Vaxchora

(cholera vaccine, live attenuated)

New Product Slideshow

MPR

Introduction

- **Brand name:** Vaxchora
- **Generic name:** Cholera vaccine, live attenuated (*V. cholerae* strain CVD 103-HgR)
- **Pharmacological class:** Cholera vaccine
- **Strength and Formulation:** 100mL per single dose; susp for oral administration after reconstitution
- **Manufacturer:** PaxVax Corporation
- **How supplied:** Single-dose carton—2 packets (Buffer + Active components)
- **Legal Classification:** Rx

Indications

- Immunization against disease caused by *Vibrio cholerae* serogroup 01 in adults 18–64 years of age traveling to cholera-affected areas

Limitations of Use

- Efficacy not established in persons living in cholera-affected areas or persons with pre-existing immunity due to previous exposure to *V. cholerae* or receipt of a cholera vaccine
- Not shown to protect against disease caused by *V. cholerae* serogroup 0139 or other non-01 serogroups

Dosage & Administration

- For oral administration only
- Avoid food or drink for 60mins before and after administration
- **≥18yrs:** Give single oral dose a minimum of 10 days before potential cholera exposure

Contraindications

- Severe allergic reaction to any previous cholera vaccine

Considerations for Special Populations

- **Pregnancy:** To enroll patients in the pregnancy exposure registry call (800) 533-5899
- **Pediatric:** <18 years: not established
- **Elderly:** ≥65 years: not established
- **Immunocompromised:** Immunologic response may be diminished

Warnings/Precautions

- Immunocompromised
- Considering whether to administer to individuals with immunocompromised close contacts

Interactions

- Avoid use within 14 days of systemic **antibiotics**
- Give vaccine ≥10 days prior to **antimalarial prophylaxis** with chloroquine
- Concomitant **immunosuppressive therapy** (eg, irradiation, antimetabolites, alkylating agents, cytotoxic drugs, high-dose corticosteroids): may get suboptimal response

Adverse Reactions

- Tiredness
- Headache
- Abdominal pain
- Nausea/vomiting
- Lack of appetite
- Diarrhea

Mechanism of Action

- Vaxchora contains live attenuated cholera bacteria that replicate in the gastrointestinal tract of the recipient
- Immune mechanisms conferring protection against cholera following receipt of Vaxchora have not been determined
- However, rises in serum vibriocidal antibody 10 days after vaccination with Vaxchora were associated with protection in a human challenge study

Clinical Trials

- Study 1 was a randomized, double-blind, saline placebo-controlled safety and immuogenicity study conducted in U.S. and Australian adults aged 18-45 years not previously exposed to cholera (n=3146)

- Patients were randomized 8:1 to receive 1 dose of Vaxchora or placebo

Clinical Trials

- At 10 days post-vaccination, the rate of seroconversion was **93.5%** (95% CI: 92.5%, 94.4%) in vaccine recipients and **4%** (95% CI: 2%, 7%) in placebo recipients

Clinical Trials

- Study 4 was a randomized, double-blind placebo-controlled safety and immunogenicity study in U.S. adults aged 46-64 years with no prior history of cholera infection or travel to a cholera-endemic area in the previous 5 years (n=398)

- Patients were randomized 3:1 to receive 1 dose of Vaxchora or placebo

Clinical Trials

- At 10 days post-vaccination, the rate of seroconversion was **90.4%** (95% CI: 86.4%, 93.5%) in vaccine recipients

- Seroconversion rates among patients aged 46-64 years were compared to patients aged 18-45 years (Study 1)

Clinical Trials

- Adults aged 46-64 years were shown to have a non-inferior rate of seroconversion by classical Inaba vibriocidal antibody at 10 days post-vaccnation vs. adults aged 18-45 years

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/vaxchora/drug/34620/