

TYPHIM Vi™

Purified polysaccharide capsule of Salmonella typhi (Ty 2 strain)

Description

TYPHIM Vi™ is a sterile solution, prepared from the purified polysaccharide capsule of *Salmonella typhi* (Ty 2 strain). The purified polysaccharide capsule is diluted in isotonic buffer solution which contains phenol as preservative. The vaccine is a clear, colourless solution. Each single dose of 0.5 mL is formulated to contain 0.025 milligrams of purified capsular polysaccharide, preserved with phenol (less than 1.25 mg per dose). The isotonic buffer solution contains 4.15 mg of sodium chloride, 0.065 mg of sodium phosphate dibasic dihydrate and 0.023 mg of sodium phosphate monobasic.

Pharmacology

This vaccine contains purified Vi capsular polysaccharide of *Salmonella typhi* (Ty 2 strain). Antibody sero-conversion is observed in over 90% of recipients 28 days after a single dose. Antibodies appear after approximately 7 to 15 days and reach peak values around 28 to 35 days after the injection. Persistence of the antibody response is at least 3 years. Protection is achieved in 60-80% of vaccinees during the first year and in 50-77% during the next 2 years.

Indications

TYPHIM Vi™ is indicated for active immunisation against typhoid fever in subjects 2 years of age and over.

Contraindications

Hypersensitivity to the vaccine or any component of the vaccine is a contraindication to use of this vaccine. TYPHIM Vi™ should not be given to anyone who is suffering or convalescing from an acute febrile illness.

Warnings

Do not inject intravenously: ensure that the needle does not enter any blood vessel.

Facilities for the management of anaphylaxis should always be available during vaccination.

Individuals with impaired immune system, such as those with an immunosuppressive disease or receiving immunosuppressive drugs may not develop the expected antibody response to TYPHIM Vi™.

Precautions

Protection is not conferred against paratyphoid fever or illness caused by non-invasive *Salmonella* following vaccination with TYPHIM Vi™. As with most vaccines, vaccination will not protect 100% of susceptible individuals (refer to pharmacology section).

Adverse Reactions

These are normally mild and short lasting. Local reactions commonly occur and include pain, swelling and erythema. Systemic reactions occur less frequently and include fever, headache, malaise, fatigue, joint pain, myalgia, nausea, vomiting, diarrhoea and abdominal pain. Very rarely cases of pruritus, rash, urticaria and exceptionally asthma, serum sickness and anaphylactoid reactions have been reported.

Use in Pregnancy and Lactation (Category B2)

There is no convincing evidence of risk to the foetus from immunisation of pregnant women using inactivated virus vaccines, bacterial vaccines or toxoids. It is not known if TYPHIM Vi™ is secreted in human milk.

Interactions with other Drugs

In clinical trials, TYPHIM Vi™ has been mixed together with Stamaril® (Yellow Fever Vaccine) or Menomune® (Meningococcal Polysaccharide Vaccine Groups A,C, Y, W-135) immediately prior to administration as a single injection.

Concomitant administration of TYPHIM Vi™ and these vaccines did not effect safety or immunogenicity.

Data concerning use with other vaccines are limited, however no interaction is anticipated when vaccines are given at separate sites.

Dosage and Administration

A single dose of 0.5 mL administered by intramuscular or subcutaneous injection.

Presentation

Single dose pre-filled syringe, unit pack

Storage

Store at +2°C to +8°C. (Refrigerate. Do not freeze).

Further Information

Shake before use.

Medicine Classification

Prescription Medicine

Manufacturer

Sanofi Pasteur SA
Lyon, France

Distributor

Australia:
Sanofi Pasteur Pty Ltd
ABN 79 085 258 797
Talavera Corporate Centre – Building D
12 – 24 Talavera Road
Macquarie Park NSW 2113
Australia
Tel: 1800 829 468

New Zealand:
sanofi-aventis new zealand limited
Level 8, James & Wells Tower
56 Cawley St
Ellerslie
Auckland
New Zealand
Telephone: 0800 727 838

Date of Preparation

1 November 2007

™Trademark of Sanofi Pasteur S.A.