

VIVOTIF® Oral

Oral Typhoid Vaccine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VIVOTIF® Oral.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child having VIVOTIF® Oral against the benefits expected.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

attack the bacteria if you come in contact with it.

Protection with VIVOTIF® Oral requires a full course of three doses.

After a full course most people will produce enough antibodies to prevent typhoid fever. However, as with all vaccines, 100% protection cannot be guaranteed.

The vaccine cannot give you or your child typhoid fever.

The chance of a severe reaction from VIVOTIF® Oral is very small, but the risks from not being vaccinated against typhoid fever may be very serious.

Do not give VIVOTIF® Oral to a child under 6 years.

The safety and effectiveness of VIVOTIF® Oral in children younger than 6 years has not been established.

Do not take VIVOTIF® Oral after the expiry date printed on the pack.

Do not take VIVOTIF® Oral if the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should take VIVOTIF® Oral, talk to your doctor, nurse or pharmacist.

Before you or your child start to take VIVOTIF® Oral.

Before you take VIVOTIF® Oral

What VIVOTIF® Oral is used for

VIVOTIF® Oral is a vaccine used to prevent typhoid fever. Typhoid fever is a severe form of infection caused by a type of *Salmonella* bacteria.

Vaccination with VIVOTIF® Oral is recommended for adults and children over 6 years of age who live in or travel through areas where typhoid fever occurs.

How it works

VIVOTIF® Oral contains live bacteria called *Salmonella typhi* strain Ty21a, which do not cause typhoid fever.

VIVOTIF® Oral works by causing your body to produce its own protection against the bacteria (germs) which cause typhoid fever. The body makes substances, called antibodies, which destroy the *Salmonella typhi* bacteria. If you have been vaccinated against *Salmonella typhi* your body is able to

When you or your child must not take VIVOTIF® Oral

Do not take VIVOTIF® Oral if you have an allergy to:

- VIVOTIF® Oral or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Do not take VIVOTIF® Oral if you have any of the following conditions:

- lowered immunity due to illness, including HIV/AIDS or cancer
- lowered immunity due to treatment with medicines, such as corticosteroids, cyclosporin or treatment for cancer (including radiation therapy)
- illness, with fever
- bowel infection.

Tell your doctor if you have reacted to any previous vaccination with an allergic reaction.

Allergic reactions may include:

- an itchy rash (also known as 'hives')
- swelling of lips, face or tongue
- difficulty breathing.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- leukaemia or any other cancers of the blood, bone marrow or lymph system.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of having VIVOTIF® Oral during pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having VIVOTIF® Oral during breastfeeding.

Taking other medicines

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

VIVOTIF® Oral and some medicines may interfere with each other. These include:

- antibiotics
- some antimalarials
- sulphonamides
- other medicines which are active against Salmonella bacteria.

These medicines may be affected by VIVOTIF® Oral, or may affect how well it works. These medicines should usually be taken after the third (final) dose of VIVOTIF® Oral. Your doctor, nurse or pharmacist will advise you about the correct timing and decide whether or not you should have this vaccine.

Having other vaccines

Tell your doctor if you have had any vaccines in the last 4 weeks.

Your doctor will advise you if VIVOTIF® Oral may be given at the same time as another vaccine.

Your doctor, nurse and pharmacist may have more information on medicines and vaccines to be careful with or avoid during vaccination with VIVOTIF® Oral.

How to take VIVOTIF® Oral

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor, nurse or pharmacist will tell you how many capsules to take and when to take them.

If you do not understand the instructions on the box, ask your

doctor, nurse or pharmacist for help.

How much to take

Take one capsule of VIVOTIF® Oral every second day, that is

Day 1 – One capsule

Day 3 – One capsule

Day 5 – One capsule

until all three capsules have been taken.

How to take it

Swallow each VIVOTIF® Oral capsule whole with a glass of cold or lukewarm water (max. 37°C), 1 hour before a meal.

Do not chew the capsules.

The capsules have a special coating to protect the contents from stomach acid. Chewing destroys this coating and then the capsules will not work.

When to take it

Take VIVOTIF® Oral on an empty stomach, 1 hour before food.

Food can interfere with the absorption of VIVOTIF® Oral.

If you forget to take it

If you forget to take a dose, tell your doctor.

Your doctor will decide whether you should keep taking your current pack of capsules or whether it would be better for you to start again with another pack.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you or your child do not feel well after having VIVOTIF® Oral.

VIVOTIF® Oral may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. You or your child may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- high temperature
- headache
- itchy rash
- eating and drinking less than usual, loss of appetite
- nausea or vomiting
- constipation
- diarrhoea
- stomach cramps or pain
- joint pain or aching muscles
- tiredness or weakness.

If there are side effects from taking VIVOTIF® Oral, these are the usual ones. Mostly they are mild and short-lived.

Allergic reaction:

As with all vaccines, there is a very small risk of a serious allergic reaction.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- skin rash, itchiness, or other severe skin reactions
- raised, itchy swellings on the skin, also called hives or nettlerash
- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing.

These are serious side effects. If you have them you may have had a serious allergic reaction to VIVOTIF® Oral. You may need urgent medical attention or hospitalisation. If they do occur, most of these side effects occur within the first few hours of vaccination.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you or your child feel unwell.

Do not be alarmed by this list of possible side effects.

You or your child may not experience any of them.

If you take too much (overdose)

If you think you or anyone else has taken too much VIVOTIF® Oral immediately telephone your doctor or the Poisons Information Centre (0800 764 766).

Ingredients

Active ingredients:

- At least 2000 million live *Salmonella typhi* Ty21a bacteria.

Inactive ingredients:

- ethylene glycol, sucrose, ascorbic acid, protein hydrolysate, lactose, magnesium stearate, hypromellose phthalate, gelatin (bovine derived), titanium dioxide, erythrosine CI45430, iron oxide yellow CI77492, iron oxide red CI77491, diethyl phthalate.

Storing VIVOTIF® Oral

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they do not store well.

Keep your pack of capsules in the refrigerator, between 2°C and 8°C. Do not freeze VIVOTIF® Oral.

Do not store VIVOTIF® Oral or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking VIVOTIF® Oral, the package is damaged or the capsules have passed their expiry date, return the medicine to your pharmacist for disposal.

The manufacture of this product includes exposure to bovine derived material. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Further information

This medicine is available only with a doctor's prescription.

Sponsor

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Manufacturer

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Date of preparation

22 February 2020

Product description

What VIVOTIF® Oral looks like

Each capsule is salmon pink and white in colour. There are three capsules in each blister pack.

VIVOTIF® is a registered trademark of Emergent Travel Health Inc., USA.