were nausea/vomiting, diarrhea, nasopharyngitis, and Myalgia and approximately less than 3% among 1,595 subjects were reported. After the second vaccination of this vaccine, during the first 7 days, the most frequently reported adverse drug reactions in the clinical trial were nausea/vomiting, diarrhea, nasopharyngitis, and Myalgia and approximately less than 5% among 1,595 subjects were reported. The incidence rate for children, adolescents, and adults was described on the table below.

(Rare: 0.1~<5%, Common: <10%)

	Total (N=1,595)	1~5 years (N=245)	6~17 years (N=360)	18~40 years (N=990)
Total	8.5%	2.8%	1.6%	4.1%
Diarrhea	2.0%	0.5%	0.5%	1.0%
Vomiting	1.3%	0.4%	0.0%	0.3%
Dizziness	5.9%	6.7%	0.0%	7.7%
Fever	3.5%	1.7%	0.6%	1.3%
Headache	1.1%	-	0.3%	0.8%

2. After taking the vaccines, 143 subjects (<10%) among 1,595 subjects were reported with the adverse effects. The adverse drug reactions during the study (28 days) were described on the table below.

	Incidence rate
	Rare (0.1~< 5%)
Gastrointestinal disorders	Vomiting, diarrhea, Dizziness
General disorders and administration site condition	Pyrexia, fatigue
Musculoskeletal and connective tissue disorders	Myalgia, pain in extremity
Nervous system disorders	Headache
Metabolism and nutrition disorders	Decreased appetite
Infections and infestations	Nasopharyngitis
Skin and subcutaneous tissue disorders	Eczema

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

[WARNINGS AND SPECIAL PRECAUTIONS]

1. As with any vaccine, immunization with Euvichol-S 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-S 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-S in pregnant or lactating women and for the fetus. Therefore, the vaccine is not recommended for use in pregnancy. However, Euvichol-S is a killed vaccine that does not replicate, is given orally and acts locally in the intestine. Hence, theoretically, Euvichol-S should not pose any risk to the human fetus. Administration of Euvichol-S to pregnant or lactating women may be considered after careful evaluation of the benefits and risk in case of medical emergency or an epidemic. Please consult national recommendations for guidance on the use of oral cholera vaccine during pregnancy.
6. No clinical study has been performed to evaluate the efficacy and safety of Euvichol-S 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.

Vaccine Vial Monitors (VVMs) are a part of the label attached on Euvichol-S supplied through EuBiologics Co., Ltd. The color dot which appears on the label of the vaccine is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vaccine 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 color will change progressively. As long as the color of this square is lighter than the color of the ring, the vaccine can be used. As soon as the color of the central square is the same color as the ring or of a darker color than the ring, the vaccine should be discarded.

[MANUFACTURER]

eubiologics

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