

## Patient Information Leaflet

### Vivotif® Oral Typhoid Vaccine

#### Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others. It may harm them.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Vivotif is and what it is used for
2. Before you take Vivotif
3. How to take Vivotif
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## 1. What Vivotif is and what it is used for

### What Vivotif is

Vivotif is a vaccine that protects you against typhoid fever.

- Typhoid fever is an infection caused by a type of Salmonella bacteria – called "Salmonella typhi".
- You can catch typhoid fever from food or water that contains these bacteria.
- Typhoid fever can kill you, unless you get special antibiotic treatment.

Vivotif is for adults and children who are at least 6 years old:

- travelling to countries where there is a risk of catching typhoid fever.
- living in countries where there is a risk of catching typhoid fever.

### How Vivotif works

The bacteria in Vivotif have been altered so that they cannot cause typhoid fever. However, they can still stimulate the body's natural defence system (immune system). This means that it may protect you against the bacteria that cause typhoid fever. Unlike most vaccines, Vivotif is a course of capsules you take by mouth.

### 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.

### Do I still need to take care after having Vivotif?

It is important that you still take care not to have food or water that may contain the bacteria that cause typhoid. This is because not everyone having a full course of Vivotif will be fully protected against typhoid fever. Also, the protection only lasts for at most three years.

## 2. Before you take Vivotif

### Do not take Vivotif if:

- you are allergic (hypersensitive) to lactose or sucrose or any of the ingredients contained in Vivotif (listed in Section 6).
- 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 treatments that depress the immune system – such as high dose corticosteroids, cancer drugs or radiotherapy.
- you have an infection with a high temperature or an illness affecting your gut (such as diarrhoea) at the moment – do not have Vivotif until you have recovered.

Do not take Vivotif if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Vivotif.

### Taking other medicines and having other vaccines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines, or have recently received any other vaccine. This is because Vivotif can affect the way some other medicines work. Also, some other medicines can affect the way Vivotif works.

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

- antibiotics – Vivotif may not work if it is taken while you are also taking antibiotics. Take Vivotif at least 3 days after the last dose of an antibiotic. Also, if possible, do not take antibiotics until 3 days after the last dose of Vivotif.
- medicines to prevent malaria – do not start these until 3 days after the last dose of Vivotif. However, tablets that contain atovaquone plus proguanil can be taken on the same days as Vivotif. Also, mefloquine can be taken on the same days as Vivotif – but leave at least 12 hours between doses of mefloquine and of Vivotif.

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

If you need to have the yellow fever vaccine or oral polio vaccine before you travel, these can be given while you are taking Vivotif.

### Pregnancy and breast-feeding

Vivotif should only be given to pregnant women if it is clearly necessary. If you are or think you may be pregnant, discuss this with your doctor or pharmacist before taking Vivotif.

It is not known if the bacteria or any other ingredients of Vivotif can pass into breast milk. If you are breast-feeding, discuss this with your doctor or pharmacist before taking Vivotif.

### Driving and using machines

Vivotif is not known to affect your ability to drive or use machines.

## 3. How to take Vivotif

Always take Vivotif exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### How much and when to take

The usual dose is 3 capsules. These are 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.

82315gbpp.105

Please turn over

Vivotif	Pil	Color:	black
	Format:	Art.Nr.	82315gbpp.105
			95x297 mm

**How to take your capsules**

- Do not crush or chew the capsules.
- Swallow the capsules with cold or lukewarm water.
- Swallow the capsules as quickly as possible after placing in your mouth.
- Take about one hour before a meal.

**How long Vivotif works for**

Protection against typhoid fever starts at about 7–10 days after taking the course of 3 capsules. Your doctor or pharmacist will advise you how soon before travelling to have your course of Vivotif.

If you are living in a place where you are likely to be exposed to the bacteria that cause typhoid fever, you may be protected for up to 3 years after vaccination.

If you travel from time to time to areas where you are at particular risk of catching typhoid fever, have a repeat course of three capsules of Vivotif every year.

**If you take more Vivotif than you should**

If you take all three doses at once by accident, tell your doctor or pharmacist. 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 or pharmacist.

**4. Possible side effects**

Like all vaccines, Vivotif can cause side effects, although not everybody gets them. The following side effects may happen with this vaccine:

**Allergic reactions** (affects less than 1 in 10,000 people).

If you have an allergic reaction, see a doctor straight away. The signs may include:

- a drop in blood pressure and fainting.

See a doctor straight away if you experience these symptoms.

**Common** (affects less than 1 in 10 people)

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

**Very rare** (affects less than 1 in 10,000 people)

- 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. How to store Vivotif**

Keep out of the reach and sight 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 to 8 °C), as the vaccine is not stable at normal room temperatures. It is essential to put the capsules back in the refrigerator between doses.

The package should be kept dry and out of the light.

**6. Further information****What Vivotif contains**

- The active substance is a live bacteria called *Salmonella enterica* serovar Typhi (abbr. *S. typhi*) (strain Ty21a). The bacteria have been freeze-dried and enclosed in a capsule. The enteric coating of the capsules protects the bacteria in the capsules from the stomach acids that could kill them. Each capsule of Vivotif contains at least  $2 \times 10^9$  live *S. typhi* (strain Ty21a). One capsule is one dose.
- The other ingredients are lactose, sucrose, amino acid-peptide mixture (Hy-Case SF), ascorbic acid (E300), magnesium stearate (E470), inactivated *S. typhi* (strain Ty21a). "Capsule": gelatin, titanium dioxide (E171), erythrosine red No. 3 (E127), ferric oxide (E172). "Capsule coating": hydroxypropylmethyl-cellulose-phthalate (HP-MCP) – 50, ethylene glycol, dibutyl phthalate, diethyl phthalate.

**What Vivotif looks like and contents of the pack**

The pack contains three enteric-coated capsules of Vivotif. The capsules have a white body and a red cap.

**Marketing Authorisation Holder**

The company responsible for placing the vaccine on the market is:

Crucell Italy S.r.l.  
Via Zambelletti 25  
20021 Baranzate (MI), Italy

**Manufacturer**

The vaccine is manufactured by:  
Crucell Switzerland LTD  
Rehhagstrasse 79  
CH-3018 Berne

If you want more information about Vivotif please ask your doctor or pharmacist or call: 0844 800 3907.

This leaflet was last revised in September 2009.