



Package leaflet: Information for the user
Vivotif®
Salmonella Typhi Ty21a

Read all of this leaflet carefully before you start taking this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vivotif is and what it is used for
2. What you need to know before you take Vivotif
3. How to take Vivotif
4. Possible side effects
5. How to store Vivotif
6. Contents of the pack and other information

1. What Vivotif is and what it is used for

Vivotif is an oral vaccine that stimulates an immune response against a type of bacteria called *Salmonella* Typhi that causes typhoid fever. It is used for protection from typhoid fever in adults and children 5 years and older.

How Vivotif works

The vaccine bacteria in Vivotif have been altered so that they cannot cause typhoid fever but still stimulate the body's natural defence system (immune system) to fight typhoid-causing bacteria.

Other types of *Salmonella* illness

There are many other types of *Salmonella* bacteria. Most of these cause illnesses with diarrhoea that are quite different to typhoid fever. They are also less serious. Vivotif cannot protect you against infections due to these other types of *Salmonella* bacteria.

2. What you need to know before you take Vivotif

Do not take Vivotif:

- if you are allergic (hypersensitive) to *Salmonella* Typhi Ty21a or any of the other ingredients of this vaccine (listed in section 6).
- if you experienced allergic reactions when you previously took Vivotif.
- if you have a poor immune system for any reason, for example, if you have had poor immunity to infections since birth. You may also have poor immunity due to certain infections or treatments that depress the immune system – such as high dose corticosteroids, cancer drugs or radiotherapy.
- if you have a high fever (above 38.5 °C) or an illness affecting your gut (such as diarrhoea) at the moment – do not take Vivotif until you have recovered.

Warnings and precautions

Not everyone taking a full course of Vivotif will be fully protected against typhoid fever. It is important to continue to adhere to hygiene advice and exercise caution regarding food and water consumed in typhoid-affected areas.

Children

Do not give this vaccine to children younger than 5 years old since the capsule is not suitable for this age group.

Other medicines and Vivotif

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines or vaccines. This includes medicines obtained without a prescription, including herbal medicines. This is because Vivotif can affect the way some other medicines and vaccines work.

In particular tell your doctor, pharmacist or nurse if you are taking:

- antibiotics – Vivotif may not work if it is taken while you are also taking antibiotics. Take Vivotif no earlier than 3 days after the last dose of an antibiotic.
- medicines to prevent malaria – do not start these until 3 days after the last dose of Vivotif unless otherwise directed by your doctor, pharmacist or nurse.

If any of the above apply to you, talk to your doctor, pharmacist or nurse before taking Vivotif.

Vivotif with food and drink

Vivotif is taken on an empty stomach and at least one hour before the next meal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Vivotif is not known to affect your ability to drive or use machines. However, do not drive or use any machines if you are feeling unwell.

Vivotif contains lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Vivotif

Always take this vaccine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

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

How much and when to take

The recommended dose is three capsules. One capsule is taken every other day.

- Take the first capsule on a chosen day. This is Day 1.
- Take the second capsule on Day 3.
- Take the third capsule on Day 5.

How to take your capsules

- Take the capsules on an empty stomach and at least one hour before the next meal.
- Do not crush or chew the capsules.
- Swallow the capsules with cold or lukewarm water (temperature not more than 37 °C).
- Swallow the capsules as quickly as possible after placing in your mouth.

Protection against typhoid fever starts at about seven to ten days after taking the course of three capsules. Your doctor, pharmacist or nurse will advise you how soon before travelling to have your course of Vivotif.

After three years, you may need to receive Vivotif again if you continue to visit areas where typhoid fever occurs. In this case, consult with your doctor, pharmacist or nurse.

If you take more Vivotif than you should

If you take all three doses at once by accident, tell your doctor, pharmacist or nurse. It is unlikely to make you ill but you may not be well protected against typhoid fever.

If you forget to take Vivotif

If you forget a dose, take it as soon as you remember. Then take the next dose about 48 hours later.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

Contact a doctor immediately if you experience the following serious side effects:

- serious allergic reactions causing swelling of the face or throat and breathlessness and/or a drop in blood pressure and fainting.

Other side effects:

Common side effects (may affect up to 1 in 10 people)

- stomach pains,
- feeling or being sick,
- diarrhoea,
- fever,
- headache,
- skin redness.

Other side effects (frequency cannot be estimated from the available data):

- skin irritation, rashes, red or lumpy raised rashes, and itching,
- weakness,
- generally feeling unwell,
- shivering,
- feeling tired,
- pins and needles,
- feeling dizzy,
- pain in your joints or muscles.
- back pain
- decreased appetite, abdominal gas, bloating
- flu-like illness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vivotif

Keep this vaccine out of the sight and reach of children.

Do not use Vivotif after the expiry date which is stated on the label.

The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C)

Keep the blister pack in the outer carton in order to protect from light.

Do not use this vaccine if you notice that the blister pack or the capsules are not intact.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vivotif contains

- Each capsule contains at least 2x10⁹ viable cells of *Salmonella* Typhi Ty21a.
- The other ingredients are lactose anhydrous, sucrose, casein acid hydrolysate, ascorbic acid (E300), magnesium stearate (E470), non-viable cells of *Salmonella* Typhi Ty21a.
Capsule shell: gelatin, titanium dioxide (E171), erythrosine (E127), iron oxide yellow (E172) and iron oxide red (E172).
Capsule coating: hydroxypropylmethylcellulose phthalate, ethylene glycol and diethyl phthalate.

What Vivotif looks like and contents of the pack

The pack contains a blister pack with three enteric-coated capsules of Vivotif. The capsules are bicoloured white and salmon.

Marketing Authorisation Holder

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Manufacturer

Emergent BioSolutions UK Ltd., Building 3, Chiswick Park, 566 Chiswick High Road, London, W4 5YA, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Czech Republic, Denmark, Finland, France, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovakia, Spain, Sweden: Vivotif
Germany: Typhoral L

This leaflet was last revised in February 2020

Other sources of information

Detailed information on this medicine is available on the MHRA website:

<http://www.mhra.gov.uk>.

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