

PRODUCT MONOGRAPH

TYPHIM Vi®

***Salmonella typhi* Vi Capsular Polysaccharide Vaccine**

Solution for Injection

Active Immunizing Agent for the Prevention of Typhoid Fever

ATC: Code J07AP03

Sanofi Pasteur Limited

Toronto, Ontario, Canada

Control No.: 216332

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TYPHIM Vi®

Salmonella typhi Vi Capsular Polysaccharide Vaccine

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration

Intramuscular

Dosage Form/Strength

Solution for injection.

Each 0.5 mL dose is formulated to contain:

Active Ingredients

Salmonella typhi (TY2 strain) purified Vi capsular polysaccharide

Clinically Relevant Non-medicinal Ingredients

Phenol

For a complete listing see [DOSAGE FORMS, COMPOSITION AND PACKAGING](#).

DESCRIPTION

TYPHIM Vi® [*Salmonella typhi* Vi Capsular Polysaccharide Vaccine] is a sterile, clear, colourless solution ready for intramuscular injection. The Vi antigen contained in TYPHIM Vi® is extracted from the bacterial capsule of *S. typhi* strain TY2. TYPHIM Vi® complies with the World Health Organization's requirement for Vi polysaccharide typhoid vaccine. (1)

INDICATIONS AND CLINICAL USE

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*.

The complete, current recommendations by the National Advisory Committee on Immunization (NACI) can be accessed at www.canada.ca/en/public-health/services/canadian-immunization-guide.html

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. (2) (See [DOSAGE FORMS, COMPOSITION AND PACKAGING](#))

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.

Administration Route-Related Precautions

Do not administer TYPHIM Vi® by intravascular injection: ensure that the needle does not penetrate a blood vessel.

TYPHIM Vi® should not be administered into the buttocks.

Febrile or Acute Disease

Vaccination must be postponed in case of febrile or acute disease. (3) However, a disease with a low-grade fever should not usually be a reason to postpone vaccination.

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. (2) Immunity may be overwhelmed by a large inoculum of *S. typhi*. Vaccinees should be informed that immunization is only one preventative measure, and that care in the selection of food and water is of primary importance. (2)

If the vaccine is administered to persons travelling to countries where typhoid fever is endemic less than 2 weeks prior to departure, optimum antibody protection may not yet be reached.

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. NACI has published recommendations for the immunization of people with hemophilia and other bleeding disorders. (2)

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. Health-care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management. (2) (4) For instructions on recognition and treatment of anaphylactic reactions, see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

Immunocompromised persons (whether from disease or treatment) may not obtain the expected immune response. (2) If possible, consideration should be given to delaying vaccination until after the completion of any immunosuppressive treatment. (2) Nevertheless, vaccination of persons with chronic immunodeficiency such as HIV infection is recommended even if the antibody response might be limited. (3)

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

Special Populations

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.

Nursing Women

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

Pediatrics

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

ADVERSE REACTIONS

Clinical Trial Adverse Drug 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.

Children

A controlled clinical trial was conducted in Indonesia in 268 children 1 to 12 years of age. Table 1 summarizes the adverse reactions reported. No severe or unusual side effects were observed.

Table 1: Percentage of children 1 to 12 years presenting with injection site or systemic reactions after immunization with TYPHIM Vi® (5) (6)

	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

Adults

Clinical trials were conducted in Houston, Texas on 154 adults 18-40 years old. Table 2 summarizes the reported adverse reactions. No severe or unusual side effects were observed. (5) (7)

Table 2: 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® (7) (8)

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
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. (7) (8)

Data from Post-Market Experience

The following additional adverse events have been reported during the marketing use of TYPHIM Vi®. (5) 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 Condition**
Malaise, asthenia
- **Immune System Disorders**
Anaphylactic/anaphylactoid reaction, including shock, serum sickness
- **Musculoskeletal and Connective Tissue Disorders**
Arthralgia, myalgia
- **Respiratory, Thoracic and Mediastinal Disorders**
Asthma
- **Nervous System Disorders**
Headache, vasovagal syncope
- **Skin and Subcutaneous Tissue Disorders**
Allergic type reactions such as pruritus, rash, urticaria

Physicians, nurses and pharmacists 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, 2905 Place Louis-R-Renaud, Laval, QC, H7V 0A3, Canada. 1-888-621-1146 (phone).

DRUG INTERACTIONS

Vaccine-Drug Interactions

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

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) (9), hepatitis A (10), and yellow fever (10). 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.

DOSAGE AND ADMINISTRATION

Recommended Dose

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*.

Administration

Inspect for extraneous particulate matter and/or discoloration before use. If these conditions exist, the product should not be administered. (See [DOSAGE FORMS, 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 a sterile needle of appropriate length to ensure that the vaccine will be delivered intramuscularly.

If using the multi-dose vial, **shake the vial well** to uniformly distribute the solution. Do not remove either the stopper or the metal seal holding it in place. Cleanse the vial stopper with a suitable germicide. Aseptic technique must be used for withdrawal of each dose. Use a separate sterile needle and syringe, or a sterile disposable unit, for each individual recipient to prevent disease transmission.

Administer the dose **intramuscularly** (I.M.). The preferred site of injection is the deltoid muscle or the anterolateral aspect of the mid thigh (vastus lateralis muscle).

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

Give the patient a permanent personal immunization record. In addition, it is essential that the physician or nurse record the immunization history in the permanent medical record of each patient. This permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

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. (11) Immunity appears within 2 to 3 weeks after injection and lasts around 3 years. (5) (6)

Pharmacodynamics

In the two clinical efficacy trials performed in highly endemic areas, the level of protection conferred (versus typhoid fever) by a single dose of the vaccine has been observed as 77% in Nepal (5) (12) and 55% in South Africa (5) (13). In non-endemic countries, seroconversion is obtained in more than 90% of subjects after a single injection. (5) (7)

Duration of Effect

The duration of protective immunity resulting from TYPHIM Vi® vaccination is unknown. Antibody titres fall with time after vaccination and immunity is thought to last around 3 years. (5) (6)

STORAGE AND STABILITY

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

Protect from light.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage forms

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

Composition

Each dose (0.5 mL) contains:

Active Ingredient

Salmonella typhi (TY2 strain) purified Vi

capsular polysaccharide	25 µg
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Other Ingredients

Excipients

phenol (as preservative)	1.100 mg
isotonic buffer solution	up to 0.5 mL

Packaging

Prefilled syringe	1 x 0.5 mL with a choice of two needles (1 x 25G x 16 mm and 1 x 25G x 25 mm)
Vial	1 x 10 mL (20 Doses)

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

Vaccine Information Service: 1-888-621-1146 or 416-667-2779.

Full product monograph available on request or visit us at www.sanofipasteur.ca

Product information as of November 2018.

Fabricated by:

Sanofi Pasteur SA

Lyon, France

Manufactured and Distributed by:

Sanofi Pasteur Limited

Toronto, Ontario, Canada

R6-1118 Canada

PART II: SCIENTIFIC INFORMATION

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 µg of purified Vi capsular polysaccharide.

CLINICAL TRIALS

Table 3: 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 (12)	double-blind, randomized, controlled trial	0.5 mL, I.M.	3457	5-44 years
South Africa (13)	double-blind, randomized, controlled trial	0.5 mL, I.M.	5692	5-15 years
Houston 1 (7)	double-blind, randomized, controlled trial	0.5 mL, I.M.	54	20-40 years
Houston 2 (7)	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

Efficacy

The protective efficacy against typhoid fever of a single intramuscular injection of 25 µg 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 Vi and 3,450 received the control vaccine. There were 165 children under 5 years of age and 304 adults over 44. (12) The protective efficacy of TYPHIM Vi® is approximately 75% as shown in Table 4. (12) 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. (12)

Table 4: Efficacy of TYPHIM Vi® against typhoid fever in Nepal (12)

TYPHOID FEVER CASES	VACCINE		EFFICACY %
	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. (13) 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 Vi vaccine (1.9 cases per annum, per 1,000 children). The incidence of typhoid in the 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). (13) 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. (13) Follow-up for 3 years following immunization showed a Vi vaccine efficacy of 50% in the third year. (6)

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. (5) 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) (7) 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%, (7) by 2 weeks in 80%, (8) and by one month in 93% of those immunized with TYPHIM Vi®. (7) 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. (7) A second dose of Vi given at 27 – 34 months following initial immunization elicited antibody levels similar to those observed following the first dose. (7) (8)

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. (14)

A clinical trial involving 400 Belgian adults (15) 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. (15)

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.

ADDITIONAL RELEVANT INFORMATION

Salmonella typhi (*Salmonella enterica* serovar Typhi) is the etiological agent of typhoid fever, an acute, febrile enteric disease transmitted by contaminated water and food. The incidence of typhoid fever is very low in industrialized countries, with an average of 70 cases reported each year in Canada. (2) The greatest risk of typhoid infection for Canadians occurs while they are travelling in countries or regions of countries where sanitation is likely to be poor. (2)

The fatality rate for untreated typhoid fever is approximately 16% but can be reduced to 1% with effective antibiotic therapy. (2) Antibiotic resistance is increasing dramatically among *S. typhi* isolates complicating the treatment of this illness. (16) Surveillance of US typhoid fever cases between 1999-2006 revealed that 43% of clinical isolates were resistant to at least one antimicrobial agent, 13% were multi-drug resistant, and 38% were resistant to nalidixic acid, an indicator of emerging resistance to fluoroquinolones. (17) This compares to only 30% of clinical isolates showing resistance to at least one antimicrobial agent in the period between 1990-1994. (18) Of the US cases of typhoid fever, only 5% of patients reported receiving the typhoid vaccine

within 5 years. (17) A Canadian study of samples isolated from travellers returning from South Asia and their contacts showed that 22% of specimens were resistant to at least 4 antibiotics. (19)

Typhoid vaccination is not required for international travel, but it is recommended for travellers to areas where there is a recognized risk of exposure to *S. typhi*. *S. typhi* is prevalent in many countries of Africa and Asia, as well as Central and South America. Vaccination is particularly recommended for travellers who will have prolonged exposure (>4 weeks) to potentially contaminated food and water in smaller cities, villages, or rural areas in countries with a high incidence of disease. However, even travellers who have been vaccinated should use caution in selecting and handling food and water. (2)

Vaccine Information Service: 1-888-621-1146 or 416-667-2779.

Full product monograph available on request or visit us at www.sanofipasteur.ca.

Product information as of November 2018.

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Sanofi Pasteur SA

Lyon, France

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Toronto, Ontario, Canada

R6-1118 Canada

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IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

TYPHIM Vi®

***Salmonella typhi* Vi Capsular Polysaccharide
Vaccine**

This leaflet is part III of a three-part "Product Monograph" published when TYPHIM Vi® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TYPHIM Vi®. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS MEDICATION

What the medication is used for:

Typhoid fever is an infectious disease spread through food and drink contaminated with the bacteria (*Salmonella typhi*) that cause 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.

What it does:

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.

The majority of persons who are vaccinated with TYPHIM Vi® will produce enough antibodies to provide protection against typhoid fever by 2 weeks after the first vaccination. Individuals travelling to typhoid fever risk areas should receive the vaccine at least 2 weeks prior to departure in order to have an adequate protective response.

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.

When it should not be used:

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.

What the medicinal ingredient is:

Each 0.5 mL dose of TYPHIM Vi® contains a purified component from the bacteria *Salmonella typhi*.

What the important nonmedicinal ingredients are:

phenol

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

If you have any of the following conditions, talk to your doctor, nurse, or pharmacist BEFORE you receive TYPHIM Vi®:

- **A high fever or serious illness.** Wait until you are better to receive the vaccination
- **An allergy to any component of the vaccine or the container.**
- **A weakened immune system.** The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.
- **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.
- **Pregnant or breast-feeding women.** It is important that you understand the risks and benefits of vaccination. TYPHIM Vi® should be given to a pregnant or nursing woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.
- **Fainting with a previous injection.** Fainting can occur following vaccination. Appropriate measures should be taken to prevent falling injury.

INTERACTIONS WITH THIS VACCINE

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.

PROPER USE OF THIS VACCINE

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:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable to this vaccine.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

A vaccine, like any other medicine, may cause serious problems, such as severe allergic reactions. The risk of TYPHIM Vi® causing serious harm is extremely small. The small risk 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, muscle pain, nausea, vomiting, and diarrhea. These side effects usually go away within a few days.

This is not a complete list of side effects. For any unexpected effects while taking TYPHIM Vi®, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

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 of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected case reports on adverse events following immunization.

For Health Care Professionals: If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public:

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

By toll-free telephone: (1-866-844-0018)

By toll-free fax: (1-866-844-5931)

By email: caefi@phac-aspc.gc.ca

Web: <http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

By regular mail:

The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road
A/L 6502A
Ottawa, Ontario
K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health-care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.sanofipasteur.ca>.

You may also contact the vaccine producer, Sanofi Pasteur Limited, for more information.
Telephone: 1-888-621-1146 (no charge) or
416-667-2779 (Toronto area).

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