PART III: CONSUMER INFORMATION

Vivotif®

Typhoid Vaccine Live Oral Attenuated Ty21a

This leaflet is part III of a three-part "Product Monograph" published when Vivotif was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Vivotif. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Vivotif (Typhoid Vaccine Live Oral Attenuated Ty21a) is a vaccine for protection of adults and children older than 5 years against typhoid fever, a disease caused by bacteria called *Salmonella enterica* serovar Typhi (abbr. *S. typhi*). You can catch typhoid fever by eating food or drinking water that has been contaminated with the *S. typhi* bacteria. Without antibiotic treatment, typhoid fever can be fatal. The vaccine is intended for persons:

- who travel to or stay in countries where there is a risk of catching typhoid fever
- with ongoing household or intimate exposure to a typhoid carrier
- who work in the laboratory and who frequently handle cultures of *S. typhi*

What it does:

Vivotif is a vaccine that is taken orally to give you protection against typhoid fever. The vaccine is made up of a strain of *S. typhi* that is no longer harmful (*S. typhi* Vaccine Strain Ty21a).

But the body doesn't know that it is not harmful, so it stimulates protective immunity to the typhoid fever bacteria. This protection lasts for 7 years. However, not all vaccinated persons will be fully protected against typhoid fever even after a full course of Vivotif. Therefore, even if you have been vaccinated, you should still take all precautions necessary to avoid food or water that may contain the bacteria that cause typhoid fever.

When it should not be used:

If you have ever had an allergic reaction to any of the ingredients contained in Vivotif.
If you have a poor immune system for any reason.

If you currently have an infection with fever or an illness affecting your gut (such as diarrhoeal illness). Vaccination should be delayed until recovering.

What the medicinal ingredient is:

Typhoid Vaccine Live Oral Attenuated Ty21a

What the important nonmedicinal ingredients are:

Amino acid mixture, ascorbic acid, lactose, magnesium stearate, sucrose.
For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

A single foil blister contains 4 capsules (4 doses) in a single package.

Each capsule contains 2.0 – 10.0 x 10^9 live *S. typhi* Ty21a bacteria. The bacteria have been freeze-dried and enclosed in a capsule with a special coating to protect it (enteric coated).

WARNINGS AND PRECAUTIONS

BEFORE you use Vivotif talk to your doctor or pharmacist if:

- you have fever or an illness in your gut.
- you are or think you might be pregnant. Vivotif should be given to a pregnant woman only if clearly needed.
- you are breast-feeding. It is not known if the live bacteria or any other component of Vivotif can pass into breast milk.

INTERACTIONS WITH THIS MEDICATION

Vivotif may not work if taken along with medicines to treat bacterial infections (antibiotics, sulfonamides included). Vivotif should not be given until at least three days after of the last dose of the antibiotic and, if possible, antibiotics should not be started within three days of the last dose of Vivotif.

Alcoholic beverages should not be consumed one hour before or two hours after taking Vivotif.

If you need to take anti malaria tablets containing chloroquine or mefloquine or the combinations atovaquone/proguanil or pyrimethamine/sulfadoxine, these can be taken on the same day as Vivotif. However, if your health care provider gives you any other medicine to prevent malaria, these should not be started until 3 days of the last dose of Vivotif. Likewise, you should wait for 3 days before beginning Vivotif after taking the medicines to prevent malaria.

Oral polio vaccine or yellow fever vaccine can be given while you are taking Vivotif. Injectable vaccines or immunoglobulins may be administered with Vivotif at the same time.

PROPER USE OF THIS MEDICATION

Usual dose:
A day should be selected to take the first capsule (Day 1). The second capsule should be taken on Day 3 (i.e., skip a day after the first capsule), the third capsule should be taken on Day 5 and the fourth capsule should be taken on Day 7.

The foil blister package containing the vaccine capsules should be inspected to ensure that the foil seal and the capsules are intact.

One capsule (each dose) should be swallowed approximately 1 hour before a meal, or two hours after a meal with cold or lukewarm water [temperature not to exceed body temperature, i.e. 37 °C (98.6 °F)]. The vaccine capsule should not be chewed or opened and should be swallowed as soon as possible after placing in the mouth.

Overdose:
Taking doses without skipping a day between doses, will not pose a danger to you. However, you may not be protected against typhoid fever. Therefore, you should tell your doctor or nurse about the mistake in how you have taken the capsules.

Missed Dose:
If you forget to take a dose, you should talk to your health care provider about how long you have missed the recommended dosage regimen.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The following side effects were reported most commonly (that is in less than one in ten persons but more than in one in hundred persons) in clinical studies:

Stomach pain, feeling or being sick (nausea and vomiting), diarrhoea, fever, flu-like illness, headache and rash.

Side effects that have been reported very rarely (that is in less than one in ten thousand persons) during normal use include:

Skin irritation, rashes, red or lumpy raised rashes, itching and hives. Severe allergic reactions with drops of blood pressure and loss of consciousness. Weakness, generally feeling unwell, shivering, tiredness, pins and needles, dizziness, joint and muscle pain.

These symptoms disappear spontaneously within a few days. *This is not a complete list of side effects. For any unexpected effects while taking Vivotif, contact your doctor or pharmacist.*

HOW TO STORE IT

Keep Vivotif out of the reach and sight of children.

Vivotif is not stable when exposed to room temperature.

Vivotif should be stored at refrigerated temperatures between 35.6 °F and 46.4 °F (2 °C and 8 °C). Vaccine capsules should be stored between doses in the refrigerator. The vaccine may be out of refrigeration during a reasonable transit time home from the clinic. If the capsules are left outside of refrigeration at room temperature 77 °F (25 °C) for up to 12 hours on a one-time only occasion, the product quality will not be affected, and the capsules can still be taken. Each blister of vaccine shows an expiration date. This expiration date is valid only if the product has been maintained between 35.6 °F and 46.4 °F (2 °C and 8 °C). The product should be stored in a dry place and protected from light.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:
If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in **your province/territory**.

For the General Public:
Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada

By toll-free telephone: 866-844-0018

By toll-free fax: 866-844-5931

Email: caefi@phac-aspc.gc.ca

Web: http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php

Mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road, A/L 6502A
Ottawa, ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health-care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

For more information or safety reporting please contact:
safety@paxvax.com or call the toll-free-number: 1-844-202-1232

This leaflet was prepared by PaxVax Inc., USA.
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