

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
2. Before Typhim Vi is given
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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, which is 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

Sodium: This vaccine contains less than 1 mmol sodium (23mg) per dose. This is a very small amount so is classed as '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 and vaccines, Typhim Vi can cause side effects, although not everybody gets them.

Possible Serious Allergic Reactions

Severe allergic reaction (anaphylaxis), which may include one or more of the following symptoms:

- urticaria/skin rashes
- swelling of the face and/or throat, difficulty in breathing, blue discolouration of the tongue or lips
- low blood pressure, rapid heart rate and weak pulse, coldness of the skin, dizziness and potentially collapse.

When allergic reactions occur, they usually develop very soon after the injection is given, while still in the clinic or doctor's surgery.

If any of these symptoms occur after leaving the place where your injection was given, you must consult a doctor IMMEDIATELY.

Serum sickness

- joint pains, skin rashes, enlarged lymph glands and generally feeling unwell.

If these symptoms occur, they usually develop 2-4 weeks after receiving the vaccine.

If these symptoms occur, consult a doctor as soon as possible.

Other Side Effects

Very common reactions (reported by more than 1 in 10 people):

- pain, redness, swelling and hardness in the area where the vaccine was injected

Common reactions (reported by less than 1 in 10 but more than 1 in 100 people):

- fever (a high temperature).

Other possible reactions:

- fainting in response to injection
- headache
- asthma
- diarrhoea, stomach ache, feeling and/or being sick
- joint/muscle pain
- rashes that have sometimes been lumpy and itchy
- tiredness
- generally feeling unwell

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. 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 S.A. at one of the following manufacturing sites:

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

or

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

The Marketing Authorisation Holder is:

Sanofi Pasteur Europe
2, Avenue Pont Pasteur
69007 Lyon
France

Distributed by:

United Kingdom:

Sanofi
One Onslow Street
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