**MECHANISM OF ACTION**

Shanchol 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 bovine and swinepox.

**CLINICAL EXPERIENCE**

A double blind, randomized, placebo controlled trial was conducted in Kolkata, India. A total of 101 (50 vaccine and 51 placebo) healthy adults (males and pregnant females) aged 16-46 years and 101 (50 vaccine and 50 placebo) healthy children (males and non-pregnant females) aged 1-17 years were administered two doses of Shanchol or placebo at an interval of two weeks. Following 2 dose immunization, 53% of adult and 80% of children vaccinees showed a ≥4 fold rise in serum F. cholerae O1 vibriocidal antibody titers. This study showed that a 2 dose regimen of Shanchol is safe, well-tolerated, and immunogenic in a cholera-endemic area.

A double blind, randomized, placebo controlled field trial was conducted in Kolkata, India. A total of 69,640 subjects aged one year or older were administered two doses of Shanchol or placebo at an interval of two weeks. The trial subjects were followed up for two years after vaccination. Over two years of follow up there were 20 episodes of cholera in the vaccine group and 60 episodes in the placebo group. Shanchol provided 67% protection against clinically significant F. cholerae O1 cholera in an endemic area for at least two years after vaccination. Importantly, protection was seen both in children vaccinated at age under five years, as well as in older persons. There were no statistically significant differences in the occurrence of reported adverse events between recipients of vaccine and placebo. The most common adverse events reported were diarrhea, fever, vomiting and abdominal pain.

The vaccine is indicated for active immunization against V.cholerae O1. 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.

**CONTRA-INDICATIONS**

Shanchol should not be administered to subjects with either known hypersensitivity to any component of the 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 all products, the possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated. As with other vaccines, immunization with the Shanchol 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.

**WARNINGS AND SPECIAL PRECAUTIONS**

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and the possible occurrence of indistinguishable events) and a clinical examination. As with any vaccine, immunization with the Shanchol may not protect 100% of susceptible persons. 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 gastrointestinal disease.

Immuno-compromised persons (subsequent to a disease or immunosuppressive therapy) may not obtain the expected immune response after vaccination with the Shanchol. If possible, in the opinion of the medical practitioner, due consideration should be given to postponing vaccination until after the completion of any immunosuppressive treatment. 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 vaccine should remain under medical supervision for at least 30 minutes after vaccination.

**SPECIAL POPULATIONS**

**HIV/AIDS**

The safety and immunogenic response of Shanchol has not been clinically evaluated in individuals with HIV/AIDS.

**Pregnancy and Lactation**

No specific clinical studies have been performed to evaluate the safety and immunogenicity of Shanchol in pregnant women and/or the fetus. The vaccine is thus not recommended for use in infants.

**KIND OF ADVERSE REACTIONS ASSOCIATED WITH Shanchol**

The following adverse events are known to occur with Shanchol use. Acute Gastroenteritis, Diarrhea, Fever, Vomiting, Abdominal pain, Icterus, Rash, Headache, Weakness, Cough, Vertigo, Dryness of mouth, Oral ulcer (rare), Sore throat (rare) and Yellowing of skin. The following adverse events are known to occur with Shanchol use. Acute Gastroenteritis, Diarrhea, Fever, Vomiting, Abdominal pain, Icterus, Rash, Headache, Weakness, Cough, Vertigo, Dryness of mouth, Oral ulcer (rare), Sore throat (rare) and Yellowing of skin.

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