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

The only cholera vaccine available in the US

Preparation, Reconstitution, and Administration

Prepare and administer VAXCHORA in a health care setting equipped to dose of medical waste.

Administration Tips

1 DOSE
VAXCHORA is administered as a single oral dose.

15 MINUTES
Reconstitution should be completed within 15 minutes of removing the carton from the refrigerator.

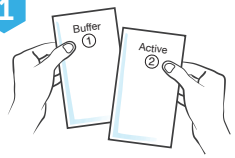
10 DAYS
VAXCHORA should be administered at least 10 days prior to potential exposure to cholera.

60 MINUTES
Patients should not eat or drink for 60 minutes before and 60 minutes after administration of VAXCHORA.

15 MINUTES
VAXCHORA must be consumed within15 minutes of reconstitution.

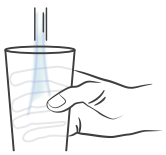
VAXCHORA should be reconstituted as follows:

1



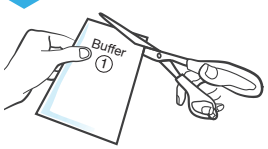
Reconstitution should be completed within 15 minutes of removing the carton from the refrigerator. Locate the 2 packets: the buffer component (Packet 1) and the active component (Packet 2).

2



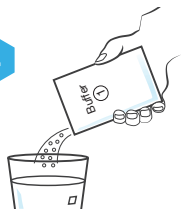
Pour 100 mL of cold or room temperature (41°F-72°F; 5°C-22°C) purified bottled water or spring bottled water into a clean, disposable cup. Do not use tap water, sparkling (carbonated) water, non-purified or non-spring bottled water, other beverages, or other liquids.

3



Use scissors to cut the top off the buffer component packet.

4

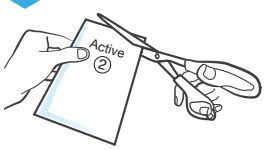


Empty buffer component packet contents into cup. Effervescence will occur.

5

Using a disposable stirrer, stir until the buffer component completely dissolves.

6



Use scissors to cut the top off the active component packet.

7

Empty the active component packet contents (lyophilized *V. cholerae* CVD 103-HgR) into the cup containing the buffer solution.

8

Stir for at least 30 seconds and until active component disperses to form a slightly cloudy suspension that may contain some white particulates. The active component may not dissolve completely.

9

VAXCHORA must be consumed within 15 minutes of reconstitution. The recipient should drink the full contents of the cup at once. Some residue may remain in the cup and should be discarded with the cup.

DISPOSE of the cup, packets, and stirrer according to standard procedures for medical waste.

Inactivate any spilled vaccine and clean any non-disposable equipment used in the preparation of VAXCHORA with 70% isopropyl alcohol or 10% bleach solution.

***NOTE:* If the packets are reconstituted in the improper order, the vaccine must be discarded.**

Indications and Usage

VAXCHORA® is a vaccine indicated for active immunization against disease caused by *Vibrio cholerae* serogroup O1 in adults 18 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

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

The safety and effectiveness of VAXCHORA have not been established in immunocompromised persons.

VAXCHORA may be shed in the stool of recipients for at least 7 days. There is a potential for transmission of the vaccine strain to non-vaccinated close contacts (e.g., household contacts). Use caution when considering whether to administer VAXCHORA to individuals with immunocompromised close contacts.

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%).

For more information about VAXCHORA, please see accompanying full Prescribing Information.

Reference: VAXCHORA [package insert]. Redwood City, CA: PaxVax, Inc.; 2019.

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