

TYPHIM Vi
Solution for injection
POLYSACCHARIDE TYPHOID VACCINE

Read all of this leaflet carefully before you start using this medicine 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 or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- 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. What you need to know before you use TYPHIM Vi
3. How to use TYPHIM Vi
4. Possible side effects
5. How to store TYPHIM Vi
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1. WHAT TYPHIM Vi IS AND WHAT IT IS USED FOR

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

Do not use TYPHIM Vi:

- if you or your child are allergic (hypersensitive) to the active substance, to any of the other components of TYPHIM Vi (listed in Section 6), to formaldehyde (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.

Take special care with TYPHIM Vi:

- 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.
- This vaccine is not indicated in children less than 2 years of age because it is not efficient enough.
- 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 fainted with a previous injection.

Use of other medicinal products:

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.

Please inform your doctor or pharmacist if you or your child take or have recently taken any other medicines, even those not prescribed.

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.

3. HOW TO USE TYPHIM Vi

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.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, TYPHIM Vi can cause side effects, although not everybody gets them.

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

- Injection site pain, injection site hardening (induration), injection site redness (erythema).

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

- Fever.

Very rare reactions (reported by less than 1 in 10 000 persons)

- Serious allergic reactions:
 - 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 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.
 - serum sickness disease: joint pain, skin rash, enlarged lymph nodes and generally feeling unwell.
When these symptoms appear, it is generally 2-4 weeks after vaccination.
- Fainting in response to injection
- Headache (cephalalgia).
- Cough, wheezing, respiratory discomfort (asthma)
- Nausea, vomiting, diarrhoea, stomach pain (abdominal pain).
- Rash, sometimes swollen and itchy (pruritus, skin rash, urticaria).
- Joint and muscle pain.
- Fatigue, generally feeling unwell.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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 sight and reach of children.

Do not use TYPHIM Vi after the expiry date stated on the box and syringe or vial 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 or vial.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 buffer solution containing 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 presented in the form of a solution for injection (0.5 ml in prefilled syringe with or without needle – box of 1) or a solution for injection in multidose vial (20 x 0.5 ml of vaccine – box of 10)

Not all pack sizes may be marketed.

The solution is clear and colourless.

Marketing Authorisation Holder, and Manufacturer

Holder

SANOFI PASTEUR

2, AVENUE PONT PASTEUR

69007 LYON

FRANCE

Distributor

SANOFI PASTEUR MSD SNC

12 RUE JONAS SALK

69007 LYON

FRANCE

Manufacturer

SANOFI PASTEUR

1541 AVENUE MARCEL MERIEUX

69280 MARCY L'ETOILE

FRANCE

This leaflet was last approved in: 04/2016.

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.