Summary of Product Characteristics

1. Name of the medicinal product

Cholvax

Inactivated Oral Cholera Vaccine BP

Available in 1.5 ml strength.

2. Qualitative and quantitative composition

Each vial contains 1.5 ml Inactivated Oral Cholera Vaccine BP as-

Active ingredients	**Quantity**
V. cholerae O1 Inaba Phil 6973 El Tor, Formaldehyde Inactivated	600 LEU*
V. cholerae O1 Inaba Cairo 48, Heat Inactivated	300 LEU
V. cholerae O1 Ogawa Cairo 50, Formaldehyde Inactivated	300 LEU
V. cholerae O1 Ogawa Cairo 50,Heat Inactivated	300 LEU
V. cholerae O139 4260B, Formaldehyde Inactivated	600 LEU
Excipients	
Thiomersal	0.15 mg
PBS (Phosphate buffer saline)	q.s to 1.5 ml

*LEU= Lipopolysaccharide ELISA Units

3. Pharmaceutical form

Suspension for Oral Administration.

4. Clinical particulars

4.1 Therapeutic indications

Cholvax is indicated for active immunization against *Vibrio cholerae*. The vaccine can be administered to anyone above the age of 1 year. Data for the safety and efficacy of the vaccine in infants (less than 1 year of age) is not available. The earliest onset of protection can be expected 7-10 days after the completion of the primary series of the vaccine. Efficacy against *Vibrio cholera* serogroup O139 was not demonstrated.

4.2 Posology and method of administration

The recommended dose of the vaccine (1.5 ml) is to be administered orally. The primary immunization schedule consists of two doses given at an interval of at least two weeks. Cholera vaccine should not be

administered parenterally (intramuscular, subcutaneous or intravenously). The vaccine is only recommended for oral administration.

The vaccine is presented as a suspension. After vigorous shaking of the vial, 1.5 ml should be poured into the mouth of the recipient. The vaccine administration may be optionally followed by water to facilitate ingestion, if needed. The vaccine can alternatively be administered with a disposable syringe (without needle) after removing the contents from the vial and squirted into the mouth of the recipient.

4.3 Contraindications

Cholera vaccine should not be administered to subjects with either known hypersensitivity to any component of vaccine, or having shown signs of hypersensitivity after previous administration of the vaccine. Formaldehyde is used during the manufacturing process and trace amounts may be present in the final product. Caution should be taken in subjects with known hypersensitivity to formaldehyde. As with other vaccines, immunization with the cholera vaccine should be delayed in the presence of any acute illness, including acute gastrointestinal illness or acute febrile illness. A minor illness such as mild upper respiratory tract infection is not a reason to postpone immunization.

4.4 Special warnings and precautions for use

Vaccination should be provided by a review of the medical history (especially with regard to previous vaccination & possible occurrence of the undesirable events) and a clinical examination. As with any vaccine immunization with the cholera vaccine may not protect 100% susceptible individuals. This vaccine is also not a substitute for therapy in case of individuals suspected to be suffering from cholera or showing signs and symptoms of an acute episode of gastro intestinal disease or acute watery diarrhea.

Immunocompromised persons (subsequent to a disease or immunosuppressive therapy) may not obtain the expected immune response after vaccination with the cholera vaccine. If possible, in the opinion of the medical practitioner, due consideration should be given to postpone vaccination until after the completion of the immunosuppressive treatment.

As with all vaccines, appropriate medical treatment should always be available in case of a rare event of anaphylactic reactions following the administration of the vaccine. For this reason, it is recommended that the vaccinee should remain under medical supervision for at least 30 minutes after vaccination.

4.5 Interaction with other medical products and forms of interaction

The vaccine should not be mixed with any other vaccine or Pharmaceutical product.

4.6 Fertility,Pregnancy and lactation

No fertility data available.

No specific clinical studies have been performed to evaluate the safety and immunogenicity of cholera vaccine in pregnant women and for the fetus. However, administration of cholera vaccine to pregnant women and nursing mother may be considered after careful evaluation of the benefits and risks in case of a medical emergency or an epidemic.

4.7 Effect on ability to drive and use machines

Not applicable to Cholvax.

4.8 Undesirable effects

The following adverse events are known to occur with cholera vaccine use. Acute gastroenteritis, diarrhea, fever, vomiting, abdominal pain, itching, rash, nausea, weakness, cough, vertigo, dryness of mouth, oral ulcer (rare), sore throat (rare) and yellowing of urine (rare). It has been observed that the incidence of adverse events is less after the second dose as compared to the first.

4.9 Overdose

Not applicable

5 Pharmacological properties

5.1 Pharmacodynamic properties

Cholvax consists of killed V. cholerae. It has been shown to be effective to administer the vaccine orally, which induces local immunity. The vaccine acts locally in the gastrointestinal tract to induce an IgA antibody response (including memory) comparable to that induced by cholera disease itself. The antibacterial intestinal antibodies prevent the bacteria from attaching to the intestinal wall thereby impeding colonization of V. cholerae O1 and V. cholerae O139. The protection against cholera is specific for both biotype and serotype.

5.2 Pharmacokinetic properties

Not applicable to Cholvax

5.3 Pre-clinical safety data

Preclinical data including single-dose, repeated dose and local tolerance studies revealed no unexpected findings and no target organ toxicity. No genotoxicity, carcinogenicity and reproductive toxicity studies have been performed.

6. Pharmaceutical particulars

6.1 List of excipients

Name of the Excipients	Quantity per single-dose
Thiomersal I.P	0.15 mg
Buffer	q.s. to 1.5 mL

6.2 Incompatibilities

The vaccine should not be mixed with any other vaccine or Pharmaceutical product.

6.3 Shelf life

24 months from the date of manufacture.

6.4 Special precautions for storage

Cholvax should be stored at $+2^0$C to $+8^0$C. The vaccine should not be frozen. The vaccine should be discarded, if the vaccine has been frozen.

6.5 Nature and contents of container

Cholvax is supplied in glass vials containing 1.5 mL as a single-dose.

6.6 Special precautions for disposal and other handling

After use, any remaining vaccine and container must be disposed of safely, according to locally agreed procedures.

7. Marketing authorization holder

Incepta Vaccine Limited, Dhaka, Bangladesh

8. Drug authorization number(s)

363-34-069

9. Date of first authorization/Renewal of the authorization

08 January, 2020

10. Date of revision of the text

November, 2025