

## ANNEX I

### SUMMARY OF PRODUCT CHARACTERISTICS

#### 1. NAME OF THE MEDICINAL PRODUCT

**TYPHIM Vi, solution for injection in prefilled syringe.**

**Polysaccharide typhoid vaccine**

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.5 mL of vaccine contains:

Polysaccharides of *Salmonella typhi* (Ty2 strain).....25 micrograms

For the full list of excipients, see section 6.1.

Typhim Vi may contain traces of formaldehyde or casein, which are used during the manufacturing process (see section 4.3).

#### 3. PHARMACEUTICAL FORM

Solution for injection in prefilled syringe.

Clear, colourless solution.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

Prevention of typhoid fever in adults and in children over 2 years of age, and especially: travellers to endemic areas, migrants, health care professionals and military personnel.

##### 4.2 Posology and method of administration

###### Posology

RESTRICTED TO ADULTS AND CHILDREN OVER 2 YEARS OF AGE.

A single injection ensures protection. If exposure to risk continues and depending on the level of exposure, revaccination will be performed every 2 to 3 years.

###### Paediatric population

The vaccination schedule is the same for children and for adults.

###### Method of administration

Intramuscular or subcutaneous route.

##### 4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1, to formaldehyde or to casein (which may be present as traces in each dose, owing to their use during the manufacturing process).

Vaccination should be postponed in case of acute febrile disease.

##### 4.4 Special warnings and precautions for use

Do not inject by the intravascular route.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection, especially in adolescents. This may be accompanied by several neurological signs

such as transient sight disorders, paraesthesia and tonic-clonic limb movements during the recovery phase. It is important that procedures be in place to avoid any injury from faints.

This vaccine protects against the risks of infection by *Salmonella typhi* but not against *Salmonella paratyphi* A or B or non-typhoidal salmonella.

The immunogenicity of TYPHIM Vi may be reduced by immunosuppressive treatment or immunodeficiency. It is then recommended to wait until the end of the treatment or disease before vaccinating. Nevertheless, vaccination of subjects with chronic immunodeficiency, such as HIV infection, is recommended even if the immune response may be limited.

Injection must be performed via the subcutaneous route in subjects with thrombocytopenia or bleeding disorders.

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available, in the event of a rare anaphylactic reaction following administration of the vaccine.

#### **Paediatric population**

This vaccine is not indicated in children under 2 years of age because of the risk of insufficient antibody response.

TYPHIM Vi contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially 'sodium-free'.

Traceability:

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

### **4.5 Interaction with other medicinal products and other forms of interaction**

This vaccine can be associated with other common vaccines (hepatitis A, yellow fever, diphtheria, tetanus, poliomyelitis, rabies, meningitis A + C and hepatitis B) during the same vaccination session, using separate injection sites.

### **4.6 Fertility, pregnancy and lactation**

#### **Pregnancy**

No reliable animal teratogenic data are available.

Currently, no sufficiently relevant clinical data are available to assess a potential teratogenic or foetotoxic effect of this vaccine when administered during pregnancy.

Because of the seriousness of the disease, and in case of high risk of exposure to typhoid fever, pregnancy is not an obstacle to the vaccination protocol.

#### **Lactation**

This vaccine can be used during lactation.

### **4.7 Effects on ability to drive and use machines**

The effects on the ability to drive and use machines have not been studied.

### **4.8 Undesirable effects**

#### **a. Summary of the safety profile**

More than 15,000 subjects received TYPHIM Vi (either in a single injection or as a second injection) in clinical studies.

The most common adverse reaction, in all age groups, was injection site pain. In adults from 18 years of age, myalgia and fatigue were the most frequently reported systemic reactions. In children and adolescents (from 2 to 17 years of age), myalgia and cephalalgia were the most frequently reported systemic reactions.

Most adverse reactions occurred within three days of vaccination. Most reactions resolved spontaneously within 1 to 3 days after onset.

**b. Tabulated list of adverse reactions**

The adverse reactions listed below come from clinical studies (pooled analysis) and worldwide post-marketing experience. The pooled analysis was performed on 6 recent studies sharing the same safety standard integrating data from 1532 subject (97 children and adolescents from 2 to 17 years of age and 1435 adults).

In each System Organ Class, the adverse events are ranked under headings of frequency, the most common reactions coming first, using the following convention:

Very common (≥ 1/10);

Common (≥ 1/100 to <1/10);

Uncommon (≥ 1/1000 to <1/100);

Rare (≥ 1/10 000 to <1/1000);

Very rare (<1/10 000) including isolated cases.

Not known: cannot be estimated from available data.

The table below summarises the frequencies of adverse reactions recorded after any dose of TYPHIM Vi in children and adolescents from 2 to 17 years of age.

Adverse reactions	Children and Adolescents 2-17 years (N=97)	Adults ≥ 18 years (N=1435)
	Frequency	Frequency
<b>Immune system disorders</b>		
Anaphylactic, anaphylactoid reactions, including shock	Not known*	
Serum sickness disease	Not known*	
<b>Nervous system disorders</b>		
Vasovagal syncope in response to injection	Not known*	
Cephalalgia	Very common	Common
<b>Respiratory, thoracic and mediastinal disorders</b>		
Asthma	Not known*	
<b>Gastrointestinal disorders</b>		
Nausea	Not known*	
Vomiting	Not known*	
Diarrhoea	Not known*	
Abdominal pain	Not known*	
<b>Skin and subcutaneous tissue disorders</b>		
Allergic-like reactions such as pruritus, skin rash, urticaria	Not known*	
<b>Musculoskeletal and connective tissue disorders</b>		
Arthralgia	Not known*	
Myalgia	Very common	Very common
<b>General disorders and administration site conditions</b>		
Injection site pain	Very common	
Injection site erythema	Very common	Common
Injection site pruritus	-	Uncommon
Injection site swelling / Oedema / Induration	Very common	Common
Malaise	Common	Very common
Fever	Common	-
Fatigue / asthenia	Common	Very common

\*reported during post-marketing surveillance

The most frequently reported adverse reactions in children and adolescents (from 2 to 17 years of age) were injection site reactions: pain (52.6%), swelling / oedema / induration (16.5%) and erythema (14.4%). The most frequently reported systemic reactions were myalgia (14.6%) and headaches (13.5%).

In adults from 18 years of age, the most frequently reported adverse reactions were injection site pain (75.6%), myalgia (47.1%) and fatigue / asthenia (25.0%).

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: "Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance - Site internet: [www.signalement-sante.gouv.fr](http://www.signalement-sante.gouv.fr)."

#### **4.9 Overdose**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

**Pharmacotherapeutic group: bacterial vaccines, ATC code: J07AP03.**

This vaccine is prepared from purified Vi capsular polysaccharides of *Salmonella typhi*. Immunity appears between 1 to 3 weeks after the injection. Protection lasts around 3 years.

A double-blind, randomized, controlled efficacy clinical study was conducted in a highly endemic area in Nepal, in children and adults from 5 to 44 years. A total of 3,457 subjects received TYPHIM Vi. Compared with the control group (23 valence-pneumococcal polysaccharide vaccine), vaccine efficacy conferred by a single dose of vaccine TYPHIM Vi was 74% (CI 95%: 49; 87) against blood culture-confirmed cases of typhoid fever throughout the 20 months of active surveillance.

Seroconversion rate (defined as 4-fold rise of anti-Vi antibody levels) was collected in 19 clinical trials. These trials were conducted in endemic and non-endemic areas in adults and children from 2 years of age representing a total of 2,137 evaluable subjects. In the adult population, the seroconversion rate ranged from 62.5% to 100% three to four weeks after a single injection, with similar magnitude of anti-Vi immune response in non-endemic areas compared to endemic areas.

Anti-Vi antibody persistence depends on endemicity, with a trend for better persistence in endemic areas (documented up to 10 years in 83 children at levels equal or above 1 µg/mL considered as a serological indicator of protection against typhoid fever). In non-endemic areas, anti-Vi antibodies persist for 2 to 3 years with rates above 1 µg/mL around 41% after two years and 35.6% after 3 years of vaccination with TYPHIM Vi. Revaccination should be carried out with a maximum interval of 3 years if the subject is still exposed to the risk.

#### **Paediatric population**

In a double-blind, randomized, controlled efficacy clinical study conducted in a highly endemic area in South Africa, a total of 5,692 subjects from 5 to 15 years of age received TYPHIM Vi. Compared with the control group (meningococcal polysaccharide vaccine of groups A and C), vaccine efficacy conferred by a single dose of vaccine TYPHIM Vi was 55% (CI 95% : 30 ; 71) against blood culture-confirmed cases of typhoid fever during a 3-year follow-up.

Immunogenicity was assessed in both endemic and non-endemic areas in paediatric population aged from 2 to 17 years. In 9 clinical studies including 733 evaluable children, three to four weeks after a single injection of TYPHIM Vi, the seroconversion rate ranged from 67% to 100%, with a magnitude of anti-Vi immune response similar to that documented in adult.

#### **5.2 Pharmacokinetic properties**

Not applicable.

#### **5.3 Preclinical safety data**

Non-clinical data revealed no special hazard for humans based on conventional studies of acute toxicity, repeat dose toxicity, local safety and hypersensitivity.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Phenol and a buffer solution containing sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate and water for injections.

### 6.2 Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

### 6.3 Shelf life

3 years

### 6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).

Do not freeze.

### 6.5 Nature and contents of container

0.5 mL of solution in prefilled syringe (type I glass) with a plunger stopper (bromochlorobutyl or bromobutyl or chlorobutyl). Box of 1 and 20.

0.5 mL of solution in prefilled syringe (type I glass) with a plunger stopper (bromochlorobutyl or bromobutyl or chlorobutyl), a tip-cap (bromochlorobutyl or synthetic isoprene-bromobutyl), without needle. Box of 1.

0.5 mL of solution in prefilled syringe (type I glass) with a plunger stopper (bromochlorobutyl or bromobutyl or chlorobutyl), a tip-cap (bromochlorobutyl or synthetic isoprene-bromobutyl), with 1 to 2 separate needles. Box of 1.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

The vaccine should be kept at room temperature for a few minutes before use.

For syringes without attached needles, the separate needle must be fitted firmly to the syringe, rotating it by a one quarter turn.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

### SANOFI PASTEUR

14 ESPACE HENRY VALLÉE

69007 LYON

FRANCE

## 8. MARKETING AUTHORISATION NUMBER(S)

- 34009 339 841 1 3: 0.5 mL of solution in prefilled syringe (type I glass) with a plunger stopper (bromochlorobutyl or bromobutyl or chlorobutyl). Box of 1.
- 34009 331 507 5 4: 0.5 mL of solution in prefilled syringe (type I glass) with a plunger stopper (bromochlorobutyl or bromobutyl or chlorobutyl). Box of 20.

- 34009 369 928 8 7: 0.5 mL of solution in prefilled syringe (type I glass) with a plunger stopper (bromochlorobutyl or bromobutyl or chlorobutyl), a tip-cap (bromochlorobutyl or synthetic isoprene-bromobutyl), without needle. Box of 1.
- 34009 369 929 4 8: 0.5 mL of solution in prefilled syringe (type I glass) with a plunger stopper (bromochlorobutyl or bromobutyl or chlorobutyl), a tip-cap (bromochlorobutyl or synthetic isoprene-bromobutyl), with one separate needle. Box of 1.
- 34009 369 930 2 0: 0.5 mL of solution in prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl), a tip-cap (bromochlorobutyl or synthetic isoprene-bromobutyl), with two separate needles. Box of 1.

## **9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION**

[to be completed later by the holder]

## **10. DATE OF REVISION OF THE TEXT**

[to be completed later by the holder]

## **11. DOSIMETRY**

Not applicable.

## **12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS**

Not applicable.

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### **GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product not subject to medical prescription.

## ANNEX II

### A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

#### A.1. Name and address of the manufacturer(s) of the biological active substance(s)

**SANOFI PASTEUR**

1541 AVENUE MARCEL MERIEUX  
69280 MARCY-L'ETOILE  
FRANCE

#### A.2. Name and address of the manufacturer(s) responsible for batch release

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

**SANOFI PASTEUR**

1541 AVENUE MARCEL MERIEUX  
69280 MARCY-L'ETOILE  
FRANCE

or

**SANOFI PASTEUR**

PARC INDUSTRIEL D'INCARVILLE  
27100 VAL DE REUIL  
FRANCE

### B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product not subject to medical prescription.

- Official batch release

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

### C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic Safety Update Reports (PSUR)**

The requirements for submission of periodic safety update reports for this vaccine are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

### D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

Not applicable

### E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES

Not applicable

## F. PRODUCT QUALITATIVE AND QUANTITATIVE COMPOSITION in EXCIPIENTS

One dose (0.5 mL) of vaccine contains:

Phenol..... ≤ 1.250 mg

Buffer solution containing:

- sodium chloride ..... 4.150 mg

- sodium dihydrogen phosphate dihydrate ..... 0.023 mg

- disodium phosphate dihydrate ..... 0.065 mg

Water for injections .....qs 0.5 mL

The vaccine contains traces of formaldehyde and casein.

## ANNEX IIIA

### LABELLING

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

#### NATURE/TYPE OUTER PACKAGING OR IMMEDIATE PACKAGING

Outer packaging

#### 1. NAME OF THE MEDICINAL PRODUCT

**TYPHIM Vi, solution for injection in prefilled syringe.**

**Polysaccharide typhoid vaccine**

#### 2. STATEMENT OF ACTIVE SUBSTANCES

One dose of 0.5 mL of vaccine contains:

Polysaccharides of *Salmonella typhi* (Ty2 strain).....25 micrograms

#### 3. LIST OF EXCIPIENTS

Phenol and a buffer solution containing sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate and water for injections.

#### 4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection (0.5 mL) in prefilled syringe <without needle> <with> <one> <two> <separate needle(s)>.

Box of 1 and/or 20.

#### 5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular (IM) or subcutaneous (SC) route.

Read the package leaflet before use.

#### 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

#### 7. OTHER SPECIAL WARNING(S), IF NECESSARY

Not applicable.

#### 8. EXPIRY DATE

EXP {MM/YYYY}

## 9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C).

Do not freeze.

## 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

### Holder

**SANOFI PASTEUR**  
14 ESPACE HENRY VALLÉE  
69007 LYON  
FRANCE

### Distributor

**SANOFI PASTEUR EUROPE**  
14 ESPACE HENRY VALLÉE  
69007 LYON  
FRANCE

## 12. MARKETING AUTHORISATION NUMBER(S)

Authorised Medicinal product No:

## 13. BATCH NUMBER

Batch {number}

## 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

## 15. INSTRUCTIONS ON USE

Prevention of typhoid fever in adults and in children over 2 years of age.

## 16. INFORMATION IN BRAILLE

[Comply with the decision of May 7, 2008 taken pursuant to article R. 5121-138 of the Public Health Code, published in the OJ of May 22, 2008]

## 17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

## 18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}

SN: {number}

**PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING**

**Pictogram on teratogenic or foetotoxic effects**

Where applicable, the pictogram mentioned in section III of article R. 5121-139 of the Public Health Code (teratogenic or foetotoxic effects) must be affixed in compliance with the implementing decree provided for in the same article.

**Pictogram on effects on the ability to drive**

Not applicable.



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**NATURE/TYPE BLISTERS/STRIPS**

Not applicable.

**1. NAME OF THE MEDICINAL PRODUCT**

Not applicable.

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Not applicable.

**3. EXPIRY DATE**

Not applicable.

**4. BATCH NUMBER**

Not applicable.

**5. OTHER**

Not applicable.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**NATURE/TYPE SMALL IMMEDIATE PACKAGING UNITS**

Prefilled syringe

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

**TYPHIM Vi, solution for injection in prefilled syringe**

Polysaccharide typhoid vaccine

IM or SC route

**2. METHOD OF ADMINISTRATION**

Not applicable.

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

Batch {number}

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

1 dose = 0.5 mL.

**6. OTHER**

Not applicable.

## ANNEX IIIB

### PACKAGE LEAFLET: INFORMATION FOR THE USER

#### Name of the medicinal product

**TYPHIM Vi, solution for injection in prefilled syringe.**

**Polysaccharide typhoid vaccine**

#### Boxed text

**Read all of this leaflet carefully before you or your child are vaccinated because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What TYPHIM Vi, solution for injection in prefilled syringe is and what it is used for
2. What you need to know before you use TYPHIM Vi, solution for injection in prefilled syringe
3. How to use TYPHIM Vi, solution for injection in prefilled syringe
4. Possible side effects
5. How to store TYPHIM Vi, solution for injection in prefilled syringe
6. Contents of the pack and other information

### 1. WHAT TYPHIM Vi, solution for injection in prefilled syringe IS AND WHAT IT IS USED FOR

**Pharmacotherapeutic group: bacterial vaccines: ATC code - J07AP03**

This medicinal product is a vaccine.

Vaccines are used to protect against infectious diseases.

This vaccine helps protect adults and children over 2 years of age against typhoid fever.

Typhoid fever is caused by a bacterium called *Salmonella typhi*. The main symptoms include high fever (40°C), headache, insomnia, dizziness, epistaxis (nose bleeding), anorexia (loss of appetite), nausea, diarrhoea and consciousness disorders.

When you or your child receive an injection of TYPHIM Vi, the body's natural defences elaborate a protection against the infection caused by this bacterium.

TYPHIM Vi is intended for travellers to endemic areas (areas where the disease is present and affects a large part of the population), migrants, health care professionals and military personnel.

### 2. What you need to know BEFORE YOU USE TYPHIM Vi, solution for injection in prefilled syringe

#### Do not use TYPHIM Vi:

- if you or your child are allergic to the active substance, to any of the other components of this vaccine (listed in section 6), to formaldehyde or to casein (used during the production of the vaccine and which may be present in it in small amounts),
- if you or your child are ill with a high temperature. Vaccination must be postponed until after you have recovered.

## Warnings and precautions

Talk to your doctor, pharmacist or nurse before using TYPHIM Vi, solution for injection in prefilled syringe.

- This vaccine protects against the typhoid fever bacterium (*Salmonella typhi*), but not against the related bacteria (*Salmonella paratyphi* A or B) or non-typhoidal salmonella.
- If you or your child have a weak immune system, due to:
  - Corticosteroid drugs, cytotoxic medicines, radiotherapy or other treatments likely to weaken your immune system. Your doctor may wait until the end of treatment.
  - HIV (Human Immunodeficiency Virus) infection or any other diseases which weaken your immune system. It is recommended to administer the vaccine although it may not protect you as well as it would in a person with a normal immune system.
- If you or your child suffer from haemophilia or if you are easily prone to bruising or bleeding.
- Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell your doctor or nurse if you or your child fainted with a previous injection.

## Children

This vaccine is not indicated in children less than 2 years of age because it is not efficient enough.

## Other medicinal products and TYPHIM Vi

TYPHIM Vi can be associated with other vaccines (hepatitis A, yellow fever, diphtheria, tetanus, poliomyelitis, rabies, meningitis A + C and hepatitis B) during the same vaccination session. However, injections must be performed in separate injection sites, i.e. in another part of the body such as the other arm or the other leg, and the vaccines must not be mixed in the same syringe.

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

## TYPHIM Vi with food and drink

Not applicable.

## Pregnancy and breast-feeding

Because of the seriousness of the disease, and in case of high risk of exposure to typhoid fever, pregnancy is not an obstacle to vaccination.

This vaccine will be used during pregnancy only if advised by your doctor.

This vaccine can be used during breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicines.

## Driving and using machines

The effects on the ability to drive and use machines have not been studied.

## TYPHIM Vi contains sodium

TYPHIM Vi contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially 'sodium-free'.

## 3. HOW TO USE TYPHIM Vi, solution for injection in prefilled syringe

### Dosage

RESTRICTED TO ADULTS AND CHILDREN OVER 2 YEARS OF AGE.

A single dose (0.5 mL) is enough.

If exposure to risk continues, revaccination will be performed every 3 years.

### Use in children and adolescents

The vaccination schedule is the same for children and for adults.

### **Method of administration**

This vaccine will be administered to you in a muscle or under the skin by a healthcare professional.  
This vaccine should never be administered into a blood vessel.

### **If you or your child use more TYPHIM Vi than you should**

Not applicable.

### **If you or your child forget to use TYPHIM Vi**

Not applicable.

### **If you or your child stop using TYPHIM Vi**

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Severe allergic reactions:**

Anaphylactic, anaphylactoid reactions, including shock which can include one or several of the following symptoms:

- urticaria, skin rash,
- swelling of face and/or neck,
- breathing difficulties, bluish discoloration of the tongue or lips,
- low blood pressure, rapid heart rate and weak pulse, skin coldness, dizziness and potentially fainting.

When these signs or symptoms appear, it is usually very soon after the injection, while the person affected is still at the medical centre or at the doctor's surgery. If one of these symptoms occurs after you have left the place where the vaccine was administered, you must consult a doctor IMMEDIATELY.

### **Other side effects**

Most side effects occurred within 3 days after vaccination. Most effects resolved spontaneously within 1 to 3 days after onset. They were reported with the following frequencies:

#### Very common: may affect more than 1 in 10 people

- Injection site pain, injection site redness (erythema)<sup>(1)</sup>, injection site swelling/oedema<sup>(1)</sup>, injection site hardening (induration)<sup>(1)</sup>,
- Headache (cephalalgia)<sup>(1)</sup>
- Muscle pain (myalgia),
- Generally feeling unwell<sup>(2)</sup>,
- Fatigue<sup>(2)</sup>, unusual weakness (asthenia)<sup>(2)</sup>

#### Common: may affect up to one in 10 people

- Fever<sup>(3)</sup>

#### Uncommon: may affect up to one in 100 people

- Injection site itching (injection site pruritus)<sup>(4)</sup>

#### Not known: cannot be estimated from available data

- Serum sickness disease: joint pain, skin rash, swelling of lymph nodes and generally feeling unwell.  
When these symptoms appear, it is generally 2-4 weeks after vaccination.
- Fainting in response to an injection (vasovagal syncope).

- Cough, wheezing, respiratory discomfort (asthma).
- Nausea, vomiting, diarrhoea, stomach pain (abdominal pain).
- Rash, sometimes swollen and itchy (pruritus, skin rash, urticaria).
- Joint pain (arthralgia).
  - (1) Common in adults,
  - (2) Common in children and adolescents (from 2 to 17 years of age),
  - (3) Not reported in adults,
  - (4) Not reported in children and adolescents (from 2 to 17 years of age).

### Reporting of side effects

If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: “Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance - Site internet: [www.signalement-sante.gouv.fr](http://www.signalement-sante.gouv.fr).” By reporting side effects, you can help provide more information on the safety of this medicine. [www.signalement-sante.gouv.fr](http://www.signalement-sante.gouv.fr)

## 5. HOW TO STORE TYPHIM Vi, solution for injection in prefilled syringe

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date, which is stated on the box and syringe label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

Do not freeze.

The vaccine must not be used if the doctor or nurse notices foreign particles in the syringe.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What TYPHIM Vi contains

- The active substance is:  
Polysaccharides of *Salmonella typhi* (Ty2 strain) .....25 micrograms  
for one 0.5 mL dose.
- The other components are: phenol and a buffer solution containing sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate and water for injections.

### What TYPHIM Vi is and contents of the pack

TYPHIM Vi is presented in the form of a solution for injection (0.5 mL in prefilled syringe with or without needles). Box of 1 or 20.

Not all pack sizes may be marketed.

The solution is clear and colourless.

### Marketing Authorisation Holder

**SANOFI PASTEUR**  
14 ESPACE HENRY VALLÉE  
69007 LYON  
FRANCE

### **Marketing Authorisation Distributor**

**SANOFI PASTEUR EUROPE**  
14 ESPACE HENRY VALLÉE  
69007 LYON  
FRANCE

### **Manufacturer**

**SANOFI PASTEUR**  
14 ESPACE HENRY VALLÉE  
69007 LYON  
FRANCE

### **Names of the medicinal product in the Member States of the European Economic Area**

Not applicable.

### **This leaflet was last revised in:**

[to be completed later by the holder]

### **Other**

Detailed information on this medicine is available on the website of ANSM (France).

The following information is intended for healthcare professionals only:

This vaccine must not be mixed with other vaccines in the same syringe.

For syringes without attached needles, the needle must be fitted firmly to the syringe, rotating it by a one quarter turn.