

WHERE TYPHOID FEVER IS
ENDEMIC AND COULD COMPROMISE
THE SAFETY OF FOOD AND WATER

 **Vivotif**[®]
(Typhoid Vaccine Live Oral Ty21a)
Capsules

VIVOTIF May Provide at Least 5 Years of Protection¹

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

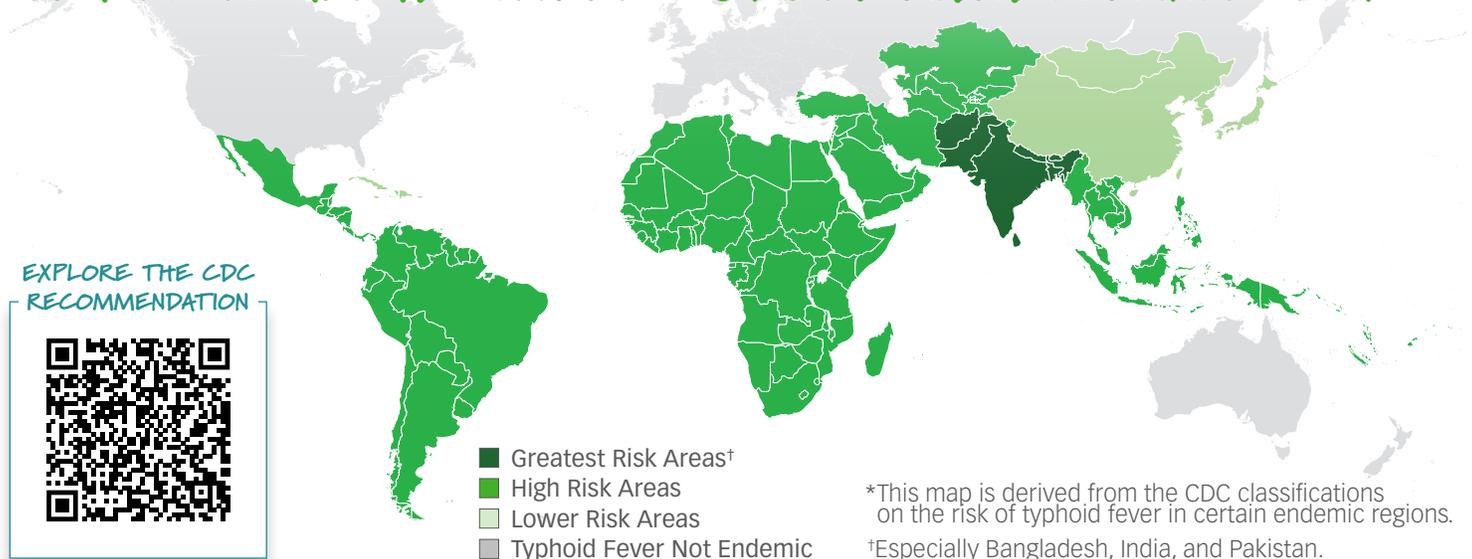
Contraindications

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 antimetabolic drugs. The vaccine should not be administered to these persons regardless of benefits.

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

Typhoid Fever Is a Potentially Severe but Preventable Travel-Related Illness²

THE CDC RECOMMENDS TYPHOID FEVER VACCINATION BEFORE TRAVEL TO AREAS WITH RECOGNIZED RISKS FOR INFECTION^{2*}



Without effective treatment, typhoid fever can last for a month, with death rates ranging between 10% and 30%²



Transmitted through the consumption of food and water contaminated with *Salmonella* Typhi²



An estimated 11–21 million cases of typhoid fever and 135,000–230,000 deaths from typhoid fever and paratyphoid fever occur worldwide each year²



About half of travelers who get typhoid fever are visiting friends or family³

Important Safety Information (continued)

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](https://vivotif.com/downloads/Vivotif_Prescribing_Information.pdf).

At Least 5 Years of Protection From Typhoid Fever¹



THE ONLY ORAL TYPHOID FEVER VACCINE^{1,2}



Results from clinical studies indicate that adults and children greater than 6 years of age may be protected against typhoid fever following the oral ingestion of 4 doses of VIVOTIF (Typhoid Vaccine Live Oral Ty21a). The efficacy of the *S. typhi* Ty21a strain has been evaluated in a series of randomized, double-blind, controlled field trials. Not all recipients of VIVOTIF will be fully protected against typhoid fever.¹



More than 1.4 million doses of VIVOTIF have been administered in controlled clinical trials and more than 150 million doses have been marketed worldwide¹

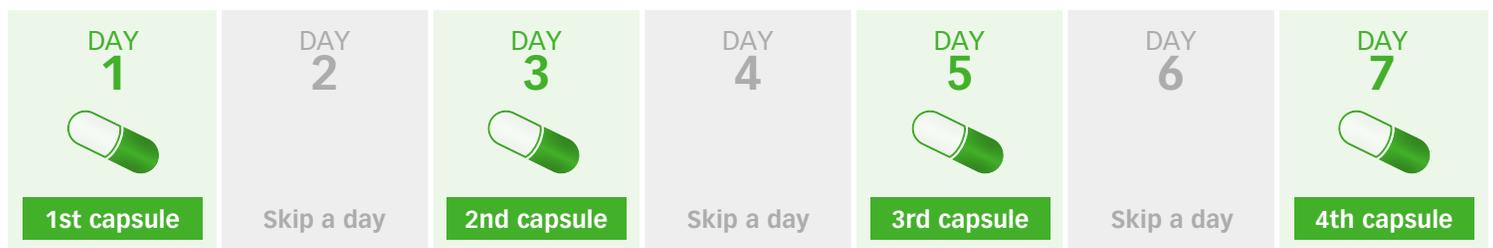


The most common adverse reactions in clinical trials were abdominal pain (6.4%), nausea (5.8%), headache (4.8%), fever (3.3%), diarrhea (2.9%), vomiting (1.5%), and skin rash (1.0%)¹

LEARN MORE ABOUT VIVOTIF



VIVOTIF capsules are taken on Days 1, 3, 5, and 7, and completed at least 1 week before travel to areas endemic for typhoid fever¹



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.

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

Help Them Stay on Course With VIVOTIF!



QUICK TIPS FOR TRAVELERS¹

-  Keep the capsules refrigerated (35.6°F–46.4°F), do not freeze
-  Complete the course of VIVOTIF at least 1 week prior to potential exposure to *S. Typhi*
-  Inspect the blister containing the vaccine capsules to ensure that the foil seal and capsules are intact
-  DO NOT take VIVOTIF while taking antibiotics or sulfonamides, as these medications may decrease the effectiveness of the vaccine
-  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
-  Take precautions even after vaccination because the vaccine does not completely protect against typhoid fever. While traveling, follow good hygiene practices and ensure the food and water you consume is as safe as possible
-  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 TAKE4 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)

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. VIVOTIF (Typhoid Vaccine Live Oral Ty21a) [package insert]. Redwood City, CA: Emergent Travel Health Inc.

2. CDC Yellow Book 2024: Typhoid & paratyphoid fever. Accessed January 5, 2024. <https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/typhoid-and-paratyphoid-fever>

3. 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>

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