

Approval Date: [December 23, 2020](#)

Product: Vaxchora®

Proper Name: Cholera Vaccine Live Oral

Manufacturer: Emergent Travel Health, Inc.

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

Description: VAXCHORA (Cholera Vaccine, Live, Oral) is a live, attenuated bacterial vaccine suspension for oral administration containing the *V. cholerae* strain CVD 103-HgR.

BLA: 125597

Regulatory Milestone: No data available

PDUFA Goal Date: June 15, 2016

Package Insert:

- [Package Insert - VAXCHORA \(Frozen\)](#)
- [Package Insert - VAXCHORA](#)

Summary Basis for Regulatory Approval: [Summary Basis for Regulatory Action - Vaxchora](#)

European Public Assessment Report: [Human medicine European public assessment report \(EPAR\): Vaxchora](#)

Advisory Committee:

An advisory committee meeting was not convened during the review of this original BLA. Whether data from human cholera challenge studies in U.S. subjects could be sufficient to demonstrate the effectiveness of a cholera vaccine in U.S. travelers to endemic areas, who are at high risk for contracting the disease, was discussed during 1993 and 1998 VRBPAC meetings. In 1993, the Committee discussed the limitations of using data from clinical field trials of the CVD-103 HgR vaccine in endemic areas to predict the effectiveness of this vaccine in naïve U.S. travelers. During the 1998 VRBPAC meeting, failure of the CVD-103 HgR vaccine to show protection in the field trials was discussed, and the Committee agreed that human challenge studies could suffice to demonstrate effectiveness of a cholera vaccine in persons not previously exposed to cholera provided that studies were adequate, well-controlled and conducted under the provisions of GCP

NCT Numbers:

- NCT03251495
- NCT00760825
- NCT01365442
- NCT01981616
- NCT03220737
- NCT03581734
- NCT02742558
- NCT01762930
- NCT03373669
- NCT01339845
- NCT04423159
- NCT01811771
- NCT03724357
- NCT00128011
- NCT02502331
- NCT00709410
- NCT01042951
- NCT02027207
- NCT02864433
- NCT02100631
- NCT03719066
- NCT00419133
- NCT02823899
- NCT02094586
- NCT01949675
- NCT01233362
- NCT02499172
- NCT01895855
- NCT03237663
- NCT00464867
- NCT01707537
- NCT02924246
- NCT00119197
- NCT01579448
- NCT03998449
- NCT01019083
- NCT01524640
- NCT01109914
- NCT03705585
- NCT01119703
- NCT00289224
- NCT02727855
- NCT01585181
- NCT00654108
- NCT02434822
- NCT00548054
- NCT01508507
- NCT00741637

- NCT02238548
- NCT02164110
- NCT00820144
- NCT01825109
- NCT00751933
- NCT02145377
- NCT00401934

EudraCT Numbers:

- 2018-003850-25

Publications:

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- Ali, M., Qadri, F., Kim, D. R., Islam, T., Im, J., Ahmmed, F., Chon, Y., Islam Khan, A., Zaman, K., Marks, F., & Clemens, J. D. (2019). Unmasking herd protection by an oral cholera vaccine in a cluster-randomized trial. *International journal of epidemiology*, 48(4), 1252–1261. <https://doi.org/10.1093/ije/dyz060>
- Mayo-Smith, L. M., Simon, J. K., Chen, W. H., Haney, D., Lock, M., Lyon, C. E., Calderwood, S. B., Kirkpatrick, B. D., Cohen, M., Levine, M. M., Gurwith, M., & Harris, J. B. (2017). The Live Attenuated Cholera Vaccine CVD 103-HgR Primes Responses to the Toxin-Coregulated Pilus Antigen TcpA in Subjects Challenged with Wild-Type *Vibrio cholerae*. *Clinical and vaccine immunology: CVI*, 24(1), e00470-16. <https://doi.org/10.1128/CVI.00470-16>
- McCarty, J. M., Gierman, E. C., Bedell, L., Lock, M. D., & Bennett, S. (2020). Safety and Immunogenicity of Live Oral Cholera Vaccine CVD 103-HgR in Children and Adolescents Aged 6-17 Years. *The American journal of tropical medicine and hygiene*, 102(1), 48–57. <https://doi.org/10.4269/ajtmh.19-0241>
- McCarty, J. M., Lock, M. D., Bennett, S., Hunt, K. M., Simon, J. K., & Gurwith, M. (2019). Age-related immunogenicity and reactogenicity of live oral cholera vaccine CVD 103-HgR in a randomized, controlled clinical trial. *Vaccine*, 37(11), 1389–1397. <https://doi.org/10.1016/j.vaccine.2019.01.077>
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Trial Evaluating Safety and Immunogenicity of the Killed, Bivalent, Whole-Cell Oral Cholera Vaccine in Ethiopia. *The American journal of tropical medicine and hygiene*, 93(3), 527–533. <https://doi.org/10.4269/ajtmh.14-0683>