# TYPHOID LIVE ORAL VACCINE Ty21a

## I. ORDER FOR ADMINISTRATION

1. Screen for contraindications
2. Provide a current Vaccine Information Statement (VIS), answering question
3. Obtain a signed Vaccine Administration Record (VAR)
4. Vivotif® (Typhoid Vaccine Live Oral Ty21a) is a live attenuated vaccine for oral administration only.
5. Dispense 4 capsules with instructions on how to take the medication to eligible individuals ≥18 years of age.

**Capsules need to be taken with cool liquid no warmer than 37°C (98.6°F)**

Pharmacist signature Date

Electronic copy of this protocol available at
http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml

Original provided courtesy of the Oregon State Public Health Division DHS Immunization Program

## II. LICENSED LIVE TYPHOID VACCINE

Typhoid oral vaccine is a live attenuated vaccine. It contains the attenuated strain *Salmonella* Typhi Ty21a, which is grown in a special bovine tissue broth containing casein dextrose and galactose, collected by centrifugation, mixed with stabilizers (lactose, amino acids) and lyophilized. The lyophilized bacteria are put into a gelatin capsule, which is coated with a solution to render them resistant to dissolution in stomach acid. The coated capsules are then packaged in a 4-capsule blister pack for distribution.

| Product Name | Vaccine components | Acceptable age range | Thimerosal |
|---|---|---|---|
| Vivotif®<br><br>Berna Biotech Ltd. | Attenuated *Salmonella* Typhi strain Ty21a (2–6.8 x $10^9$ colony-forming units and 5–50 x $10^9$ non-viable bacterial cells per capsule) attenuated *Salmonella* Typhi strain Ty21a | ≥6 years | NONE |

## III. INDICATIONS FOR USE

Oral typhoid vaccine is indicated for immunization of adults and children six years or older against disease caused by *Salmonella* Typhi. Immunization (ingestion of all four doses) should be completed at least one week prior to potential exposure.

Routine immunization against typhoid fever is not recommended in the United States. However, immunization is indicated under the following conditions:

- Expected intimate exposure to a household contact with typhoid fever.
- Travelers to areas of the world with a risk of exposure to typhoid fever.
- Workers in microbiology laboratories with expected frequent contact with *S.* Typhi.

Protection is not 100%. Studies have shown that immunity to typhoid fever is relative and can be overcome by a large infecting dose. Thus, persons should be advised to avoid contact with or ingestion of potentially contaminated food or water.

An optimal schedule for booster doses is not yet established. It is recommended, however, that a booster of four vaccine capsules every other day be repeated every five years if exposure to *S.* Typhi is possible.

## IV. DOSAGE & ADMINISTRATION

A. **Instruct patient and review the following instructions**. Provide manufacturer's instruction card.

1. Inspect blister to ensure that foil seal and capsule are intact.
2. Each capsule should be taken on an empty stomach. Swallow one capsule one hour before a meal with a clear, non-alcoholic cold or lukewarm (≤37°C or 98.6°F), drink on alternate days (day 1, 3, 5, 7). Indicate days on instruction card.
3. Do not chew capsule.
4. Swallow as soon as possible after placing in mouth.
5. Patient should call vaccine administrator if vaccine is taken incorrectly or mishandled.

| **VACCINE LIVE ORAL Ty21a** | | | | | |
|---|---|---|---|---|---|
| **Vaccination** | **Age** | **Dose, route of administration** | **Number of doses** | **Interval Between each dose[1]** | **Boosting Interval** |
| Primary series | ≥18 yrs[2] | 1 capsule, oral | 4 | 48 hrs | N/A |

| | | | | | |
|---|---|---|---|---|---|
| Booster | ≥18 yrs[2] | 1 capsule, oral | 4 | 48 hrs | Every 5 yrs |

[1] Missed doses: prolonging the interval between doses by 2–4 days does not interfere with immunity achieved after the concluding dose of the basic series. Ingest all 4 capsules within 10 days (Grabenstein, *ImmunoFacts*).

[2] Although this vaccine is licensed for persons ≥6 years of age, Oregon pharmacists, by law, may not administer this vaccine to persons <18 years of age.

B. **Dispense vaccine with prescription label and provide client with adequate insulation for safe transport** (e.g., provide sufficient ice on warm days to protect vaccine until client can get vaccine to cold storage).

## V. CONTRAINDICATIONS

1. Hypersensitivity to any component of the vaccine or the enteric-coated capsule.

2. Do not give during an acute febrile illness. Postpone if persistent diarrhea or vomiting is occurring.

3. Do not give to a person receiving sulfonamides or antibiotics as these may inactivate the vaccine. If patient is on prophylactic antibiotics, stop for four days, then start Ty21a vaccine course. Restart antibiotic four days after completion of vaccine course.

4. Administration of proguanil (a component of Malarone®) with Ty21a is associated with a significant decrease in immune reponse to the vaccine. Proguanil should be administered only if ≥10 days have elapsed since the final dose of Ty21a was ingested. Concomitant treatment with mefloquine or chloroquine does not result in significant reduction of antibody response to Ty21a.

5. Live-attenuated Ty21a should not be used among immuno-compromised persons, including those persons known to be infected with human immunodeficiency virus. The vaccine should not be administered to these persons regardless of benefits. The available parenteral vaccine presents a theoretically safer alternative for this group.

6. No data exist on the use of Ty21a in pregnant or nursing women. Vivotif® should be given to a pregnant woman only if clearly needed.

7. Do not administer to children less than six years of age.

## VI. ADVERSE REACTIONS

Reported adverse reactions are infrequent and include diarrhea, abdominal pain, nausea, fever, headache, skin rash, vomiting, and urticaria of the trunk and extremities. One case of non-fatal anaphylactic shock has been reported.

## VII. OTHER CONSIDERATIONS

1. Available data suggest simultaneous administration of oral polio vaccine (not available currently) or yellow fever vaccine with Ty21a does not decrease its immunogenicity.

2. Any single dose can be missed by up to 48 hours past the regular time for the dose and the remaining capsules must be completed on the 48-hour schedule between doses.

3. If nausea, abdominal cramps or vomiting persist longer than 24 hours, the patient likely has an underlying GI illness and the vaccine course should be interrupted. If interruption is longer than 48 hours, the vaccine regimen should be restarted.

4. For questions, call Berna Biotech Ltd. at 1-800-533-5899 from 9 a.m. to 5 p.m. Eastern Standard Time and ask for the Medical Department.

## VIII. STORAGE OF VACCINE

- Store at 2°–8°C (35°–46° F) before use and between doses. If frozen, thaw the capsules before administration. Product can tolerate 48 hours at 25°C (77°F). (Grabenstein, *ImmunoFacts*)

- While refrigeration is recommended, the potency of the vaccine is not harmed if a patient mistakenly places it in the freezer. Simply instruct them to remove it from the freezer and place in the refrigerator (per Berna Products representative).

- Under no circumstances should Ty21a be exposed to direct sunlight.

## IX. REFERENCES

1. Berna Biotech Ltd. Vivotif® package insert. Available at http://www.bernaproducts.com/PDFs/Vivotif2004PIL.pdf

2. CDC. Typhoid vaccine: recommendation of the Advisory Committee on Immunization Practices (ACIP). MMWR 1994; 43(RR-14): 1–7. Available at http://www.cdc.gov/MMWR/PREVIEW/MMWRHTML/00035643.htm

3. CDC. Health Information for International Travel 2008, Atlanta: U.S. Department of health and Human Services, Public Health Service, 2007: 345–9. Available at http://wwwn.cdc.gov/travel/yellowBookCh4-Typhoid.aspx

*4.* Grabenstein JD. *ImmunoFacts*: *Vaccines and Immunologic Drugs 2008*. St. Louis, Missouri: Wolters Kluwer Health; 2007: 172–6.