

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)⁽¹⁾, injection site swelling/oedema⁽¹⁾, injection site hardening (induration)⁽¹⁾,
- Headache (cephalgia)⁽¹⁾
- Muscle pain (myalgia),
- Generally feeling unwell ⁽²⁾,
- Fatigue ⁽²⁾, unusual weakness (asthenia)⁽²⁾

Common: may affect up to one in 10 people

- Fever ⁽³⁾

Uncommon: may affect up to one in 100 people

- Injection site itching (injection site pruritus) ⁽⁴⁾

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."

By reporting side effects, you can help provide more information on the safety of this medicine. 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

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Marketing Authorisation Distributor

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