Prescribing Information: AVAXIM®, suspension for injection in a prefilled syringe, Hepatitis A vaccine (inactivated, adsorbed)

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

Presentation: Suspension for injection. Available as a 0.5 millilitre single dose prefilled syringe containing 160 antigen units of inactivated hepatitis A virus.

Indication: For primary or booster immunisation against infection caused by hepatitis A virus in susceptible adults and adolescents aged 16 years and above.

Dosage and Administration: A single 0.5 millilitre dose should be administered by intramuscular injection in the deltoid region. Immediately before use the syringe should be shaken well to obtain an homogenous suspension. To provide long term protection, a booster should be given between 6 and 36 months later. AVAXIM may be used as a booster in subjects from 16 years of age, vaccinated with another inactivated hepatitis A vaccine (monovalent or with purified Vi polysaccharide typhoid) 6 months to 36 months previously. The vaccine is to be injected intramuscularly. AVAXIM may be administered subcutaneously under exceptional circumstances (e.g. in patients with thrombocytopenia or in patients at risk of haemorrhage). Do not inject intravascularly. Also avoid administration into buttocks.

Special Populations:

Pregnancy and lactation: AVAXIM should not be used during pregnancy unless clearly necessary and following an assessment of the risks and benefits. The use of this vaccine is possible during breast-feeding.

Contraindications: Hypersensitivity to the active substance(s), to any of the excipients or to neomycin which may be present in the vaccine in trace amounts. Hypersensitivity following a previous injection of this vaccine. Vaccination should be delayed in subjects with acute severe febrile infections.

Precautions and Warnings: The effect of AVAXIM on individuals late in the incubation period of hepatitis A has not been documented. Immunogenicity could be impaired in immunosuppressed patients. AVAXIM is unnecessary for individuals raised in areas of high endemicity and/or with a history of jaundice as they may be immune to hepatitis A. Testing for antibodies to hepatitis A prior to a decision on immunisation should be considered in such situations. If not, seropositivity against hepatitis A is not a contraindication. AVAXIM is as well tolerated in seropositive as in seronegative subjects. Caution is advised for the use of AVAXIM in patients with liver disease. No clinical data on concomitant administration of AVAXIM with other inactivated vaccine(s) or recombinant hepatitis B virus vaccine have been generated. AVAXIM can be given at the same time as immunoglobulin but at different sites, however, antibody titres could be lower than after vaccination with AVAXIM alone. AVAXIM must not be mixed with other vaccines in the same syringe. AVAXIM can be administered at the same time as Vi polysaccharide typhoid vaccine or with a yellow fever vaccine reconstituted with a Vi polysaccharide typhoid vaccine, but at different sites. 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. AVAXIM is essentially 'potassium-free' and 'sodium-free' as it contains less than 1mmol of potassium (39 mg) and sodium (23 mg) per dose. It also contains 2 mg of alcohol (ethanol) in each 0.5 ml dose; the small amount will not have any noticeable effects. AVAXIM contains 10 microgram phenylalanine in each 0.5 ml dose which is equivalent to 0.17 microgram/kg for a 60 kg person. Phenylalanine may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Adverse Reactions: Very common side effects include: asthenia and mild injection site pain. Common side effects include: myalgia/arthralgia, headache, gastrointestinal tract disorders (nausea, vomiting, decreased appetite, diarrhoea, abdominal pain) and mild fever. In post-marketing experience other adverse reactions have been reported and include anaphylactic reaction, vasovagal syncope in response to injection, urticaria and rashes associated or not with pruritus. For a complete list of undesirable effects please refer to the Summary of Product Characteristics.

List price: Single dose prefilled syringes in single packs, basic NHS cost £21.72; packs of 10 single dose prefilled syringes, basic NHS cost £217.20.

Legal Category: POM

M**arketing Authorisation Number**: PL 46602/0001

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 035 2525. Alternatively, send via email to UK-drugsafety@sanofi.com