

CHOLERA VACCINE LIVE ORAL

Cholera Vaccine Live Oral

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Introduction

Cholera vaccine is commercially available in the US as an oral live, attenuated bacterial vaccine containing *Vibrio cholerae* (*V. cholerae*) strain CVD 103-HgR derived from *V. cholerae* serogroup O1.¹ Cholera vaccine live oral is used to stimulate active immunity against *V. cholerae* serogroup O1.¹ This is the only cholera vaccine available in the US; other types of oral cholera vaccines may be available in other countries.³

Uses

■ Prevention of Cholera Infection

Cholera vaccine live oral is used in persons 2–64 years of age traveling to cholera-affected areas for active immunization against disease caused by *Vibrio cholerae* (*V. cholerae*) serogroup O1.¹

Efficacy of cholera vaccine live oral for prevention of cholera has not been established in individuals living in cholera-affected areas and has not been established in individuals who have preexisting immunity because of previous exposure to *V. cholerae* or previous vaccination with a cholera vaccine.¹

Cholera vaccine live oral has not been shown to provide protection against disease caused by *V. cholerae* serogroup O139 or any other non-O1 serogroups.¹

Cholera is an acute, intestinal infection caused by toxigenic *V. cholerae* serogroup O1 or O139 that manifests as acute watery diarrhea; cholera infections due to *V. cholera* serogroup O139 are uncommon.^{3,4} About 10% of cholera episodes can manifest as cholera gravis, characterized by profuse watery diarrhea, often accompanied by nausea and vomiting, which if left untreated can cause severe dehydration, hypovolemic shock, and death within hours.^{3,4} For untreated cholera, the case-fatality ratio can reach as high as 50%; with adequate and timely fluid replacement, the case-fatality ratio goes down to <1%.^{3,4} Individuals who may be at increased risk for poor clinical outcomes if infection with toxigenic *V. cholerae* occurs include those without rapid access to medical care and rehydration therapy; those with medical conditions worsened by dehydration (e.g., cardiovascular disease, renal disease); those with low gastric acidity related to antacid therapy, partial gastrectomy, or other causes; those with blood type O; and pregnant women.³ Cholera is transmitted principally by ingestion of water and/or food that is contaminated with feces from individuals with *V. cholerae* infection and generally occurs in countries that lack clean drinking water or proper sanitation.⁴

Cholera is uncommon in the US, but is endemic in approximately 50 countries, primarily in South Asia, Southeast Asia, and Africa.^{3,4} Epidemics of cholera are associated with inadequate sanitation and unsafe water.³ According to the World Health Organization (WHO), between January 1, 2025 and July 27, 2025, there were 382,718 cases of cholera and acute watery diarrhea (including 4478 fatalities) reported from 31 countries.⁸ Between 2017 and 2022, there were 39 confirmed cases of cholera in the US in individuals who had been traveling internationally in the week before their illness.⁴ The US Centers for Disease Control and Prevention (CDC) state that the risk of acquiring cholera is higher in persons traveling to countries where cholera is endemic or epidemic; healthcare and response workers in cholera-affected areas; and people without access to safe food or water, who do not follow handwashing recommendations, or who do not use latrines or other sanitation systems.⁴

Clinical Experience

Safety and efficacy of a single dose of cholera vaccine live oral for prevention of cholera have been evaluated in a randomized controlled trial in adults 18–45 years of age.^{1,2} Clinical trials have also evaluated safety and immunogenicity following vaccination of a single dose of cholera vaccine in adults 18–64 years of age and in pediatric patients 2–17 years of age.^{1,12,13,14,15,16}

A randomized, double-blind, placebo-controlled, phase 3, *V. cholerae* challenge study evaluated the efficacy of cholera vaccine live oral in 197 healthy adults 18–45 years of age in the US who did not have a history of cholera infection and had not traveled to cholera-endemic areas during the previous 5 years (i.e., US residents immunologically naive to cholera).^{1,2} Patients were randomized 1:1 to receive 1 dose of cholera vaccine live oral (about 5×10^8 colony-forming units [CFU]) or saline placebo.^{1,2} To evaluate efficacy of the vaccine in preventing moderate to severe cholera diarrhea, 68 individuals who received the cholera vaccine live oral and 66 individuals who received a placebo received a cholera challenge (oral dose of approximately 1×10^5 CFU of live, wild-type *V. cholerae* O1 El Tor Inaba strain N16961 in 30 mL of sodium bicarbonate buffer) given either 10 days or 3 months later.^{1,2} Study participants had a mean age of 31 years (range: 18–45 years) and 63% were male;² about half of the participants had blood type O (a blood type associated with an increased risk of severe cholera).^{1,2} Participants were closely monitored in an inpatient setting and diarrheal stools were collected from the time of cholera challenge until discharge from the inpatient unit.^{1,2} Those who developed diarrhea received oral or IV rehydration as needed and anti-infective treatment (ciprofloxacin) was given 4 days after cholera challenge (or earlier if indicated).² The co-primary efficacy end points were the prevention of moderate to severe cholera diarrhea at 10 and 90 days post-vaccination.^{1,2} In addition, a vibriocidal antibody assay was used to measure serum levels of neutralizing antibodies against the *V. cholerae* vaccine strain to evaluate these antibodies as a possible correlate of protection against cholera.^{1,2}

Moderate to severe cholera diarrhea (defined as cumulative diarrheal purge of 3 liters or more collected through day 10 after cholera challenge) occurred in approximately 6 or 12% of vaccinees who received the cholera challenge 10 days or 3 months, respectively, after the vaccine dose; 59% of placebo recipients had moderate to severe diarrhea following cholera challenge.^{1,2} Efficacy of the vaccine in preventing moderate to severe cholera diarrhea was approximately 90 or 80% in vaccine recipients who received the cholera challenge 10 days or 3 months, respectively, after the vaccine dose.^{1,2} In the subset of study participants with blood type O, efficacy was approximately 85 and 78% in those who received the cholera challenge 10 days and 3 months, respectively, after the vaccine dose.² Results of the vibriocidal antibody assays indicated that there was a strong correlation between serum vibriocidal antibody seroconversion (defined as a 4-fold or greater increase in serum vibriocidal antibody titer over baseline) and protection against moderate to severe cholera diarrhea.² The overall rate of serum vibriocidal antibody seroconversion was approximately 90% in vaccine recipients and all but 1 of these individuals seroconverted by day 10 after the vaccine dose (i.e., before cholera challenge).² Vibriocidal antibody seroconversion rates and geometric mean titers (GMTs) of vibriocidal antibody in vaccinees with blood type O were similar to those reported in vaccinees with non-O blood types.²

In a randomized, double-blind, phase 3 study evaluating the immunogenicity of cholera vaccine live oral, 3146 adults 18–45 years of age in the US or Australia not previously exposed to cholera were randomized 8:1 to receive a single oral dose of the cholera vaccine or placebo.^{1,12} At 10 days post-vaccination, the classical Inaba vibriocidal antibody seroconversion rates were 93.5% in vaccine recipients and 4% in placebo recipients.^{1,12} For the El Tor Inaba, Classical Ogawa, and El Tor Ogawa *V. cholerae* serogroup O1 subtypes (3 of the 4 major subtypes of *V. cholerae* serogroup O1, along with classical Inaba), seroconversion rates at 10 days post-vaccines were 91.4, 87.1, and 89.2%, respectively, for patients 18–45 years of age.¹

A randomized, double-blind, phase 3 study evaluated the immunogenicity of cholera vaccine live oral in adults 46–64 years of age who had no prior history of cholera infection or travel to a cholera-endemic area in the previous 5 years.^{1,13} Patients were randomized 3:1 to receive a single dose of the vaccine or placebo.^{1,13} The classical Inaba vibriocidal antibody seroconversion rate at 10 days for patients 45–65 years of age who received the vaccine was 90.4%; this rate was found to be noninferior to the seroconversion rate (93.5%) in patients 18–45 years of age who received the vaccine.^{1,13} For the El Tor Inaba, Classical Ogawa, and El Tor Ogawa *V. cholerae* serogroup O1 subtypes, the seroconversion rates for adults 45–65 years of age 10 days post-vaccination were 91.0, 73.2, and 71.4%, respectively.^{1,13}

A randomized, double-blind, placebo-controlled, phase 4 study evaluated the immunogenicity of a single dose of the cholera vaccine live oral in 550 pediatric patients 2–17 years of age not previously exposed to cholera.^{1,14,15} The classical Inaba vibriocidal antibody seroconversion rates at 10-days post-vaccination in this study were compared with the seroconversion rates in adults 18–45 years of age.¹ The 10-day post-vaccination seroconversion rate for pediatric vaccine recipients 2–17 years of age was 98.5%.¹ The seroconversion rate in pediatric patients 6–17 years of age was 98.6% in those who received the vaccine and 2.1% in those who received placebo.¹⁴ For pediatric patients 2–5 years of age, the seroconversion rates were 98.1 and 0% in vaccine and placebo recipients, respectively.¹⁵ For both pediatric patient age groups, the seroconversion rates were determined to be noninferior to the rate in adults 18–45 years of age.^{14,15} In a long-term follow-up study of adolescents 12–17 years of age, the serum vibriocidal antibody seroconversion persisted in most vaccine recipients, with a rate of 64.5% recorded at day 730 (2 years) post-vaccination.¹⁶

Clinical Perspective

The CDC maintains a list of specific areas of active cholera transmission.¹¹⁵ All travelers to cholera-affected areas should follow safe food and water precautions and proper sanitation and personal hygiene measures.^{3,4} Travelers should seek prompt medical care, particularly fluid replacement, if they develop severe diarrhea.³

For US travelers, the US Public Health Service Advisory Committee on Immunization Practices (ACIP) recommends cholera vaccine live oral for persons 2–64 years of age who will be traveling to an area of active cholera transmission.^{3,4,115} These areas are defined as a province, state, or other administrative subdivision within a country with endemic or epidemic cholera caused by toxigenic *V. cholerae* O1.^{3,4} This includes areas that have had cholera activity within the past year and are prone to recurrence of cholera epidemics; it does not include areas with only rare imported or sporadic cholera cases.^{3,4}

ACIP states that routine use of cholera vaccine is not recommended for most travelers from the US since the majority do not visit areas with active cholera transmission.^{3,4,115}

Dosage and Administration

■ General

Pretreatment Screening

- Screen patients for underlying immunocompetence or use of immunosuppressive therapy to determine appropriateness of vaccine.¹
- Screen for recent antimicrobial therapy to determine timing of vaccine administration.¹
- Determine past and planned use of other vaccines to determine appropriate timing of vaccine administration.¹

Dispensing and Administration Precautions

- Follow the detailed preparation instructions closely and in sequence.^{1,}
- The dispensing cup (including any residue remaining in the cup), stirrer, and empty component packets should be handled and disposed according to standard procedures for medical waste.^{1,}
- Use 70% isopropyl alcohol or 10% bleach to clean any nondisposable equipment used to prepare the suspension of cholera vaccine live oral and to inactivate any spilled vaccine.^{1,}

■ Administration

Cholera vaccine live oral is administered as an oral suspension.^{1,}

Vaccine recipients should be instructed to avoid eating or drinking for 60 minutes before and after ingestion of cholera vaccine live oral.^{1,} Cholera vaccine live oral is provided by the manufacturer in a single-dose carton that contains a foil packet of lyophilized live, attenuated *Vibrio cholerae* (V. cholerae) CVD 103-HgR (active component) and a foil packet of dry powder buffer (buffer component).^{1,} These 2 components must be reconstituted and mixed together according to the manufacturer's instructions to provide an oral suspension containing cholera vaccine live oral.^{1,}

Following reconstitution, if desired, no more than 4 g (1 teaspoon) of sucrose (table sugar) or no more than 1 g (1/4 teaspoon) of non-flavored stevia sweeteners may be added and stirred into the suspension.^{1,} Do not add any other sweeteners or medicinal flavorings as this can reduce the effectiveness of the vaccine.^{1,} If sucrose and non-flavored stevia are added, administer the final oral suspension containing cholera vaccine live oral within 30 minutes after preparation.^{1,} If sugar or sweetener has not been added, administer the final oral suspension within 4 hours of reconstitution at room temperature (~21°C).^{1,} Ensure the entire contents of the cup (100 mL) is swallowed at one time.^{1,}

The packets containing the active component and buffer component should be stored in the original carton, refrigerated at 2–8°C, and protected from light and moisture.^{1,} Packages may be stored at 9–25°C for no more than 24 hours prior to reconstitution.^{1,}

Improper storage or handling of vaccines may reduce vaccine potency resulting in reduced or inadequate immune responses in vaccinees.^{134,} All vaccines should be inspected upon delivery and monitored during storage to ensure that the appropriate temperature is maintained.^{134,} Vaccine that has been mishandled or has not been stored at the recommended temperature should not be administered.^{134,} If there are concerns about mishandling, the manufacturer or state or local health departments should be contacted for guidance on whether the vaccine is usable.^{134,}

Reconstitution

To prepare the oral suspension containing cholera vaccine live oral, reconstitute the packet containing the dry powder buffer (buffer component) by opening the packet with scissors and pouring the contents into a clean disposable cup that contains 100 mL of cold or room temperature (5–22°C) purified, spring, or sparkling bottled water; the buffer component should not be reconstituted using tap water, non-purified bottled water, or any other beverage or liquid.^{1,} The dry powder buffer and water will effervesce after being combined; stir with a disposable stirrer until the powder buffer is completely dissolved.^{1,} For pediatric patients 2–5 years of age, discard half the buffer solution after mixing.^{1,}

After the buffer is dissolved, open the packet containing lyophilized cholera vaccine (active component) with scissors and pour the contents into the cup containing the reconstituted buffer.^{1,} Stir the mixture for at least 30 seconds to form a slightly cloudy suspension that may contain some white particles; the lyophilized vaccine may not dissolve completely.^{1,}

If the buffer component and active component are not reconstituted and mixed in the proper sequence, the vaccine must be discarded.^{1,}

■ Dosage

Prevention of Cholera Infection

For prevention of disease caused by *V. cholerae* serogroup O1 in adults 18–64 years of age traveling to cholera-affected areas, a single dose of cholera vaccine live oral should be administered at least 10 days before potential exposure to cholera.^{1,} The dose consists of 100 mL of reconstituted oral suspension.^{1,}

For prevention of disease caused by *V. cholerae* serogroup O1 in pediatric patients 6–17 years of age traveling to cholera-affected areas, a single dose of cholera vaccine live oral should be administered at least 10 days before potential exposure to cholera.^{1,} The dose consists of 100 mL of reconstituted oral suspension.^{1,}

For prevention of disease caused by *V. cholerae* serogroup O1 in pediatric patients 2–5 years of age traveling to cholera-affected areas, a single dose of cholera vaccine live oral should be administered at least 10 days before potential exposure to cholera.^{1,} The dose consists of 50 mL of reconstituted oral suspension.^{1,}

■ Special Populations

Hepatic Impairment

The manufacturer makes no specific dosage recommendations for patients with hepatic impairment.^{1,}

Renal Impairment

The manufacturer makes no specific dosage recommendations for patients with renal impairment.^{1,}

Geriatric Patients

Cholera vaccine live oral is not indicated in adults 65 years of age or older.^{1,}

Cautions

■ Contraindications

- History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or to a previous dose of any cholera vaccine.^{1,}

■ Warnings/Precautions

Altered Immunocompetence

Safety and efficacy of cholera vaccine live oral have not been established in immunocompromised individuals.^{1,} The immunologic response to the vaccine may be diminished in individuals with altered immunocompetence related to disease or immunosuppressive therapy.^{1,}

The US Public Health Service Advisory Committee on Immunization Practices (ACIP) states that individuals with altered immunocompetence generally should not receive live vaccines since these individuals may be at increased risk for adverse reactions to such vaccines and may have diminished or suboptimal immune responses to vaccines.^{1,34,}

Shedding and Transmission

Cholera vaccine live oral contains live, attenuated *Vibrio cholerae* that may be shed in the stool of vaccine recipients for at least 7 days and may be transmitted to non-vaccinated close contacts (e.g., household contacts).^{1,} The total duration of fecal shedding of the *V. cholerae* vaccine strain following vaccination is unknown.^{1,}

Because the vaccine strain of *V. cholerae* is shed in the stool of vaccinees and may potentially be transmitted, vaccinees should take precautions (i.e., thorough and frequent handwashing, especially after bowel movements and before preparing and handling food) for at least 14 days after vaccination.^{1,}

In addition, caution is advised when considering whether to administer cholera vaccine live oral to individuals with immunocompromised close contacts.^{1,}

Limitations of Vaccine Efficacy

Cholera vaccine live oral will not provide protection against *V. cholerae* serogroups not represented in the vaccine (e.g., *V. cholerae* serogroup O139, other non-O1 serogroups).^{1,}

Efficacy of cholera vaccine live oral for prevention of cholera has not been established in individuals living in cholera-affected areas and has not been established in individuals who have preexisting immunity because of previous exposure to *V. cholerae* or previous vaccination with a cholera vaccine.^{1,}

Duration of Immunity

Duration of immunity and protection against cholera after vaccination with cholera vaccine live oral has not been fully determined.^{3,} The duration of protection conferred by the primary dose beyond the 3-month period studied in adults aged 18–45 years of age is unknown.^{1,} Data to date in adults 18–45 years of age indicate that the duration of efficacy of the vaccine is 90% at 10 days after vaccination and 80% at 3 months after vaccination.^{3,} In a clinical study, approximately 90% of vaccinees still had vibriocidal antibody responses 6 months (180 days) after a single dose of cholera vaccine live oral.^{2,}

Safety and efficacy of revaccination or booster doses of cholera vaccine live oral have not been established.^{1,3,} ACIP does not currently make a recommendation on use of booster doses.^{3,}

Specific Populations

Pregnancy

Data are not available to date regarding use of cholera vaccine live oral in pregnant women.^{3,}

Because cholera vaccine live oral is not absorbed systemically following oral administration, vaccination during pregnancy is not expected to result in fetal exposure to the vaccine.^{1,}

*Clinicians should consider that cholera infection is associated with adverse pregnancy outcomes, including fetal death.^{1,} Clinicians also should consider that the vaccine strain of *V. cholerae* may be shed in the stools of vaccinated mothers for at least 7 days after vaccination and there is potential for transmission of the vaccine strain from the mother to the infant during vaginal delivery.^{1,}*

Lactation

Data are not available to date regarding use of cholera vaccine live oral in nursing women.^{3,}

Because cholera vaccine live oral is not absorbed systemically following oral administration, vaccination in nursing women is not expected to result in exposure to the vaccine in breast-fed infants.^{1,}

Pediatric Use

Safety and efficacy of cholera vaccine live oral have not been established in pediatric patients younger than 2 years of age.^{1,}

Geriatric Use

Safety and efficacy of cholera vaccine live oral have not been established in adults 65 years of age or older.^{1,}

■ Common Adverse Effects

Adverse effects reported in more than 3% of adults following a single dose of cholera vaccine live oral include tiredness (31%), headache (29%), abdominal pain (19%), nausea/vomiting (18%), lack of appetite (17%), and diarrhea (4%).^{1,}

Adverse effects reported in pediatric patients 12 to <18 years of age following a single dose of cholera vaccine live oral include headache (45%), tiredness (41%), abdominal pain (38%), lack of appetite (29%), and nausea (22%).^{1,}

Adverse effects reported in pediatric patients 6 to <12 years of age following a single dose of cholera vaccine live oral include tiredness (35%), abdominal pain (27%), headache (26%), lack of appetite (15%), and nausea (14%).^{1,}

Adverse effects reported in pediatric patients 2 to <6 years of age following a single dose of cholera vaccine live oral include tiredness (31%), loss of appetite (19%), and abdominal pain (17%).^{1,}

Drug Interactions

■ Anti-infective Agents

Antibacterial Agents

Because systemic antibacterials may be active against the *Vibrio cholerae* strain contained in cholera vaccine live oral, these drugs potentially could prevent the degree of bacterial replication that is necessary to induce an immune response to the vaccine.^{1,} The duration of possible interference with the immune response to cholera vaccine live oral probably depends on the antimicrobial activity and half-life of the antibacterial agent.^{3,}

The manufacturer of cholera vaccine live oral states that the vaccine should not be administered to individuals who have received oral or parenteral antibacterials within the last 14 days.^{1,} However, the US Public Health Service Advisory Committee on Immunization Practices (ACIP) states that, in certain situations when travel to cholera endemic or epidemic areas cannot be postponed, it may be acceptable to administer cholera vaccine live oral even if fewer than 14 days have elapsed since antibacterial therapy was discontinued.^{3,}

Chloroquine

Data from a study evaluating a similar cholera vaccine suggest that concomitant use of cholera vaccine live oral and chloroquine may decrease the immune response to the vaccine.^{1,} The manufacturer states that cholera vaccine live oral should be administered at least 10 days before chloroquine antimalarial prophylaxis is initiated.^{1,}

■ Immunosuppressive Agents

The immune response to cholera vaccine live oral may be reduced in individuals receiving immunosuppressive therapy (e.g., alkylating agents, antimetabolites, corticosteroids [at greater than physiologic doses], cytotoxic drugs, radiation therapy).^{1,}

Individuals receiving immunosuppressive therapy may have diminished or suboptimal antibody responses to vaccines.^{1,} Generally, administration of live vaccines to patients with altered immunocompetence should be avoided.^{3,} The recommendations for administration of live vaccines to specific immunocompromised patients should be consulted.^{134,}

■ Vaccines

Data are not available regarding concurrent administration of cholera vaccine live oral and other vaccines,^{1,3,} including other vaccines used in travelers (e.g., typhoid vaccine).^{3,}

Typhoid vaccine live oral Ty21a

Although specific data are not available, it has been suggested that the buffer component of cholera vaccine live oral may interfere with typhoid vaccine live oral Ty21a enteric-coated tablets.^{3,} Therefore, if immunization with cholera vaccine live oral and typhoid vaccine live oral Ty21a are both indicated prior to travel, some experts recommend that the first dose of typhoid vaccine live oral Ty21a be administered at least 8 hours after cholera vaccine live oral.^{3,}

Description

Cholera vaccine live oral contains live, attenuated *Vibrio cholerae* (*V. cholerae*) strain CVD 103-HgR and is used to stimulate active immunity to *V. cholerae* serogroup O1.^{1,2,}

The *V. cholerae* CVD 103-HgR vaccine strain is constructed from the *V. cholerae* serogroup O1 classical Inaba strain 569B by deleting the catalytic domain sequence of the toxigenic cholera toxin A subunit gene (*ctxA*), which prevents the vaccine strain from synthesizing active cholera toxin.^{1,} The vaccine strain remains able to synthesize the nontoxic, immunogenic cholera toxin B subunit gene (*ctxB*).^{1,6,} In addition, a unique phenotypic marker is inserted into the hemolysin gene locus (*hlyA*) to enable differentiation of the vaccine strain from wild-type *V. cholerae* serogroup O1.^{1,}

The *V. cholerae* CVD 103-HgR vaccine strain is grown in a medium consisting of casamino acids, yeast extract, mineral salts, and an anti-foaming agent; the vaccine strain is collected by filtration and is diafiltered and concentrated.¹

The bacteria are concentrated by ultrafiltration before addition of a stabilization solution containing ascorbic acid (an antioxidant), Hy-Case SF (hydrolyzed casein [a protein derived from cow's milk], a cryoprotectant), and sucrose (a cryoprotectant).¹ The stabilized bacteria are lyophilized, milled, and blended with anhydrous lactose (a bulking agent).¹ The active component blend is filled into packets.¹ The buffer component is manufactured by blending together sodium bicarbonate (a gastric acid neutralizer), sodium carbonate (a buffer), ascorbic acid (a buffer and water chlorine neutralizer), and anhydrous lactose (a manufacturing flow aid).¹ The buffer component blend is filled into packets.¹

Following oral administration of cholera vaccine live oral, the live, attenuated *V. cholerae* CVD 103-HgR vaccine strain replicates in the GI tract and induces a local mucosal immune response in the small intestine.¹ The exact immunologic mechanism by which cholera vaccine live oral provides protection against *V. cholerae* serogroup O1 has not been determined,¹ but is thought to be related to immune responses at the intestinal mucosal surface.³ Because intestinal immunity cannot be easily measured in clinical trials, serum vibriocidal antibodies have been used as a surrogate marker to indicate an immune response to cholera vaccine live oral.³

In studies in adults 18–45 years of age, serum vibriocidal antibody was detected within 10 days following a single dose of cholera vaccine live oral and approximately 90–94% of vaccinees seroconverted after a single vaccine dose.^{1,2} Seroconversion in these studies was defined as a 4-fold or greater increase in serum vibriocidal antibody titers from baseline to day 10 after vaccination.^{1,2} The seroconversion rate in adults 46–64 years of age appears to be similar to that in adults 18–45 years of age.¹ The seroconversion rate in pediatric patients 2–17 years of age was 98.5% after a single dose.¹

Cholera vaccine live oral is not absorbed systemically following oral administration.¹ Approximately 11% of adults who receive a single dose of cholera vaccine live oral shed the vaccine strain of *V. cholerae* in their stools for at least 7 days after the vaccine dose.^{1,6}

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from [MedlinePlus](#) (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Advise patients of the risks and benefits of vaccination with cholera vaccine live oral.¹
- Advise patients that routine vaccination against cholera is not recommended in the US,³ but may be used to prevent cholera in certain individuals traveling to cholera-affected areas.^{1,3}
- Advise patients that cholera vaccine may not provide complete protection in all vaccinees and will not protect against disease due to cholera strains not represented in the vaccine.¹ Advise vaccinees of the importance of taking precautions against exposure to cholera by avoiding contact with or ingestion of potentially contaminated food or water.¹
- Advise patients that the vaccine strain of *Vibrio cholerae* may be shed in stool for at least 7 days after vaccination and potentially can be transmitted to close contacts (e.g., household contacts).¹ To minimize the risk of transmission of the vaccine strain, advise patients to take precautions (i.e., thorough and frequent handwashing, especially after bowel movements and before handling or preparing food) for at least 14 days after vaccination.¹
- Inform vaccine recipients about the most common adverse reactions that have been reported within 7 days after vaccination with cholera vaccine live oral (e.g., tiredness, headache, abdominal pain, nausea/vomiting, lack of appetite, diarrhea) and importance of contacting a clinician if any adverse reactions occur.¹ Clinicians or individuals can report any adverse reactions that occur following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or [\[Web\]](#).³
- Advise patients of the importance of informing clinicians of existing or contemplated concomitant therapy, including prescription and OTC drugs, as well as any concomitant illnesses.¹
- Advise patients of the importance of informing clinicians if they are or plan to become pregnant or are breast-feeding.¹
- Inform patients of other important precautionary information.¹

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Cholera Vaccine Live Oral

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Oral	Kit, for oral use	Powder for oral suspension, 4×10^8 to 2×10^9 CFU of live attenuated <i>Vibrio cholerae</i> CVD 103-HgR per packet (active component) Powder for oral suspension, sodium bicarbonate 2.16–2.41 g, sodium carbonate 0.24–0.49 g, ascorbic acid 1.5–1.8 g, and lactose 0.18–0.22 g per packet (buffer component)	Vaxchora [®]	Bavarian Nordic A/S

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

AHFS Drug Information[®]. © Copyright, 1959-2026, American Society of Health-System Pharmacists[®], 4500 East-West Highway, Suite 900, Bethesda, MD 20814. Original Publication Date: March 16, 2017. Database Extraction: 08/31/2026 15:08:40 +0000+	
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ASHP is the national professional organization whose more than 43,000 members include pharmacists, student pharmacists, and pharmacy technicians who serve as patient care providers on healthcare teams in acute and ambulatory settings.



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