Prescribing Information: ViATIM® Suspension and solution for suspension for injection in a pre-filled syringe, Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine

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

Presentation: Suspension and solution for suspension for injection in a pre-filled syringe. Available as a 1 millilitre single dose in a pre-filled, dual-chamber syringe, containing 25 micrograms of Salmonella typhi (Ty2 strain) capsular Vi polysaccharide and 160 antigen units of inactivated hepatitis A virus. Neomycin is used in the manufacturing process.

Indication: For simultaneous active immunisation against typhoid fever and hepatitis A virus infection in subjects from 16 years of age.

Dosage and Administration: A single 1 millilitre dose should be administered by slow intramuscular injection in the deltoid region. ViATIM may be administered subcutaneously in patients with thrombocytopenia or in patients at risk of haemorrhage. Do not inject intravascularly or into buttocks. The two vaccine components should only be mixed immediately prior to injection. To provide long term protection against infection caused by the hepatitis A virus, a booster injection of inactivated hepatitis A vaccine should be given 6 to 36 months later (preferably within 6-12 months). ViATIM may be used as a booster vaccine in subjects who have received an inactivated hepatitis A vaccine 6 to 36 months earlier, and who require protection against typhoid fever. If continued protection against typhoid is required, a second dose of ViATIM may be given if approximately 36 months have elapsed since the first dose

Special Populations:

Fertility, pregnancy and lactation: Data on a limited number of exposed pregnancies indicate no adverse effects of ViATIM on pregnancy or on the health of the foetus/new born child. However, caution should be exercised when prescribing to pregnant women. When the patient is considered to be at risk of only one of hepatitis A or typhoid fever, the monovalent vaccine should be used. As there are no data on the excretion of ViATIM in human breast milk, the decision to vaccinate a breast feeding woman should take into account the benefit of breast-feeding to the child and the benefit of ViATIM to the woman.

Contraindications: Known hypersensitivity to the active substances, any of the excipients of ViATIM (including formaldehyde) or to neomycin (present in trace amounts as a residual of the manufacturing process). Vaccination should be delayed in subjects with an acute severe febrile illness.

Precautions and Warnings: As with all vaccines, appropriate facilities and medicines should be readily available in case of anaphylaxis or hypersensitivity following injection. ViATIM has a minor influence on the ability to drive and use machines. Immunogenicity of the vaccine may be impaired in immunosuppressed or immunodeficient patients. The effect of ViATIM on individuals in the incubation period of hepatitis A is not known. ViATIM does not protect against infection caused by Salmonella Enterica other than serotype typhi or against other known liver pathogens including hepatitis B, C and E viruses. ViATIM must not be mixed with any other vaccine in the same syringe. 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. ViATIM contains phenylalanine which may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. ViATIM also contains small amounts of alcohol (ethanol) and less than 1 mmol potassium (39 mg) and less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'potassium-free' and 'sodium-free'. The small amount of alcohol in this medicine will not have any noticeable effects.

Interactions: Concomitant administration of ViATIM and Td-IPV at 2 separate sites can be performed. Interaction studies with ViATIM and other inactivated vaccines have not been performed. However based on data from the concomitant administration of the monovalent vaccines with inactivated or live vaccines at different injection sites, no interference with immune responses to any of those antigens would be expected. (Data based on typhoid Vi polysaccharide vaccine with diphtheria-tetanus (DT), tetanus-inactivated poliomyelitis (T-IPV), rabies, meningococcal polysaccharide A/C, hepatitis B and from the concomitant administration of the monovalent inactivated hepatitis A vaccine with hepatitis B vaccines, and monovalent vaccines (typhoid Vi polysaccharide vaccine and inactivated hepatitis A vaccine) with yellow fever vaccine.)

Adverse Reactions: Very common adverse reactions include: headache, myalgia, malaise, asthenia, injection site disorders (pain, induration, oedema, erythema). Common adverse reactions include: nausea, diarrhoea, arthralgia and fever. Serious adverse reaction frequency not known: anaphylactic/anaphylactoid reactions, including shock, serum sickness, vomiting, aggravation of asthma, paresthesia, and vasovagal syncope. No data on the safety of ViATIM in children and adolescents below 16 years are available. For a complete list of undesirable effects please refer to the Summary of Product Characteristics.

List price: Single dose prefilled syringe in single pack, basic NHS cost £35.76

Legal Category: POM

M**arketing Authorisation Number**: PL 46602/0009

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

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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