Vivotif®
(Live, Oral, Strain Salmonella typhi Ty21a)
Oral Typhoid Vaccine

PATIENT INFORMATION LEAFLET

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.

Your medicine will be referred to as Vivotif throughout the following leaflet.

In this leaflet:
1. What Vivotif is and what it is used for
2. Before you take Vivotif
3. How to take Vivotif
4. Possible side effects
5. How to store Vivotif
6. Further information

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 no earlier than after the last dose of an antibiotic.
- medicines to prevent malaria – do not start these until 3 days after the last dose of Vivotif.

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

If you need to have oral polio vaccine or a live attenuated parenteral vaccine, e.g. yellow fever, 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. In the case of breast-feeding, Vivotif should only be given to you if clearly necessary.

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.

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.

If you forget to take Vivotif

If you forget a dose, take it as soon as you remember.

If you take more Vivotif than you should

If you take all three doses at once by accident, tell 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 1,000 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,
- headache,
- skin redness.

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.

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.

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.

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,
- 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,
- Back pain,
- Decreased appetite, abdominal gas, bloating,
- Flu-like illness.

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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

5. HOW TO STORE VIVOTIF
Keep 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 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.

If your capsules become discoloured or show any other signs of deterioration, consult your doctor or pharmacist who will tell you what to do.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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 2x10⁹ 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, magnesium stearate, inactivated S. typhi (strain Ty21a).
  “Capsule”: gelatin, titanium dioxide, erythrosine, yellow iron oxide and red iron oxide.

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 salmon coloured cap.

MANUFACTURER AND PRODUCT LICENCE HOLDER:
Manufactured by Crucell Switzerland S.A., Rehhagstrasse 79, CH-3018 Berna, Switzerland.

Procured from within the EU by Product Licence holder Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

Leaflet revision and issue date (Ref) 28.11.16[5]

Vivotif is a trademark of Crucell Switzerland AG.