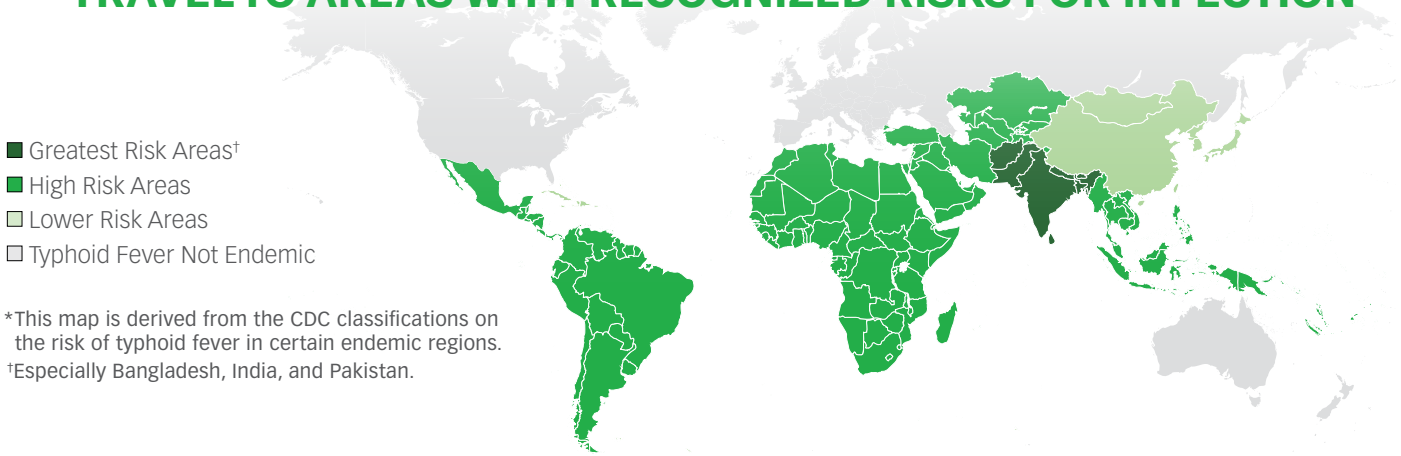
TRAVEL IS BACK—

are they ready to explore the world again?

Vivotif®
(Typhoid Vaccine Live Oral Ty21a)
Capsules

THE CDC RECOMMENDS TYPHOID FEVER VACCINATION BEFORE TRAVEL TO AREAS WITH RECOGNIZED RISKS FOR INFECTION[1]*



*This map is derived from the CDC classifications on the risk of typhoid fever in certain endemic regions.
†Especially Bangladesh, India, and Pakistan.

Typhoid fever is a potentially severe, occasionally fatal illness caused by the bacterium *Salmonella* Typhi.[1‡] It can be transmitted through the consumption of food and water contaminated with *Salmonella* Typhi[1]

An estimated **11–21 million cases** of typhoid fever and **135,000–230,000 deaths** from typhoid fever and paratyphoid fever occur worldwide each year[1]

Travelers headed to **Asia** (greatest risk for infection in **South Asia**), **Africa**, and **Latin America** are at high risk for typhoid fever[1]

About **half of travelers** who get typhoid fever are **visiting friends or family**[2]

‡Without effective treatment, typhoid fever can last for a month, with death rates ranging between 10% and 30%.[1]

Indication and Usage

VIVOTIF is indicated for immunization of adults and children greater than 6 years of age against disease caused by *Salmonella typhi*.

Routine typhoid vaccination is not recommended in the United States of America. Selective immunization against typhoid fever is recommended for the following groups: 1) travelers to areas in which there is a recognized risk of exposure to *S. typhi*; 2) persons with intimate exposure (e.g., household contact) to an *S. typhi* carrier; and 3) microbiology laboratorians who work frequently with *S. typhi*. There is no evidence to support the use of typhoid vaccine to control common source outbreaks, disease following natural disasters, or in persons attending rural summer camps.

Not all recipients of VIVOTIF will be fully protected against typhoid fever. Vaccinated individuals should continue to take personal precautions against exposure to typhoid organisms. The vaccine will not afford protection against species of Salmonella other than *Salmonella typhi* or other bacteria that cause enteric disease. The vaccine is not suitable for treatment of acute infections with *S. typhi*.

Important Safety Information

Contraindications

VIVOTIF is contraindicated in patients with a hypersensitivity to any component of the vaccine or the enteric-coated capsule. The vaccine should not be administered to persons during an acute febrile illness. Safety of the vaccine has not been demonstrated in persons deficient in their ability to mount a humoral or cell-mediated immune response, due to either a congenital or acquired immunodeficient state including treatment with immunosuppressive or antimitotic drugs. The vaccine should not be administered to these persons regardless of benefits.

Warnings and Precautions

Acute Gastrointestinal Illness: VIVOTIF is not to be taken during an acute gastrointestinal illness.

Concomitant Administration With Sulfonamides and Antibiotics: The vaccine should not be administered to individuals receiving sulfonamides and 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.

Administration in Patients With Diarrhea or Vomiting: Vaccination should be postponed if persistent diarrhea or vomiting is occurring.

Need to Complete the Entire Vaccination Series of 4 Doses on the Correct Schedule: Unless a complete immunization schedule is followed, an optimum immune response may not be achieved. Not all recipients of VIVOTIF will be fully protected against typhoid fever.

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

One Oral Course of VIVOTIF May Help Provide Protection From Typhoid Fever for at Least 5 Years[3]

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Capsules

VIVOTIF CAPSULES ARE TAKEN ON DAYS 1, 3, 5, AND 7, AND COMPLETED AT LEAST 1 WEEK BEFORE TRAVEL TO AREAS ENDEMIC FOR TYPHOID FEVER[3]

DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1st capsule	Skip a day	2nd capsule	Skip a day	3rd capsule	Skip a day	4th capsule

Keep the capsules refrigerated (35.6°F–46.4°F), do not freeze

Take by mouth 1 hour before a meal with cold or lukewarm (temperature not to exceed body temperature, e.g., <37°C [98.6°F]) drink

Swallow the capsule as soon after placing in the mouth as possible. Do not open or chew capsule

Travelers can receive text message reminders with the TAKE4 program!

To enroll in the TAKE**4** text reminder program, travelers text "TRAVEL" to 1-833-207-3377 or scan the QR code on the day of their first dose. They will receive a text every other day reminding them to take their next dose and to refrigerate the remaining capsules.*

*The information requested will be used by Bavarian Nordic to send text message reminders. Message and data rates may apply. This is a recurring program that includes a number of messages over the course of 7 days. At any time during the program, travelers may text "HELP" for assistance or "STOP" to discontinue receiving messages.

Important Safety Information (continued)

Warnings and Precautions (continued)

Not All Recipients Will Be Protected — Need for Safety Vigilance: Not all recipients of VIVOTIF will be fully protected against typhoid fever. Vaccinated individuals should continue to take personal precautions against exposure to typhoid organisms (i.e., travelers should take all necessary precautions to avoid contact or ingestion of potentially contaminated food or water).

Concomitant Administration With Anti-malarial Drugs: Several anti-malaria drugs, such as mefloquine, chloroquine, and proguanil (approved in the United States as 1 of the 2 active ingredients in Malarone and its generic equivalents) possess anti-bacterial activity, which may interfere with the immunogenicity of VIVOTIF. A study in healthy adults showed that mefloquine and chloroquine can be administered together with VIVOTIF. Proguanil should be administered only if 10 days or more have elapsed since the final dose of VIVOTIF was ingested.

Pregnancy/Nursing: It is not known whether VIVOTIF can cause fetal harm when administered to pregnant women or can affect reproduction capacity. VIVOTIF should be given to a pregnant woman only if clearly needed. There are no data to warrant the use of this product in nursing mothers. It is not known if VIVOTIF is excreted in human milk.

Adverse Reactions

In 2 trials conducting active surveillance for adverse reactions in persons receiving 3 doses (VIVOTIF recipients in the safety dataset, n=483), the most common adverse reactions were abdominal pain (6.4%), nausea (5.8%), headache (4.8%), fever (3.3%), diarrhea (2.9%), vomiting (1.5%), and skin rash (1.0%). Only the incidence of nausea occurred at a statistically higher frequency in the vaccinated group as compared to the placebo group. Reports to the manufacturer from early post-marketing clinical experience (1991-1995), during which time over 60 million doses (capsules) were administered, included all the adverse reactions identified above, as well as urticaria in the trunk and/or extremities (n=13), and 1 isolated, non-fatal case of anaphylactic shock considered to be an allergic reaction to the vaccine.

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://vivotif.com/downloads/Vivotif_Prescribing_Information.pdf.

CDC, Centers for Disease Control and Prevention.

References: 1. CDC Yellow Book 2024: Typhoid & paratyphoid fever. Accessed January 5, 2024. https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/typhoid-and-paratyphoid-fever
2. Centers for Disease Control and Prevention. National Typhoid and Paratyphoid Fever Surveillance Annual Summary, 2020. Accessed January 5, 2024. https://www.cdc.gov/typhoid-fever/reports/annual-summary-2020.html
3. VIVOTIF (Typhoid Vaccine Live Oral Ty21a) [package insert]. Redwood City, CA: Emergent Travel Health Inc.

US-VIV-2300089 | January 2024

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