Prescribing Information: TYPHIM Vi® solution for injection (Typhoid Polysaccharide Vaccine)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Available as a 0.5 mL single dose in a pre-filled syringe, containing 25 µg of purified Vi capsular polysaccharide of *Salmonella typhi* (Ty 2 strain).

Indication: Active immunisation against typhoid fever caused by *Salmonella typhi* in adults and children 2 years of age or older.

Dosage and Administration: A single 0.5 mL dose should be administered preferably by intramuscular (IM) injection, although the subcutaneous route may be used. Do not administer by intravascular injection. Ensure that the vaccine does not penetrate a blood vessel. Vaccination should occur at least 2 weeks prior to potential exposure to infection with *Salmonella typhi*. Revaccination with a single 0.5 mL dose should be given at intervals of three years to individuals who remain at risk.

Special Populations: Paediatric population: In children over 2 years of age a single 0.5 mL dose should be administered. The response to vaccination may be suboptimal in children under 2 years of age.

Contraindications: Hypersensitivity to the active substance, to any of the excipients or to any residual substances that may be present as traces such as formaldehyde or casein. Febrile or acute illness.

Warnings and Precautions: The vaccine does not protect against *Salmonella paratyphi* A or B or non-typhoidal Salmonellae. As with any vaccine, vaccination may not result in protection against typhoid in all recipients. Prior to immunisation: As with all injectable vaccines, appropriate facilities and medication should be available in the event of anaphylaxis. As a precautionary measure, adrenaline injection (1:1000) must be immediately available in case of unexpected anaphylactic or serious allergic reactions. Prior to vaccination, the health status and medical history (e.g. adverse events after previous immunisation) of the recipient should be established. In subjects who have a history of serious or severe reaction within 48 hours of a previous injection with a vaccine containing similar components, the need for the vaccination must be carefully considered, following a risk-benefit assessment. Administration precautions: Administer with caution to patients with thrombocytopenia or bleeding disorders since bleeding may occur following IM administration to these subjects. The immunogenicity of TYPHIM Vi may be reduced by immunosuppressive treatment or immunodeficiency. In such cases it is recommended to postpone vaccination until the end of the disease or treatment. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response might be limited. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Excipients of known effect: TYPHIM Vi contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Interactions: Separate injection sites must be used in case of concomitant vaccine administration. TYPHIM Vi may be administered during the same vaccination session with other common vaccines (yellow fever, diphtheria, tetanus, poliomyelitis, rabies prepared on Vero cells, meningitis A+C, hepatitis A and hepatitis B).

Fertility, pregnancy and lactation: Data on the use of this vaccine in pregnant women are limited. Therefore, the administration of the vaccine during pregnancy is not recommended. TYPHIM Vi should be given to pregnant women only if clearly needed and following an assessment of the risks and benefits. It is not known whether this vaccine is excreted in human milk. Caution must be exercised when TYPHIM Vi is administered to a breast-feeding mother.

Adverse Reactions: Very common: *Adults:* myalgia, injection site pain, malaise, fatigue/asthenia *Paediatric population:* headache, myalgia, injection site reactions (pain, erythema, swelling, oedema, induration). Common: *Adults:* headache, injection site reactions (erythema, swelling, oedema, induration) *Paediatric population:* malaise, fever, fatigue/asthenia. Other Serious Adverse Drug Reactions: anaphylactic/anaphylactoid reactions (including shock), serum sickness disease, vasovagal syncope in response to injection, asthma, abdominal pain, allergic type reactions (such as pruritus, rash, urticaria), arthralgia. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List price: Single dose pre-filled syringes in single packs: £11.16; Packs of 10 single dose pre-filled syringes: £111.60.

Legal Category: POM

Marketing Authorisation Number: PL 23228/0003

Marketing Authorisation Holder: Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France

Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com