PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

TYPHIM Vi®

Salmonella typhi Vi Capsular Polysaccharide Vaccine

Solution for Muscular Injection

A single dose of 0.5 mL contains 25 mcg of Purified Vi capsular polysaccharide of *Salmonella typhi* (Ty2 strain)

Active Immunizing Agent for the Prevention of Typhoid Fever

ATC: Code J07AP03

Sanofi Pasteur Limited

Toronto, ON Canada

www.sanofi.ca

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RECENT MAJOR LABEL CHANGES

4 Dosage and Administration	04/2023

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

TYPHIM Vi® is indicated for active immunization against *S. typhi*, the organism which causes typhoid fever.

TYPHIM Vi® is recommended for active immunization in persons 2 years of age and older, in the following situations:

1. Travellers to endemic or epidemic areas or where sanitary conditions may be doubtful and where travellers may be exposed to potentially contaminated food and water, particularly when prolonged exposure is anticipated.
2. Travellers with reduced or absent gastric acid secretion.
3. People with ongoing household or intimate exposure to an *S. typhi* carrier.
4. Laboratory workers who frequently handle cultures of *S. typhi*.

1.1 Pediatrics

Pediatrics (≥2 years of age): TYPHIM Vi® is recommended for active immunization in persons 2 years of age and older.

Pediatrics (0 - <2 years of age):

No data are available to Health Canada; therefore, TYPHIM Vi® has not been authorized for use in children below 2 years of age.

2 CONTRAINDICATIONS

Hypersensitivity

Known systemic hypersensitivity reaction to any component of TYPHIM Vi®, or its container, or a life-threatening reaction after previous administration of the vaccine or a vaccine containing one or more of the same components are contraindications to vaccination (See DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING).

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

See WARNINGS AND PRECAUTIONS for administration route-related precautions.

4.2 Recommended Dose and Dosage Adjustment

The recommended dose for adults and children is a single injection of 0.5 mL given intramuscularly.

Revaccination is recommended every three years under conditions of repeated or continuous exposure to *S. typhi*.

4.4 Administration

For intramuscular use only. Do not inject intravascularly.

The preferred site of injection is the deltoid muscle or the anterolateral aspect of the mid thigh (vastus lateralis muscle). The vaccine should not be injected in the gluteal area or areas where there may be a major nerve trunk and/or blood vessel.

Instructions for use:

Inspect for extraneous particulate matter and/or discolouration before use. If these conditions exist, the product should not be administered. (See DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING).

Shake the pre-filled syringe well to uniformly distribute the solution before use.

Remove the tip cap from the syringe and attach the provided sterile needle to ensure that the vaccine will be delivered intramuscularly.

Needles should not be recapped and should be disposed of according to biohazard waste guidelines.

5 OVERDOSAGE

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

Table 1: Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	Each 0.5 mL dose is formulated to contain: **Active Ingredient:** *Salmonella typhi* (TY2 strain) purified Vi capsular polysaccharide: 25 mcg	Isotonic buffer solution, phenol (as preservative)

Description

TYPHIM Vi® is supplied as a sterile, clear, colourless solution ready for intramuscular injection.

Component	Quantity (per 0.5 mL dose)
Salmonella typhi (TY2 strain) purified Vi capsular polysaccharide	25 mcg
Phenol (as preservative)	1.100 mg
Isotonic buffer solution	Up to 0.5 mL

Packaging

Prefilled syringe 1 x 0.5 mL with one needle
(1 x 25G x 25 mm)

The plunger stopper of the syringe for this product does not contain dry natural latex rubber.

7 WARNINGS AND PRECAUTIONS

General

Before administration of TYPHIM Vi®, health-care providers should inform the recipient or their parent or guardian of the benefits and risks of immunization, inquire about the recent health status of the recipient, review the recipient's history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindication to immunization and comply with any local requirements regarding information to be provided to the recipient, parent or guardian before immunization.

It is extremely important that the recipient, parent or guardian be questioned concerning any symptoms and/or signs of an adverse reaction after a previous dose of vaccine containing similar components. (See CONTRAINDICATIONS and ADVERSE REACTIONS.)

Syncope (fainting) has been reported following vaccination with TYPHIM Vi®. Procedures should be in place to prevent falling injury and manage syncopal reactions.

Febrile or Acute Disease

Vaccination must be postponed in case of febrile or acute disease. However, a disease with a low-grade fever should not usually be a reason to postpone vaccination.

Hematologic

As with all injectable vaccines, TYPHIM Vi® must be administered with caution to persons suffering from coagulation disorders or on anticoagulant therapy to avoid the risk of hematoma formation following an intramuscular administration.

Immune

The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated. Epinephrine Hydrochloride Solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.

As each dose may contain traces of formaldehyde and casein, which are used during vaccine production, caution should be exercised when the vaccine is administered to subjects with hypersensitivity to these substances.

Immunocompromised persons (whether from disease or treatment) may not obtain the expected immune response. If possible, consideration should be given to delaying vaccination until after the completion of any immunosuppressive treatment. Nevertheless, vaccination of persons with chronic immunodeficiency such as HIV infection is recommended even if the antibody response might be limited.

No data are available on the response to TYPHIM Vi® in chronic *S. typhi* carriers.

Protection

As with any vaccine, immunization with TYPHIM Vi® may not protect 100% of susceptible individuals.

This vaccine will not provide protection against species of *Salmonella* other than *S. typhi* or against other bacteria that cause enteric disease.

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.*

7.1 Special Populations

7.1.1 Pregnant Women

Animal reproduction studies have not been conducted with TYPHIM Vi®.

Data on the use of this vaccine in pregnant woman are limited. Therefore, the administration of the vaccine during pregnancy is not recommended. TYPHIM Vi® should be given to pregnant women only if clearly needed and following an assessment of the risks and benefits.

7.1.2 Breast-feeding

It is not known whether this vaccine is excreted in human milk. Caution must be exercised when TYPHIM Vi® is administered to a breast-feeding mother.

7.1.3 Pediatrics (≥ 2 years of age)

TYPHIM Vi® is not approved for use in children below 2 years of age.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Adverse event information is derived from clinical trials and worldwide post-marketing experience

In clinical studies, children (aged ≥ 2 years) and adults received TYPHIM Vi® either in a single injection or as a second injection.

The most frequently reported adverse reaction in all age groups after administration of TYPHIM Vi® was injection site pain. In adults 18 years of age and older, myalgia and fatigue were the most frequently reported systemic reactions. In children and adolescents (from 2 through 17 years of age), myalgia and headache were the most frequently reported systemic reactions.

The adverse reactions observed during clinical trials were generally of mild to moderate intensity and appeared within 3 days after vaccination. Most reactions resolved spontaneously within 1 to 3 days after onset.

8.2 Clinical Trial Adverse Reactions

Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice. The adverse reaction information from clinical trials does however, provide a basis for identifying the adverse events that appear to be related to vaccine use and for approximating rates of those events.

A pooled analysis has been performed on 6 studies sharing the same safety standard integrating data from 1,532 subjects (97 children and adolescents from 2 through 17 years of age and 1,435 adults).

Table 2 summarizes the frequencies of subjects experiencing at least one solicited adverse reaction that was recorded within 7 days following vaccination in 1,435 adults and 97 children and adolescents from 2 through 17 years of age.

Table 2: Solicited Adverse Reactions within 7 Days after Vaccination with TYPHIM Vi®

	Children and Adolescents 2 – 17 years (N=97)	**Adults** ≥ 18 years (N=1,435)
Adverse Reactions	**%† - Frequency**	**%† - Frequency**
General disorders and administration site conditions		
Injection site pain	52.6%	75.6%
Injection site erythema	14.4%	7.7%
Injection site swelling/oedema/induration	16.5%	6.0%
Malaise	6.3%	13.3%
Fever	1.0%	0%
Fatigue/asthenia	4.8%	25.0%
Nervous system disorders		
Headache	13.5%	7.8%
Musculoskeletal and connective tissue disorders		
Myalgia	14.6%	47.1%

N: Number of subjects analyzed according to safety analysis set.

†: For each reaction, the frequency has been defined by the number of subjects experiencing the reaction divided by the number of subjects with available data.

Injection site pruritus was an unsolicited adverse reaction recorded 28 days following vaccination with TYPHIM Vi®. The frequency of adult ≥ 18 years (N=1435) subjects experiencing this adverse reaction was observed to be 0.1%.

The percentage of adverse reactions reported from 2 other controlled clinical trials is presented in Table 3 and Table 4.

A controlled clinical trial was conducted in Indonesia in 268 children 1 to 12 years of age.

Table 3: Percentage of children 1 to 12 years presenting with injection site or systemic reactions after immunization with TYPHIM Vi®

	CHILDREN (AGE IN MONTHS)		
	12 - 24 **(n = 21)**	**24 - 60** **(n = 66)**	**60 - 144** **(n = 88)**
Injection Site Reactions (%)			
Soreness at the injection site	4.8	4.6	21
Pain at the injection site	9.6	9.1	19

Erythema at the injection site	0	4.6	10.2
Induration	4.8	3	2.3
Systemic Reactions (%)			
Fever	0	3	3.4
Headache	0	0	0
Decreased Activity	0	4.6	0
Rash	0	0	0

Two clinical trials were conducted in Houston, Texas on 154 adults 18-40 years old. No severe or unusual side effects were observed.

Table 4: Percentage of 18 to 40-year-old adults presenting with injection site or systemic reactions within the first 24 to 48 hours after immunization with TYPHIM Vi®

REACTION	TYPHIM Vi® Trial 1 (n = 54)	TYPHIM Vi® Trial 2 (n = 98)
Injection Site Reactions (%)		
Injection site tenderness	98	96.9
Injection site pain	40.7	26.5
Induration	14.8	5.1
Erythema at injection site	3.7	5.1
Systemic Reactions (%)		
Malaise	24	8.3
Fever	2	3.1
Headache	20.3	16.3
Myalgia	7.4	3.1

Table 4: Percentage of 18 to 40-year-old adults presenting with injection site or systemic reactions within the first 24 to 48 hours after immunization with TYPHIM Vi® (continued)

REACTION	TYPHIM Vi® Trial 1 (n = 54)	TYPHIM Vi® Trial 2 (n = 98)
Nausea	1.9	8.1
Vomiting	1.9	0

Diarrhea	0	3.0

Adults who received a booster dose of TYPHIM Vi® 27 to 34 months following the initial dose were more likely to develop erythema and/or induration (10/55) than those given a first dose (13/182), but the rate of systemic reactions was not increased.

8.5 Post-Market Adverse Reactions

The following additional adverse events have been reported during the marketing use of TYPHIM Vi®. Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

- **Gastrointestinal Disorders**
  Nausea, vomiting, diarrhea, abdominal pain
- **General Disorders and Administration Site Conditions**

  Injection site inflammation, lymphadenopathy, flu-like episode
- **Immune System Disorders**
  Anaphylactic/anaphylactoid reactions, including shock, serum sickness
- **Musculoskeletal and Connective Tissue Disorders**
  Arthralgia, cervical pain
- **Respiratory, Thoracic and Mediastinal Disorders**
  Asthma
- **Nervous System Disorders**
  Headache, Vasovagal syncope with and without convulsions, loss of consciousness
- **Skin and Subcutaneous Tissue Disorders**
  Allergic type reactions such as pruritus, rash, urticaria

Health professionals should report any adverse occurrences temporally associated with the administration of the product in accordance with local requirements and to the Pharmacovigilance Department, Sanofi, Canada. 1-888-621-1146 (phone).

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

Immunosuppressive treatments may interfere with the development of the expected immune response. (See WARNINGS AND PRECAUTIONS). No interaction with other medication is currently known.

9.4 Drug-Drug Interactions

Concomitant Vaccine Administration

TYPHIM Vi® may be administered simultaneously with other vaccines commonly administered to international travellers, including vaccines which protect against meningococcus (groups A and C),

hepatitis A, and yellow fever. There is no known interaction between TYPHIM Vi® and other live or inactivated vaccines. As the vaccine is inactivated, concomitant administration of other vaccine(s) given at other injection sites is unlikely to interfere with immune responses. Vaccines administered simultaneously should be given at separate sites using separate syringes.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

This vaccine contains purified Vi capsular polysaccharide of *Salmonella typhi* (Ty2 strain). TYPHIM Vi® confers significant protection against typhoid fever based on the production of measurable antibodies, predominantly of the IgG class. Immunity appears within 2 to 3 weeks after injection and lasts around 3 years.

10.3 Pharmacokinetics

Duration of Effect

The duration of protective immunity resulting from TYPHIM Vi® vaccination depends on the endemic area. Antibody titres fall with time after vaccination and immunity is thought to last around 3 years.

11 STORAGE, STABILITY AND DISPOSAL

Store at 2° to 8°C (35° to 46°F). **Do not freeze**. Discard product if exposed to freezing.

Protect from light.

12 SPECIAL HANDLING INSTRUCTIONS

Do not use the vaccine after the expiration date.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: *Salmonella typhi* Vi Capsular Polysaccharide Vaccine

Product Characteristics

TYPHIM Vi® is a sterile, clear, colourless solution ready for intramuscular injection. The antigenic component is the cell surface Vi polysaccharide extracted from *Salmonella typhi* strain TY2. The organism is grown in a semi-synthetic medium. Casein-derived raw materials are used early in manufacturing during the fermentation process. The capsular polysaccharide is precipitated from the concentrated culture supernatant by the addition of hexadecyltrimethylammonium bromide and the product is purified by differential centrifugation and precipitation. Phenol, 1.100 mg per 0.5 mL dose, is added as a preservative. Each 0.5 mL dose of vaccine is formulated to contain 25 mcg of purified Vi capsular polysaccharide.

14 CLINICAL TRIALS

14.1 Trial Design and Study Demographics

Table 5: Summary of demographics and study design of the trials with TYPHIM Vi®

Study #	Trial Design	Dosage, Route of Administration and Duration	Study subjects receiving TYPHIM Vi®	Age Range
Nepal	double-blind, randomized, controlled trial	0.5 mL, I.M.	3457	5-44 years
South Africa	double-blind, randomized, controlled trial	0.5 mL, I.M.	5692	5-15 years
Houston 1	double-blind, randomized, controlled trial	0.5 mL, I.M.	54	20-40 years
Houston 2	double-blind, randomized trial (lot consistency study)	0.5 mL, I.M.	100	20-40 years
Indonesia	double-blind, randomized, controlled trial	0.5 mL, I.M.	268	1-12 years

14.2 Study Results

Efficacy

The protective efficacy against typhoid fever of a single intramuscular injection of 25 mcg of TYPHIM Vi® was assessed in clinical trials. A randomized, double-blind, controlled trial done in Nepal focused on a target population 5 - 44 years of age. There were 6,907 vaccinated subjects, of whom 6,438 were members of the target population; 3,457 received TYPHIM Vi® and 3,450 received the control vaccine. There were 165 children under 5 years of age and 304 adults over 44. The protective efficacy of TYPHIM Vi® is approximately 75% as shown in Table 6. The seroconversion rates (≥4-fold rise in serum antibodies), 76.9% in the 5 - 14 year age group, 79.1% in the 15 - 44 year age group and 62.5% in the over 45 - 55 year age group, were similar to the protective efficacy. This provides evidence that serum antibodies to the Vi antigen confer immunity to typhoid fever.

Table 6: Efficacy of TYPHIM Vi® against typhoid fever in Nepal

TYPHOID FEVER CASES	VACCINE		EFFICACY %
	TYPHIM Vi®	Control	
Culture Positive	9	32	72
Clinically Suspected	5	25	80
Combined	14	57	75

In a second double-blind, controlled efficacy trial conducted in South Africa 11,384 children ages 5 - 16 were immunized with TYPHIM Vi® or a control vaccine, while a total of 23,075 children were followed. A total of 239 cases of blood-culture proven *S. typhi* infection occurred during the 21 month follow-up period among the 23,075 children participating (5.9 cases per annum, per 1,000 children). There were 173 cases in the unvaccinated group (n = 11,691) (8.5 cases per annum, per 1,000 children), 47 cases in the children immunized with control vaccine (4.7 cases per annum, per 1,000 children) and 19 cases in children immunized with the TYPHIM Vi® vaccine (1.9 cases per annum, per 1,000 children). The incidence of typhoid in the TYPHIM Vi® immunized children was significantly lower than in the control vaccinated children ($p < 0.001$). Estimates of vaccine efficacy after 21 months ranged from 60% (comparison to control group, all cases from date of immunization) to 81% (comparison to untreated group, all cases 6 weeks post immunization). Serology in a random sample of 0.5% of vaccinees showed an increase in anti-Vi antibodies as measured by radioimmunoassay and enzyme-linked immunosorbent assay. Antibody levels remained significantly elevated at 6 and 12 months post vaccination. Follow-up for 3 years following immunization showed a Vi vaccine efficacy of 50% in the third year.

A double-blind, controlled safety and immunogenicity trial of TYPHIM Vi® involving 268 Indonesian children was designed to include younger children. The overall seroconversion rate was 98.7% one month after vaccination. The seroconversion rates for the different age groups were: 100% for 12 – 24 months, 98% for 24 – 60 months and 99% for children 60 – 144 months. Although antibody levels to Vi antigen are generally correlated with the protective levels, there are no specific data available to

substantiate the efficacy in children 2 to 5 years old. No data are available on revaccination doses in children.

In the developed world, most individuals have not had previous exposure to *S. typhi*. Immunogenicity trials performed in Houston, Texas in a racially mixed adult American population (n = 182) showed seroconversion rates and antibody levels equal to, or greater than, those seen in South Africa or Nepal. A four-fold rise in antibody level occurred by 1 week in 60%, by 2 weeks in 80%, and by one month in 93% of those immunized with TYPHIM Vi®. In a sub-group followed for nearly three years post-immunization (n = 39), protective levels of antibody were still evident in 64% of individuals at 11 months and in 38% at 27 months. A second dose of TYPHIM Vi® given at 27 – 34 months following initial immunization elicited antibody levels similar to those observed following the first dose.

French military experience suggests a high level of effectiveness when travelers from the developed world have been vaccinated with TYPHIM Vi®. Between 1991 – 1995, more than 1.3 million members of the French military were vaccinated with TYPHIM Vi®. Epidemiological surveillance was conducted through hospitalization and laboratory registries. Although 225,000 individuals travelled to endemic areas with an estimated exposure to *S. typhi* of 16 million person days, no cases of typhoid fever were reported.

A clinical trial involving 400 Belgian adults compared the tolerability and immunogenicity of a commercially available Vi polysaccharide vaccine to TYPHIM Vi®. TYPHIM Vi® produced a more immediate immune response with 86.4% of individuals who received TYPHIM Vi® seroconverting by day 7 compared to only 65.6 – 76.7% of those receiving the other vaccine.

Safety

Adverse reactions reported after vaccination with TYPHIM Vi® were usually mild and short lasting. They consisted mainly of injection site reactions (pain, edema, redness) and mild systemic reactions such as headache or malaise (See ADVERSE REACTIONS). Tolerance has been studied in more than 10,000 subjects both in countries of high and low endemicity.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

Literature based data in animals revealed no unexpected findings and no target organ toxicity.

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 Pasteur 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/aefi-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 Pasteur at 1-888-621-1146 (no charge)

This leaflet was prepared by Sanofi Pasteur Limited.

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