TYPHIM Vi

Solution for Injection in a Prefilled Syringe

1 NAME OF THE MEDICINAL PRODUCT

TYPHIM Vi, solution for injection in a prefilled syringe

Polysaccharide typhoid vaccine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.5 ml of vaccine contains:

Purified Vi capsular polysaccharides of *Salmonella typhi* (Ty2 strain) 25 micrograms

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection in a 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 of 0.5 ml. 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

Intramuscular or subcutaneous route

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients or to formaldehyde (which may be present as traces in each dose, owing to its 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.

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

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

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.

4.5 Interaction with other medicinal products and other forms of interaction

This vaccine can be administered with hepatitis A and yellow fever vaccines during the same vaccination session, using separate injection sites.

Data concerning use with other vaccines (diphtheria, tetanus, poliomyelitis, rabies, meningitis A+C and hepatitis B) are limited. However, no interaction is anticipated when vaccines are given at separate sites using separate syringes.

4.6 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 risk 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 a reason not to administer the vaccine.

Lactation

It is not known whether this vaccine is excreted in human milk. Caution must be exercised when Typhim Vi is administered to a nursing mother.

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

The adverse events come from clinical studies and worldwide post-marketing experience.

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, <1/10), uncommon (≥1/1000, <1/100), rare (≥1/10 000 , <1/1000), very rare (<1/10 000) including isolated cases.

Clinical studies

During clinical development, more than 10 000 people received TYPHIM Vi (first or second injection). The most common adverse events were mild injection site reactions. They generally occurred within 48 hours of vaccination and disappeared within two days.

General disorders and administration site conditions

Very common: injection site pain, injection site induration, injection site erythema.

Common: fever.

Post-marketing experience

Based on spontaneous reporting, the following adverse events have also been reported during the commercial use of TYPHIM Vi. These events were very rarely reported. However, the exact incidence is not known (cannot be estimated based on the available data).

Immune system disorders

Anaphylactic, anaphylactoid reactions, including shock; serum sickness disease.

Nervous system disorders

Cephalalgia.

Respiratory, thoracic and mediastinal disorders

Asthma.

Gastrointestinal disorders

Nausea, vomiting, diarrhoea, abdominal pain.

Skin and subcutaneous tissue disorders

Allergic-like reactions such as pruritus, skin rash, urticaria.

Musculoskeletal and connective tissue disorders

Arthralgia, myalgia.

General disorders and administration site conditions

Fatigue, malaise.

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.

4.9 Overdose

Not applicable

5 Pharmacological properties

5.1 Pharmacodynamic properties

ANTI-TYPHOID VACCINE

Pharmacotherapeutic group: bacterial vaccines: ATC code: J07AP03.

Vaccine prepared from purified Vi capsular polysaccharides of *Salmonella typhi*. Immunity appears about 15 days to 3 weeks after the injection. Protection lasts around 3 years.

During studies carried out in highly endemic areas, a seroprotection rate (for typhoid fever) of 77% in Nepal and 55% in South Africa has been observed after one vaccine injection. In industrialized countries, seroconversion is observed in more than 90% of subjects after a single injection.

In a study conducted in Indonesia in children up to 10 years of age, GMTs and seroconversion rates were of the same order of magnitude in children 2 through 5 years of age and 5 through 10 years of age. This supports the recommendation for Typhim Vi vaccination from 2 years of age. The immune response induced by Typhim Vi administration in children from 2 years of age is over the WHO proposed correlate of protection against typhoid fever (at least ≥1 µg/mL).

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

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 a prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl) - Box of 1 and 20.
- 0,5 ml of solution in a prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl), a tip-cap (chlorobromobutyl), without needle - Box of 1.
- 0,5 ml of solution in a prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlrobutyl or bromobutyl), a tip-cap (chlorobromobutyl), with 1 or 2 separate needles – Box of 1.

Not all pack sizes or presentations may be marketed.

6.6 Instructions for use, handling and disposal

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

7 MARKETING AUTHORISATION HOLDER

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8 DATE OF REVISION OF THE TEXT

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