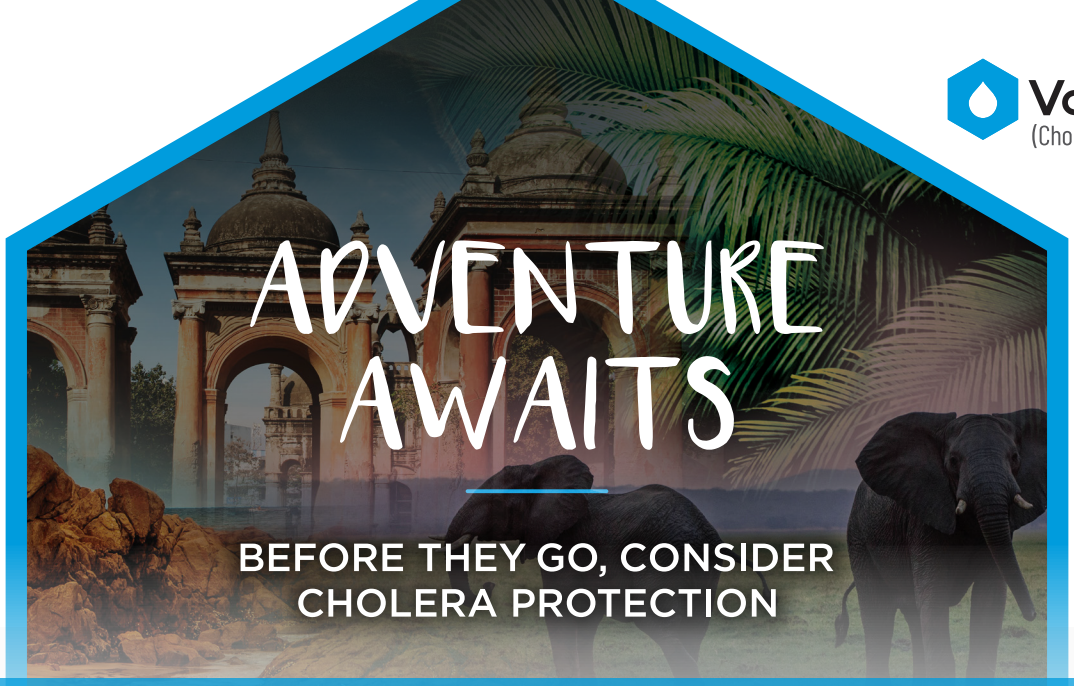
Vaxchora®
(Cholera Vaccine, Live, Oral)
100 mL Oral Suspension



ADVENTURE AWAITS

BEFORE THEY GO, CONSIDER CHOLERA PROTECTION

VAXCHORA CAN HELP PROTECT TRAVELERS AGAINST CHOLERA WITH A SINGLE ORAL DOSE[1]

THE CDC RECOGNIZES APPROXIMATELY 50 COUNTRIES[2] WHERE CHOLERA IS ENDEMIC – 28 OF WHICH ARE CONSIDERED AREAS OF ACTIVE TRANSMISSION[3]

THE CDC RECOMMENDS CHOLERA VACCINATION FOR PEOPLE (2–64 YEARS OLD) TRAVELING TO AREAS OF ACTIVE CHOLERA TRANSMISSION[2,3]

AFRICA
Burundi, Cameroon, Democratic Republic of the Congo, Ethiopia, Kenya, Malawi, Mozambique, Niger, Nigeria, Republic of the Congo, Somalia, South Africa, Sudan, South Sudan, Tanzania, Zambia, Zimbabwe

ASIA
Afghanistan, Bangladesh, India, Pakistan, Philippines

MIDDLE EAST
Iraq, Lebanon, Syria, Yemen

AMERICAS
Dominican Republic, Haiti

Cholera is an acute diarrheal illness caused by *Vibrio cholerae* serogroup O1 or O139. Cholera usually causes mild to moderate symptoms, but severe cases may lead to death if left untreated[4]

Cholera is estimated to be responsible for 1.3–4.0 million cases and 21,000–143,000 deaths worldwide each year[5,6]

When assessing a traveler's risk for cholera infection, consider age and pre-existing medical conditions that may be worsened by dehydration from cholera[3]

Indication and Usage

VAXCHORA is a vaccine indicated for active immunization against disease caused by *Vibrio cholerae* serogroup O1 in persons 2 through 64 years of age traveling to cholera-affected areas.

Limitations of Use: The effectiveness of VAXCHORA has not been established in persons living in cholera-affected areas. The effectiveness of VAXCHORA has not been established in persons who have pre-existing immunity due to previous exposure to V. cholerae or receipt of a cholera vaccine. VAXCHORA has not been shown to protect against disease caused by *V. cholerae* serogroup O139 or other non-O1 serogroups.

Important Safety Information

Contraindications

VAXCHORA is contraindicated in persons who have a history of severe allergic reaction (e.g., anaphylaxis) to any ingredient of VAXCHORA or to a previous dose of any cholera vaccine.

Warnings and Precautions

Immunocompromised Persons: The safety and effectiveness of VAXCHORA have not been established in immunocompromised persons and the immunologic response to VAXCHORA may be diminished in immunocompromised individuals.

Shedding and Transmission: Because VAXCHORA may be shed in the stool of recipients for at least 7 days and the vaccine strain can potentially be transmitted to non-vaccinated close contacts (e.g., household contacts), use caution when considering whether to administer VAXCHORA to individuals with immunocompromised close contacts.

Please see additional Important Safety Information throughout and full Prescribing Information or visit https://vaxchora.com/downloads/Vaxchora_Prescribing_Information.pdf.

HELP PROTECT FROM CHOLERA WITH A SINGLE ORAL DOSE[1]

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VAXCHORA studies included age groups ranging from 2 through 64 years[1]

Challenge Study Conducted in Adults Aged 18–45 Years

VAXCHORA recipients were divided into 2 cohorts, 1 challenged at 10 days and the other at 3 months post-vaccination

EFFICACY IN THE PREVENTION OF MODERATE TO SEVERE DIARRHEA (STUDY 2)[1*†‡]

90.3% effective at **10 days** post-vaccination

[95% CI = 62.7%, 100.0%]

79.5% effective at **3 months** post-vaccination

[95% CI = 49.9%, 100.0%]

5.7% (2/35) of VAXCHORA recipients who were challenged at 10 days developed moderate to severe diarrhea

12.1% (4/33) of VAXCHORA recipients who were challenged at 3 months developed moderate to severe diarrhea

9% (6/68) of VAXCHORA recipients who were challenged across the two cohorts developed moderate to severe diarrhea following challenge vs **59.1% (39/66)** of combined placebo recipients who were challenged

Immunogenicity Studies Conducted in Subjects Ranging From 2–64 Years of Age

SEROCONVERSION >90% ACROSS ALL AGE GROUPS AT 10 DAYS POST-VACCINATION[1‡]

STUDY 5: 98.5% in children and adolescents aged 2–17 years vs **1.5%** with placebo

[98.3% CI = 96.2%, 99.4%]

STUDY 1: 93.5% in adults aged 18–45 years vs **4%** with placebo

[95% CI = 92.5%, 94.4%]

STUDY 4: 90.4% in adults aged 46–64 years

[95% CI = 86.4%, 93.5%]

*Moderate or severe diarrhea defined as ≥3.0 L or ≥5.0 L, respectively, within 10 days after being challenged with *V. cholerae* O1 El Tor Inaba N16961.[1,7]

†Vaccine efficacy = [(Attack Rate in Placebo Group - Attack Rate in Vaccine Group)/Attack Rate in Placebo Group] x 100.[1]

‡Seroconversion defined as a ≥4-fold rise in serum vibriocidal antibody from baseline to 10 days post vaccination against the vaccine strain classical Inaba. Based on the observed association between seroconversion and protection from *V. cholerae* disease in the challenge study conducted in adults aged 18–45, seroconversion rate at 10 days post-vaccination was used to evaluate response to vaccination in other age groups.[1]

Important Safety Information (continued)

Adverse Reactions

In adults 18-45 years old, the most common adverse reactions (incidence >3%) were tiredness (31%), headache (29%), abdominal pain (19%), nausea/vomiting (18%), lack of appetite (17%), and diarrhea (4%).

The most common adverse reactions for children and adolescents (incidence ≥10%) were:

- Cohort 1 – age 12-<18 years: headache (45%), tiredness (41%), abdominal pain (38%), lack of appetite (29%), and nausea (22%)
- Cohort 2 – age 6-<12: tiredness (35%), abdominal pain (27%), headache (26%), lack of appetite (15%), and nausea (14%)
- Cohort 3 – age 2-<6: tiredness (31%), lack of appetite (19%), and abdominal pain (17%)

Drug Interactions

Antibiotics: Avoid concomitant administration of VAXCHORA with systemic antibiotics since these agents may be active against the vaccine strain and prevent a sufficient degree of multiplication to occur in order to induce a protective immune response. Do not administer VAXCHORA to patients who have received oral or parenteral antibiotics within 14 days prior to vaccination.

Antimalarial Prophylaxis: Immune responses to VAXCHORA may be diminished when administered concomitantly with chloroquine. Administer VAXCHORA at least 10 days before beginning chloroquine.

Immunosuppressive Treatments: Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune response to VAXCHORA.

Patient Counseling

Food and Water Safety Vigilance: Vaccine recipients should be advised to exercise caution regarding food and water consumed in cholera-affected areas, in accordance with the recommendations from the Centers for Disease Control and Prevention for the prevention of cholera in travelers.

To report SUSPECTED ADVERSE REACTIONS, contact Bavarian Nordic at 1-844-4BAVARIAN or the US Department of Health and Human Services by either visiting www.vaers.hhs.gov/reportevent.html or calling 1-800-822-7967.

Please see full Prescribing Information or visit https://vaxchora.com/downloads/Vaxchora_Prescribing_Information.pdf.

CDC, Centers for Disease Control and Prevention.

References: 1. VAXCHORA (Cholera Vaccine, Live, Oral) [package insert]. Redwood City, CA: Emergent Travel Health Inc. **2.** Collins JP, Ryan ET, Wong KK, et al. Cholera vaccine: recommendations of the Advisory Committee on Immunization Practices, 2022. *MMWR Recomm Rep*. 2022;71(2):1-8. **3.** CDC. Travelers' health. Cholera information for health care professionals. Accessed January 5, 2024. https://wwwnc.cdc.gov/travel/page/cholera-travel-information **4.** CDC Yellow Book 2024: Cholera. Accessed January 5, 2024. https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/cholera **5.** World Health Organization. Cholera. Fact sheets. Accessed January 5, 2024. https://www.who.int/news-room/fact-sheets/detail/cholera **6.** Ali M, Nelson AR, Lopez AL, et al. Updated global burden of cholera in endemic countries. *PLoS Negl Trop Dis*. 2015;9(6):e0003832. **7.** Chen WH, Cohen MB, Kirkpatrick BD, et al. Single-dose live oral cholera vaccine CVD 103-HgR protects against human experimental infection with *Vibrio cholerae* O1 El Tor. *Clin Infect Dis*. 2016;62(11):1329-1335.

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