

## 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 doctor or pharmacist.

### 1. Why am I using Typhim Vi?

Typhim Vi contains the active ingredient salmonella typhi Vi polysaccharide (Ty2 strain). Typhim Vi is a vaccine used to help prevent typhoid fever, which is caused by a bacterium called Salmonella typhi. Typhim Vi may be given to people aged 2 years and older.

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

### 2. What should I know before I use Typhim Vi?

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

**Talk to your doctor 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 Typhim Vi?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Typhim Vi 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 Typhim Vi?

Typhim Vi is given as an injection, usually into the muscle of your upper arm or thigh, by a doctor or nurse.

Typhim Vi should be given at least 14 days before any risk of coming into contact with typhoid bacteria.

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

### 5. What should I know while using Typhim Vi?

|                                    |   |
|------------------------------------|---|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>Keep an updated record of your vaccinations.</li><li>Report any side effects to your doctor</li></ul>   |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"><li>Do not have Typhim Vi if you have or have had recently illness, with fever.</li><li>Do not use if your child is under 2 years of age.</li></ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>Typhim Vi is usually stored in the doctor's surgery or clinic. However, if you need to store Typhim Vi keep it in its original packaging in the refrigerator, between 2°C and 8°C. Do not freeze Typhim Vi.</li></ul> |

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

### 6. Are there any side effects?

The most common side effects of Typhim Vi are local reaction around the injection site, headaches, tiredness, weakness or fatigue, feeling unwell, decreased activity, raised temperature, aching muscles, muscle tenderness or weakness, not caused by exercise, nausea, vomiting, diarrhoea, stomach pains, joint pain, asthma, fainting, and skin reactions such as rash, itching and itchy rash.

Serious side effects can include sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing. It can also include allergic reactions, symptoms for which include fever, swelling, skin rash, enlargement of the lymph nodes. If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

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.

# Typhim Vi™

Active ingredient: *Salmonella typhi* Vi polysaccharide

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Typhim Vi. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Typhim Vi.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Typhim Vi?

**Typhim Vi contains the active ingredient *Salmonella typhi* Vi Polysaccharide (Ty2 strain).** Typhim Vi is a vaccine used to help prevent typhoid fever, which is caused by a bacterium called *Salmonella typhi*.

The organism which causes typhoid fever can be passed on through contaminated food or water. If you are in an area where there is a risk of getting typhoid fever, in addition to having Typhim Vi, it is also very important to be careful with your personal, food and water hygiene. Hygiene will also help avoid illness caused by other bacteria in the water.

Typhim Vi may be given to people aged 2 years and older.

Typhim Vi works by causing your body to produce its own protection against typhoid fever. It does this by making substances, called antibodies, which destroy the *Salmonella typhi* organism. If you have been vaccinated against *Salmonella typhi*, your body is able to attack that organism if you come in contact with it.

Your body usually takes several weeks after vaccination to fully develop this protection against typhoid fever.

You must have one dose at least 2 weeks before you may be exposed to typhoid fever.

If you are continually or repeatedly exposed to the *Salmonella typhi* organism, it is recommended that you have an injection of Typhim Vi every 3 years.

Most people will make enough antibodies against *Salmonella typhi*. 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 Typhim Vi is very small, but the risks from not being vaccinated against typhoid fever may be very serious.

**If you want more information on personal care in areas where there is a risk of getting typhoid fever, talk to your doctor, nurse or pharmacist.**

## 2. What should I know before I use Typhim Vi?

### Warnings

#### Do not use Typhim Vi if:

- you are allergic to Typhim Vi, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have, or recently have had, an illness, with fever.
- your child is under 2 years of age. Typhim Vi vaccine is a polysaccharide vaccine: just as with other polysaccharide vaccines, children under 2 years are too young to make sufficient antibodies to this type of vaccine

#### Check with your doctor if you:

- have any other medical conditions such as
  - lowered immunity due to illness. Examples are some blood disorders, HIV/AIDS or cancer
  - lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy) as you may not make the expected amount of antibody
  - a low platelet count or are prone to easy bruising or bleeding
- take any medicines for any other condition
- have reacted to any previous vaccination with an allergic reaction.

During treatment, 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 doctor if you are pregnant or intend to become pregnant.**

Your doctor will discuss the possible risks and benefits of having Typhim Vi during pregnancy.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

It is not known if Typhim Vi passes into breast milk. Your doctor will discuss the possible risks and benefits of having Typhim Vi during breast-feeding.

### Children under 2 years of age

Typhim Vi is not recommended for use in children under 2 years of age. Typhim Vi vaccine is a polysaccharide vaccine: just as with other polysaccharide vaccines,

children under 2 years are too young to make sufficient antibodies to this type of vaccine.

**If you are not sure whether you or your child should have Typhim Vi, talk to your doctor or pharmacist.**

### 3. What if I am taking other medicines?

Tell your doctor 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.

**Some medicines may interfere with Typhim Vi and affect how it works.**

Your doctor or pharmacist will advise you and decide whether or not to give the vaccine.

**Having other vaccines.**

Your doctor will advise you if Typhim Vi is to be given at the same time as another vaccine. Your doctor and pharmacist may have more information on medicines and vaccines to be careful with, or avoid, during vaccination with Typhim Vi.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Typhim Vi.**

### 4. How do I use Typhim Vi?

**How much to use**

- The dose is the same for adults and children, 0.5 mL of vaccine.
- Typhim Vi is given as an injection, usually into your upper arm muscle, by a doctor or nurse. For children, the muscle of the upper thigh may be preferred.
- Typhim Vi should not be injected directly into a vein, or any blood vessel.

**When to use Typhim Vi**

- Typhim Vi should be given at least 14 days before any risk of coming into contact with typhoid bacteria.
- If you live in an area where you are at risk of getting typhoid fever, it is recommended that you have an injection of Typhim Vi every 3 years.

**If you use too much Typhim Vi**

Overdose is unlikely as your doctor is giving you the injection.

- **If you have any concerns, ask your doctor.**

### 5. What should I know while using Typhim Vi?

**Things you should do**

- If you want more information on personal care in areas where there is a risk of getting typhoid fever, talk to your doctor, nurse or pharmacist.
- Keep an updated record of your vaccinations.
- Report any side effects to your doctor

**Call your doctor straight away if you:**

- Do not feel well after having Typhim Vi.

Remind any doctor, dentist or pharmacist you visit that you have had Typhim Vi.

**Looking after your medicine**

Typhim Vi is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Typhim Vi:

- Keep Typhim Vi in the original pack until it is time for it to be given.
- Keep it in the refrigerator, between +2°C and +8°C
- **Do not freeze Typhim Vi.** Freezing destroys the vaccine.

**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 doctor or pharmacist if you have any further questions about side effects.

Typhim Vi may have unwanted side effects in a few people. Usually they occur at the site of the injection, in the first 48 hours.

**Less serious side effects**

| Less serious side effects   | What to do  |
|---|---|
| <p><b>At the injection site:</b></p> <ul style="list-style-type: none"><li>• pain or discomfort</li><li>• tenderness</li><li>• redness</li><li>• hard lump</li></ul> <p><b>Systemic side effects:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• tiredness, weakness or fatigue</li><li>• generally feeling unwell</li><li>• decreased activity</li><li>• raised temperature</li><li>• aching muscles, muscle tenderness or weakness, not caused by exercise</li><li>• nausea</li><li>• vomiting</li><li>• diarrhoea</li><li>• stomach pains</li><li>• joint pain</li><li>• asthma</li><li>• fainting</li></ul> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |

| Less serious side effects  | What to do |
|--|------------|
| <ul style="list-style-type: none"> <li>• skin reactions such as rash, itching or itchy rash</li> </ul> |            |

### Serious side effects

| Serious side effects  | What to do   |
|---|--|
| <ul style="list-style-type: none"> <li>• Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing</li> <li>• Allergic reactions, symptoms for which include fever, swelling, skin rash, enlargement of the lymph nodes</li> </ul> | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

**Tell your doctor or pharmacist 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](http://www.tga.gov.au/reporting-problems) in Australia or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Typhim Vi contains

|   |  |
|---|--|
| <b>Active ingredient (main ingredient)</b>      | Salmonella typhi Vi<br>Polysaccharide (Ty2 strain)   |
| <b>Other ingredients (inactive ingredients)</b> | phenol<br>sodium chloride<br>dibasic sodium phosphate dihydrate<br>monobasic sodium phosphate dihydrate<br>water for injection<br>formaldehyde (trace)<br>casein (trace) |

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

The manufacture of this product includes exposure to bovine materials. 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.

Typhim Vi does not contain lactose, sucrose, gluten, tartrazine or other azo or non-azo type of dyes.

### What Typhim Vi looks like

Each dose of Typhim Vi consists of one syringe pre-filled with 0.5 mL of clear colourless liquid (Aust R 45073).

### Who distributes Typhim Vi

Distributed in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

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