

Vivotif® Oral

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your healthcare provider.

1. Why am I using Vivotif® Oral?

Vivotif® Oral contains the active ingredient *Salmonella typhi* (live, attenuated). 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.

For more information, see Section [1. Why am I using Vivotif® Oral?](#) in the full CMI.

2. What should I know before I use Vivotif® Oral?

Do not use if you have ever had an allergic reaction to Vivotif® Oral or any of the ingredients listed at the end of the CMI.

Talk to your healthcare provider if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Vivotif® Oral?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Vivotif® Oral and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Vivotif® Oral?

- Take one capsule of Vivotif® Oral every other day until all 3 capsules have been taken.
- Swallow each Vivotif® Oral capsule whole with a glass of cold or lukewarm water (max. 37°C), one hour before a meal. Do not chew the capsules.

More instructions can be found in Section [4. How do I use Vivotif® Oral?](#) in the full CMI.

5. What should I know while using Vivotif® Oral?

Things you should do (More instructions can be found in sections below)	<ul style="list-style-type: none">• Remind any healthcare provider you visit that you are using Vivotif® Oral. Tell your healthcare provider 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.• After a full course most people will produce enough antibodies to prevent typhoid fever. However, as with all vaccines, 100% protection cannot be guaranteed. Continue to follow hygiene advice and take special care with food and water in areas where typhoid fever occurs.
Things you should not do (More instructions can be found in section below)	<ul style="list-style-type: none">• Do not take Vivotif® Oral if you have any of the following conditions:<ul style="list-style-type: none">– lowered immunity– illness, with fever– bowel infection.• Do not eat or drink for one hour after taking Vivotif® Oral. It will affect how the vaccine works
Looking after your medicine	<ul style="list-style-type: none">• Keep your pack of capsules in the refrigerator, between 2°C and 8°C. Do not freeze Vivotif® Oral.

For more information, see Section [5. What should I know while using Vivotif® Oral?](#) in the full CMI.

6. Are there any side effects?

Vivotif® Oral may have unwanted side effects in **some** 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. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Vivotif[®] Oral

Active ingredient(s): *Salmonella typhi* (live, attenuated)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Vivotif[®] Oral. **You should also speak to your healthcare provider if you would like further information or if you have any concerns or questions about using Vivotif[®] Oral.**

Where to find information in this leaflet:

- [1. Why am I using Vivotif[®] Oral?](#)
- [2. What should I know before I use Vivotif[®] Oral?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Vivotif[®] Oral?](#)
- [5. What should I know while using Vivotif[®] Oral?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Vivotif[®] Oral?

Vivotif[®] Oral is an Oral Typhoid Vaccine. It contains live bacteria called *Salmonella typhi*, 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 attack the bacteria if you come in contact with it.

Protection with Vivotif[®] Oral requires a full course of 3 doses.

Vivotif[®] Oral is used to prevent typhoid fever.

2. What should I know before I use Vivotif[®] Oral?

Warnings

Do not use Vivotif[®] Oral if:

- You are allergic to Vivotif[®] Oral, or any of the ingredients listed at the end of this leaflet.
- 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.

Always check the ingredients to make sure you can use this medicine.

Check with your healthcare provider if you:

- have any other medical conditions
- take any medicines for any other condition

During the vaccination course, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your healthcare provider if you are pregnant or intend to become pregnant.

Talk to your healthcare provider if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your healthcare provider or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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 3rd (final) dose of Vivotif[®] Oral. Your healthcare provider will advise you about the correct timing and decide whether or not you should have this vaccine.

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

Your healthcare provider will advise you if Vivotif[®] Oral may be given at the same time as another vaccine.

Check with your healthcare provider if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Vivotif[®] Oral.

4. How do I use Vivotif® Oral?

How much to take / use

- Take one capsule of Vivotif® Oral every second day, until all 3 capsules have been taken, that is:
Day 1 – 1 capsule
Day 3 – 1 capsule
Day 5 – 1 capsule

Follow the instructions provided or until your healthcare provider tells you to stop.

When to take / use Vivotif® Oral

Take Vivotif® Oral on an empty stomach, one hour before food. Food can interfere with the absorption of Vivotif® Oral. Swallow each Vivotif® Oral capsule whole with a glass of cold or lukewarm water (max. 37°C). 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.

If you forget to use Vivotif® Oral

If you forget to take a dose, tell your healthcare provider.

Your healthcare provider 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.

If you use too much Vivotif® Oral

If you think that you have used too much Vivotif® Oral, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**) for Australia, or **National Poisons Centre** (by calling **0800 POISON** or 0800 764 766) for New Zealand or
- contact your healthcare provider, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Vivotif® Oral?

Things you should do

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 nettle rash
- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing.

Tell your healthcare provider 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.

Remind any doctor, dentist or pharmacist you visit that you are using Vivotif® Oral

As with all vaccines, 100% protection cannot be guaranteed. Continue to follow hygiene advice and take special care with food and water in areas where typhoid-fever occurs.

Things you should not do

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.

Do not give Vivotif Oral to a child under 6 years. The safety and effectiveness of Vivotif Oral in children under 6 years has not been established.

Vivotif® Oral with food and drink

Do not eat or drink for one hour after taking Vivotif® Oral. It will affect how the vaccine works

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

There is insufficient information to know if alcohol affects the effectiveness of Vivotif® Oral.

Looking after your medicine

- Keep your capsules in the pack until it is time to take them.
- Keep your pack of capsules in the refrigerator, between 2°C and 8°C. Do not freeze Vivotif® Oral.

Follow the instructions in the carton on how to take care of your medicine properly.

Store Vivotif® Oral in **its** packaging in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or

- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your healthcare provider or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Constipation Stomach cramps or pain Diarrhoea, Nausea, Vomiting Eating and drinking less than usual Loss of appetite, High temperature, headache and itchy rash Joint pain or aching muscles Tiredness or weakness.	Speak to your healthcare provider if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
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.	Call your healthcare provider straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your healthcare provider if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your healthcare provider before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a healthcare provider's prescription.

What Vivotif® Oral contains

Active ingredient (main ingredient)	At least 2000 million live <i>Salmonella typhi</i> .
Other ingredients (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.

Do not take this medicine if you are allergic to any of these ingredients.

What Vivotif® Oral looks like

Vivotif® Oral is salmon-pink and white in colour. There are 3 capsules in each blister pack. (Aust R 322340).

Who distributes Vivotif® Oral

Australia:

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This leaflet was prepared in December 2024.

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