

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TYPHIM Vi®

Salmonella typhi Vi Capsular Polysaccharide Vaccine

Read this carefully before you or your child receive TYPHIM Vi®. This leaflet is a summary and will not tell you everything about TYPHIM Vi®. Talk to your doctor, nurse or pharmacist if you have any questions about this vaccine.

What is TYPHIM Vi® used for?

Typhoid fever is an infectious disease spread through food and drink contaminated with the bacteria (*Salmonella typhi*) that causes the illness. It is a serious illness that may be fatal, particularly if not treated promptly.

TYPHIM Vi® is a vaccine used to prevent typhoid fever. This vaccine may be given to persons 2 years of age and older.

How does TYPHIM Vi® work?

TYPHIM Vi® causes the body to produce its own natural protection against typhoid fever. After you receive the vaccine, your body begins to make substances called antibodies. Antibodies help the body to fight disease. If a vaccinated person comes into contact with the germ that causes this disease, the body is usually ready to destroy it.

It is important that travelers to areas where a recognized risk of exposure to typhoid exists, get immunized at least two weeks prior to expected exposure to *S. typhi*.

However, as with all vaccines, 100% protection cannot be guaranteed.

The body does not develop long-term protection against typhoid fever. Hence repeat vaccination 2-3 years after previous vaccination is recommended for individuals at continued risk of exposure to typhoid fever causing bacteria.

What are the ingredients in TYPHIM Vi®?

Medicinal ingredient: purified component from the bacteria *Salmonella typhi*.

Non-medicinal ingredients: isotonic buffer solution and phenol.

TYPHIM Vi® comes in the following dosage forms:

TYPHIM Vi® is a liquid vaccine that is injected into a muscle. A single dose is 0.5 mL.

Do not use TYPHIM Vi® if:

TYPHIM Vi® should not be used by persons who are known to have a severe allergy to any ingredient in the vaccine or its container, or who have had a severe allergic reaction after receiving a vaccine that contained similar ingredients.

To help avoid side effects and ensure proper use, talk to your doctor or nurse BEFORE you or your child receives TYPHIM Vi®. Talk about any health conditions or problems you or your child may have, including if you or your child:

- **Have a high fever or serious illness.** Delay the vaccination until the person is better.
- **Have an allergy to any component of the vaccine or the container,** including formaldehyde and casein, which are used during vaccine manufacturing and may be present in the vaccine in trace amounts.
- **Have a weakened immune system.** The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems. If possible, try to postpone the vaccination until after you have completed the treatment that affects your immune system.
- **Have a bleeding disorder or taking blood thinning medications.** Tell the person giving you the injection about your condition. The injection must be done carefully to prevent excessive bleeding.
- **Are pregnant or breast-feeding.** It is important that you understand the risks and benefits of vaccination. Tell the person giving you the injection if you are pregnant or breast-feeding. The health care professional will recommend whether or not you should receive TYPHIM Vi®.
- **Have fainted with a previous injection.** Fainting can occur following vaccination. Appropriate measures should be taken to prevent falling injury.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

DO NOT mix TYPHIM Vi® with other vaccines or medicinal products in the same syringe. However, TYPHIM Vi® may be given with other vaccines such as for meningitis, hepatitis A, and yellow fever during the same visit as long as injected into separate sites.

How to take TYPHIM Vi®:

Usual Dose:

A single dose of 0.5 mL is recommended for immunization of persons 2 years of age and older.

The vaccine should be given in the muscle, preferably in the deltoid (shoulder) region.

Overdose:

If you think you, or a person you are caring for, have taken too much TYPHIM Vi®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable to this vaccine.

What are the possible side effects from using TYPHIM Vi®?

These are not all the possible side effects you may feel when taking TYPHIM Vi®. If you experience any side effect not listed here, contact your healthcare professional.

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of TYPHIM Vi® causing serious harm is extremely small. The small risks associated with TYPHIM Vi® are much less than the risks associated with getting the disease.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after receiving TYPHIM Vi®.

Serious side effects are rare.

Some people who receive TYPHIM Vi® may have mild side effects such as pain or tenderness at the injection site, associated with redness and swelling. Other possible side effects commonly reported may include fever, headache, general feeling of weakness and discomfort, and muscle pain. These side effects usually go away within a few days.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Sanofi cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store the vaccine in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze.** Throw the product away if it has been exposed to freezing.

Protect from light.

Do not use after the expiration date.

Keep out of reach and sight of children.

If you want more information about TYPHIM Vi®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database>); the Sanofi Canada website (www.sanofi.ca) or by calling the vaccine producer, Sanofi at 1-888-621-1146 (no charge)

This leaflet was prepared by Sanofi Vaccines Canada Ltd.

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