Prescribing Information: TYPHIM Vi® (Typhoid Polysaccharide Vaccine)

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

Presentation: Solution for injection. Available as a 0.5 millilitre single dose in a pre-filled syringe, containing 25 micrograms 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: In adults and children over 2 years of age a single 0.5 millilitre dose should be administered preferably by intramuscular injection although the subcutaneous route may be used. The response to vaccination may be suboptimal in children under 2 years of age. Revaccination with a single 0.5 millilitre dose should be given at intervals of three years to individuals who remain at risk.

Special Populations: 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.

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.

Precautions and Warnings: The vaccine does not protect against Salmonella paratyphi A or B or non-typhoidal Salmonellae. As with all vaccines:1) facilities for the management of anaphylaxis should always be available during vaccination; 2) vaccination may not result in protection against typhoid in all recipients. Prior to vaccination, the health status and medical history (e.g. adverse events after previous immunisation) of the recipient should be established. Administer with caution to patients with thrombocytopenia or bleeding disorders. Immunogenicity may be impaired in immunosuppressed or immunodeficient patients. In such cases it is recommended to postpone vaccination until the end of the disease or treatment if possible. 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.

Adverse Reactions: In adults from 18 years of age, very common side effects include injection site pain, myalgia, malaise and fatigue/asthenia. Common side effects in adults include headache and injection site erythema and swelling/oedema/induration. In children and adolescents (from 2 to 17 years of age), very common side effects include local reactions at the site of injection (pain, swelling, oedema, induration and erythema), myalgia and headache. Common side effects in children/adolescents include malaise, fever and fatigue/asthenia. Other side effects have been reported in both age groups although their incidence is not known. These include anaphylactic/anaphylactoid reactions including shock, serum sickness disease, vasovagal syncope, asthma, nausea, vomiting, diarrhoea, abdominal pain, allergic type reactions (pruritus, rash, urticaria) and arthralgia.

For a complete list of undesirable effects please refer to the Summary of Product Characteristics.

List price: Single dose pre-filled syringes in single packs, basic NHS cost £11.16; packs of 10 single dose pre-filled syringes, basic NHS cost £111.60.

Legal Category: POM

M**arketing Authorisation Number**: PL 46602/0008

Marketing Authorisation Holder: Sanofi Pasteur Europe, 14 Espace Henry Vallée, 69007 Lyon, France.

Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT

Date of preparation: December 2023

Document Number: MAT-XU-2305642 (v1.0)

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