

Information for patients

Read this leaflet carefully before taking or using the medicine. This medicine has been prescribed for you personally, therefore you should not give it to other persons. Keep this package leaflet, you may need to read it again.

Vivotif®

Live oral vaccine for active immunisation against typhoid fever

What is Vivotif and when is it used?

Typhoid fever is an acute febrile disease caused by the bacterium *Salmonella enterica* serovar Typhi (abbr. *S. typhi*), which leads to abdominal cramps, diarrhoea and loss of appetite. Without specific antibiotic treatment, typhoid fever can be fatal. Unfortunately, it appears that *Salmonella* responsible for typhoid fever have become increasingly resistant to conventional antibiotics.

Infection is caused by ingesting bacteria (*S. typhi*) with contaminated food or water, which explains its widespread occurrence in regions with poor hygiene. Vivotif is an oral vaccine for protection against typhoid fever. By taking an altered form of *S. typhi* that is no longer harmful (*S. typhi* strain Ty21a), the body develops immunity to typhoid fever bacteria. Vivotif is recommended, on medical prescription, as a precaution before travelling to or taking up residence in regions with poor hygiene.

What else should be considered?

Even if you have been vaccinated, you should continue to take personal precautions to avoid contact or ingestion of food and drink potentially contaminated with *Salmonella*.

When should Vivotif not be used?

Vivotif should not be taken in case of hypersensitivity to any ingredients of the vaccine or in case of congenital or acquired immune deficiency or simultaneous treatment with medicines that affect the immune system or the vaccine.

When is caution required when using Vivotif?

Tell your doctor or pharmacist if you

– are suffering from another disease or illness,

– have allergies, or

– are taking oral or locally administered medicines (including those purchased by yourself). Vivotif should not be taken in case of acute febrile illnesses or acute gastrointestinal infections, as well as during and up to 3 days after treatment with antibiotics. In case of planned prophylaxis against malaria, an interval of 3 days between the last dose of Vivotif and the start of the malaria prophylaxis should be kept. It is recommended that malaria prophylaxis be started in the last week before travelling.

Vivotif may be given if malaria prophylaxis with chloroquine, mefloquine, combination products pyrimethamine/sulfadoxin or atovaquone/proguanil has been started. If malaria prophylaxis with antimalarial medicines other than those stated above has been started, the prophylaxis should be stopped and you should wait 3 days before taking Vivotif.

May Vivotif be taken during pregnancy or when breast-feeding?

Based on previous experience, there is no known risk to the child if used according to instructions. However, systematic scientific studies have never been performed. It is recommended to avoid medicines as much as possible during pregnancy and while breast-feeding, or ask your doctor or pharmacist for advice.

How is Vivotif used?

For adults and children over 5 years of age, a total of 3 vaccine doses are required, namely one capsule on each of days 1, 3 and 5. Each capsule is to be swallowed with cold or lukewarm water (not more than 37 °C) on an empty stomach, one hour before a meal.

Immune protection becomes effective about 10 days after taking the last dose, so that Vivotif vaccination should be started not later than 2 weeks before travelling. Immune protection lasts for at least one year and for 3 years in case of continuous residence in areas with frequent occurrence of the disease. Yearly vaccination is recommended when travelling to areas of poor hygiene. In endemic areas, revaccination is recommended every 3 years. Revaccination consists of 3 doses in the same way as for the first vaccination.

Do not change the prescribed dosage yourself. If you think that the action of the medicine is too weak or too strong, talk to your doctor or pharmacist.

Parenteral vaccines such as those for yellow fever, measles, mumps, rubella and chickenpox may be administered at the same time.

What side effects can Vivotif have?

The following side effects may occur when taking or using Vivotif: abdominal pain, nausea, headache, fever, diarrhoea, vomiting, skin rash, tiredness, malaise, shivering, dizziness, pins and needles, aching muscles and joints, and allergic reactions. These symptoms disappear spontaneously within a few days.

If you notice side effects that are not described here, tell your doctor or pharmacist.

What else has to be considered?

Vivotif must be stored in a refrigerator (+2 to +8 °C) and be protected from light. The product must not be used after the expiry date shown on the container after "Exp.". For further information, please contact your doctor or pharmacist who have extensive technical information at their disposal.

What does Vivotif contain?

Each dose of Vivotif contains not less than 2 billion viable organisms of the attenuated strain *Salmonella typhi* Ty21a in a lyophilized form.

Inactive ingredients: lactose, sucrose, ascorbic acid, amino acids-peptides mixture (Hy-Case-SF), magnesium stearate, erythrosin red No. 3 (E127) and gelatin.

Where can you obtain Vivotif?

Vivotif can be obtained from your doctor or from a pharmacy, on prescription.

What packs are available?

One pack contains 3 gastro-resistant capsules.

Marketing authorization holder/Manufacturer

Berna Biotech Ltd

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