OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
TYPHOID LIVE ORAL VACCINE Ty21a

I. Order:

1. Check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥11 years for contraindications.
3. Provide an Adolescent Well Visit Flyer to those 11—18 years of age.
4. Provide a current Vaccine Information Sheet (VIS) answering any questions.
5. Obtain a signed Vaccination Administration Record (VAR)
6. Vivotif® (Typhoid Vaccine Live Oral Ty21a) is a live attenuated vaccine for oral administration only.
7. Dispense 4 capsules to eligible individuals with instruction on how to take the medication.

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

Immunizing Pharmacist Signature                Date
For multiple signatures see: http://1.usa.gov/PharmacyImmunizationProtocols
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\(^1\) containing casein, dextrose and galactose, collected by centrifugation, mixed with stabilizer and lyophilized. The lyophilized bacteria are put into a gelatin capsule, which is coated with an organic solution to render them resistant to dissolution in stomach acid. The enteric-coated, salmon/white capsules are then packaged in a 4-capsule blister pack for distribution\(^2\).

\(^2\)Vivotif\(^\circledR\) package insert (2006).

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>ACCEPTABLE AGE RANGE</th>
<th>THIMEROSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vivotif(^\circledR) Crucell Vaccines Inc.</td>
<td>Attenuated <em>Salmonella</em> 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 <em>Salmonella</em> Typhi strain Ty21a.</td>
<td>≥6 years</td>
<td>None</td>
</tr>
</tbody>
</table>
## III. RECOMMENDATIONS FOR USE

1. Oral typhoid vaccine is indicated for immunization of adults and children six years or older against disease caused by *Salmonella Typhi*.

2. Immunization (ingestion of all four doses) should be completed at least one week prior to potential exposure.

3. Routine immunization against typhoid fever is not recommended in the United States. Immunization against typhoid fever is indicated for the following groups:
   a) Travelers to areas in which there is a recognized risk of exposure to *S. Typhi*, particularly those who will have prolonged exposure to potentially contaminated food and drink.
   b) Persons with intimate exposure (i.e., continued household contact) to a documented *S. Typhi* carrier, and
   c) Microbiology laboratorians who frequently work with *S typhi*.

4. Current CDC advisories should be consulted with regard to areas with a risk of exposure to *S. Typhi*. Travelers should use caution in selecting food and water, even if vaccinated.

5. Re-immunization every five years under conditions of repeated or continued exposure to *Salmonella Typhi* is recommended.

6. The vaccine will not protect against serotypes of *Salmonella* other that *S. Typhi*. 
IV. A. VACCINE SCHEDULE

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Age</th>
<th>Dose, route of administration</th>
<th>Number of doses</th>
<th>Interval Between each dose&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Boosting Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary series</td>
<td>≥11 yrs</td>
<td>1 capsule, oral</td>
<td>4</td>
<td>48 hrs</td>
<td>N/A</td>
</tr>
<tr>
<td>Booster</td>
<td>≥11 yrs</td>
<td>1 capsule, oral</td>
<td>4</td>
<td>48 hrs</td>
<td>Every 5 yrs</td>
</tr>
</tbody>
</table>

<sup>1</sup> 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*).

V. A. VACCINE ADMINISTRATION AND TRANSPORT

*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.
V. B. VACCINE SCHEDULE, ADMINISTRATION AND TRANSPORT cont.

V. C. VACCINE TRANSPORT

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).

VI. CONTRAINDICATIONS AND PRECAUTIONS

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 any antibacterial agent, stop for four days, and then start Ty21a vaccine course. Restart antibiotic four days after completion of vaccine course.
4. Mefloquine and Atovaquone-proguanil at prophylaxis doses can be given concurrently with Live-attenuated Ty21a. However, since Live-attenuated Ty21a vaccine should be completed 7 days prior to traveling, there should be no opportunity for concomitant administration with atovaquone/proguanil in most travelers.
5. Live-attenuated Ty21a should not be used by 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.
8. If typhoid vaccination is warranted, it should not be delayed because of administration of viral vaccines.
VII. SIDE EFFECTS AND ADVERSE REACTIONS

<table>
<thead>
<tr>
<th>Effect</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>6.4%</td>
</tr>
<tr>
<td>Nausea</td>
<td>5.6%</td>
</tr>
<tr>
<td>Fever</td>
<td>0% - 5%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2.9%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1.5%</td>
</tr>
<tr>
<td>Skin rash</td>
<td>1.0%</td>
</tr>
<tr>
<td>Headache</td>
<td>0% - 5%</td>
</tr>
</tbody>
</table>

Source: Package insert: 2006

VIII. OTHER CONSIDERATIONS

1. All 4 doses of Vivotif® should be completed at least 1 week prior to potential exposure to S. Typhi.

2. Available data suggest simultaneous administration of oral polio vaccine (not licensed in US) or yellow fever vaccine with Ty21a does not decrease its immunogenicity.

3. 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.

4. 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.

5. For questions, call Crucell at 1-800-533-5899 from 8 a.m. to 5 p.m. Eastern Standard Time and ask for the Medical Department.
IX. STORAGE AND HANDLING

1. Store at 2°–8°C (35°–46° F) before use and between doses. If frozen, thaw the capsules before administration. Vivotif® remains stable for up to 24 hours outside of refrigeration as long as it is not over 80°F or in direct sunlight. Per Crucell Medical Liaison, 2010.

2. 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).

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

X. ADVERSE EVENTS REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.hhs.gov. In addition, a copy of the reporting form should be reported to the patient’s primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4).

REFERENCES


To request this material in an alternative format (e.g., Braille) or for more information, or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 or 711 for TTY. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

Electronic copy of this protocol available at: http://1.usa.gov/PharmacyImmunizationProtocols