PACKAGE LEAFLET: INFORMATION FOR THE USER

TYPHIM Vi®,

Solution for injection

Purified Vi Capsular Polysaccharide of *Salmonella typhi* (Ty 2 Strain).

Read all of this leaflet carefully before you 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 vaccine has been prescribed for you only. Do not pass it on to others.
- If you 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.

In this leaflet:

1. WHAT TYPHIM Vi IS AND WHAT IT IS USED FOR

Typhim Vi is a vaccine. Vaccines are used to protect against infectious diseases.

This vaccine helps to protect adults and children who are aged 2 years and over against typhoid fever. It may not be effective in children under 2.

When the vaccine is given to you or your child, the body's natural defences will produce protection against typhoid fever.

Typhoid fever is an infectious disease. Symptoms are a headache with a fever that gets worse over three to four days. Additional symptoms include cough, sore throat and altered behaviour.

This vaccine will only protect against typhoid fever. It will not work against any other disease, such as paratyphoid fever or food poisoning. It cannot cause typhoid fever.

As with any vaccine, not everyone who receives this vaccine will definitely be protected against typhoid fever.

2. BEFORE TYPHIM Vi IS GIVEN

To make sure that this vaccine is suitable for you or your child, it is important to tell your doctor or nurse if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor or nurse to explain.

Do not use this vaccine if you or your child is:

- allergic (hypersensitive) to Typhim Vi or any of its ingredients (see section 6 for a list of ingredients).
- allergic (hypersensitive) to formaldehyde or casein, which are used during vaccine production and may be present in small amounts.
- ill with a high temperature. The vaccination will be delayed until you/your child have recovered.

Take special care with this vaccine
Tell your doctor or nurse if you or your child has:
- a blood disorder such as haemophilia (a condition where you bruise or bleed easily) because bleeding may occur at the injection site.
- a poor or reduced immune system, due to:
  - corticosteroids, cytotoxic drugs, radiotherapy or any other treatment that weakens the immune system. The doctor or nurse may wait until the course of treatment has finished.
  - HIV infection or any disease that weakens the immune system. The vaccine may not protect as well as it protects people with normal immune systems.

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.

Receiving other vaccines or medicines
This vaccine can generally be given at the same time as other vaccines provided that they are given in different parts of the body (e.g. the other arm or leg) and are not mixed in the same syringe.

This vaccine can be given at the same time as other common vaccines including:
- yellow fever
- diphtheria
- tetanus
- poliomyelitis
- rabies (prepared on Vero cells)
- meningitis A + C
- hepatitis A and hepatitis B

Tell your doctor, nurse or pharmacist if you or your child are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
If you are pregnant, trying to become pregnant or are breast feeding, tell your doctor or nurse. They will decide whether or not to delay the vaccination.

Ask your doctor, nurse or pharmacist for advice before taking any medicine.

Driving and using machines
Tiredness has been reported in some people after receiving this vaccine so you must take extra care when driving or using machines. If you are affected do not drive or use machines.

Important information about some of the ingredients of Typhim Vi
Typhim Vi contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. HOW TYPHIM Vi IS GIVEN

The vaccine will be given by a doctor or nurse who has been trained in the use of vaccines and who is equipped to deal with any uncommon severe allergic reaction to the injection.

Dosage
Typhim Vi is given as a single injection of half a millilitre of the vaccine to adults and children aged 2 years and over. The vaccine should be given at least 2 weeks before protection against typhoid fever is required. Protection lasts for 3 years so you or your child may need another dose after this time.

How the vaccine is administered
The doctor or nurse will shake the syringe immediately before use and check that the liquid is not discoloured and has no unexpected particles in it.

The vaccine is given as an injection into a muscle or deep under the skin, in the outer part of the upper arm or leg. They will avoid giving the injection into a blood vessel. Your doctor or nurse will make a note of the details of the injection.

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

4. POSSIBLE SIDE EFFECTS

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

Serious 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 clinic or at the doctor's surgery. If one of these symptoms occurs after you have left the place where the injection was administered, you must consult a doctor IMMEDIATELY.

Other side effects

Most side effects appeared within 3 days after vaccination. Most reactions 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

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Not known: frequency cannot be estimated from the available data

Adverse Reactions Experienced	**Children and Adolescents** 2-17 years	**Adults** ≥ 18 years
	Frequency	Frequency
Serum sickness disease: joint pain, skin rash, enlarged lymph nodes and generally feeling unwell.*	Not known	
Fainting in response to injection (vasovagal syncope)	Not known	
Headache	Very common	Common
Cough, wheezing, respiratory discomfort (asthma)	Not known	
Nausea, vomiting, diarrhoea, stomach pain (abdominal pain)	Not known	
Rash, sometimes swollen and itchy (pruritus, skin rash, urticaria)	Not known	
Joint pain (arthralgia)	Not known	
Muscle pain (myalgia)	Very common	

Adverse Reactions Experienced	Children and Adolescents 2-17 years	Adults ≥ 18 years
	Frequency	Frequency
Injection site pain	Very common	
Itching at the injection site (injection site pruritus)	-	Uncommon
Injection site redness (erythema), injection site swelling/oedema, injection site hardening (induration)	Very common	Common
Generally feeling unwell (malaise)	Common	Very common
Fever	Common	-
Fatigue, unusual weakness (asthenia)	Common	Very common

*****When these symptoms appear, it is generally 2-4 weeks after vaccination

Reporting of side effects in the UK
If you 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

Reporting of side effects in Ireland
If you 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TYPHIM Vi

- Keep out of the reach and sight of children.
- The vaccine must be stored in a refrigerator between 2°C and 8°C. Do not freeze.
- Keep the syringe in the outer carton in order to protect from light.
- Do not use Typhim Vi after the expiry date (EXP) which is stated on the carton and syringe label. The expiry date refers to the last day of that month.
- Vaccines must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of vaccines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Typhim Vi contains

The active substance is purified Vi capsular polysaccharide of *Salmonella typhi* (Ty 2 strain).
Each 0.5 millilitre dose of Typhim Vi contains 25 micrograms of the active substance.

The other ingredients are phenol, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate and Water for injections.

What Typhim Vi looks like and contents of the pack
Typhim Vi is provided as a solution for injection. The solution is a clear colourless liquid. The vaccine

comes in a prefilled glass syringe (without an attached needle) which contains a single 0.5 millilitre injection. The syringes are available as a single unit pack or as a pack of ten.
Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
The manufacturer responsible for batch release is Sanofi Pasteur at one of the following manufacturing sites:

Sanofi Pasteur,
Campus Mérieux,
1541 avenue Marcel Mérieux,
69280 Marcy l'Etoile,
France

or

Sanofi Pasteur,
Parc Industriel D'Incarville,
27100 Val de Reuil,
France

The Marketing Authorisation Holder is:
Sanofi Pasteur Europe
14 Espace Henry Vallée
69007 Lyon
France

Distributed by:
United Kingdom:
Sanofi
410 Thames Valley Park Drive
Reading
Berkshire
RG6 1PT
UK
Tel: 0800 035 2525

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