

# TYPHIM Vi™

Purified polysaccharide capsule of *Salmonella typhi* (Ty 2 strain)

## Consumer Medicine Information

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### What is in the leaflet

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This leaflet answers some common questions about TYPHIM Vi™.

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 TYPHIM Vi™ against the benefits they expect it will have.

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

**Keep this leaflet.**

You may need to read it again.

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### What TYPHIM Vi™ is used for

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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.

**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.**

### ***How TYPHIM Vi™ works***

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, a booster dose is recommended every 2 to 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.

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## **Before you are given TYPHIM Vi™**

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### ***When you or your child must not be given it***

**Do not have TYPHIM Vi™ if you have an allergy to:**

- TYPHIM Vi™ or any of the ingredients listed at the end of this leaflet.

Do not have TYPHIM Vi™ if you have, or recently have had, an:

- illness, with fever.

**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.

**Do not have TYPHIM Vi™ after the expiry date printed on the pack.**

**Do not have TYPHIM Vi™ if the packaging is torn or shows signs of tampering.**

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

### ***Before you or your child is given TYPHIM Vi™***

**Tell your doctor if you or your child have reacted to any previous vaccination with any of the following:**

- an allergic reaction. Allergic reactions may include an itchy rash (also known as 'hives'), swelling of lips, face or tongue which may cause difficulty breathing.

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

- 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
- if you have a low platelet count or are prone to easy bruising or bleeding. If this is the case, after the injection, firm pressure will need to be applied to the injection site for at least 2 minutes.

**Tell 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.

**Tell your doctor if you are breast-feeding.**

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.

### ***Taking other medicines***

**Tell your doctor 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.**

Some medicines and TYPHIM Vi™ may interfere with each other.

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™.

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## **How TYPHIM Vi™ is given**

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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.

### ***How much is given***

An entire single 0.5 mL dose is given for the first vaccination. The dose is the same for adults and children. The prefilled syringe is for use once only. The booster dose is also 0.5 mL, for adults and children.

### ***Overdose***

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

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

### ***When TYPHIM Vi™ is given***

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 2 to 3 years.

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## **Side effects**

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All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

**Tell your doctor or pharmacist as soon as possible if you or your child does not feel well after having TYPHIM Vi™.**

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.

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

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

- reaction around the injection site such as, pain or discomfort, tenderness, redness, burning or stinging, firm swelling or hard lump
- headache
- tiredness, weakness or fatigue
- generally feeling unwell, inactive
- raised temperature

- soreness, aching muscles, back pain, muscle tenderness or weakness (not caused by exercise)
- nausea or vomiting
- diarrhoea
- stomach pains
- asthma.

These are common side effects of TYPHIM Vi™. Mostly these are mild and do not last long.

**Tell your doctor immediately if you notice any of the following:**

- skin rash, itchy spots or red lumps on the skin
- painful joints
- itchiness in the first 48 hours.

These may be serious side effects. You or your child may need urgent medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- 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.

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are rare.

**Other side effects not listed above may occur in some patients. Tell your doctor 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.

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## **Storing TYPHIM Vi™**

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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 it where children cannot reach it.**
- **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.

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## Product description

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### ***What TYPHIM Vi™ looks like***

Each dose of TYPHIM Vi™ consists of one syringe pre-filled with 0.5 mL of clear colourless liquid.

### ***Ingredients***

Each dose contains:

#### **Active ingredients:**

- 25 micrograms of part of the outer coat of the bacterium, *Salmonella typhi* (Ty2 strain).

#### **Other ingredients:**

Very small amounts of:

- phenol
- sodium chloride
- sodium phosphate dibasic dihydrate
- sodium phosphate monobasic.

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

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.

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## Further information

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TYPHIM Vi™ is available only with a doctor's prescription.

**Ask your doctor if you are unsure about anything or want more information about TYPHIM Vi™.**

### ***Manufacturer***

**Sanofi Pasteur SA**

Lyon, France

### ***Distributor***

Australia:

**Sanofi Pasteur Pty Ltd**

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