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

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

Presentation: Available as a 0.5 mL single dose pre-filled syringe containing 160 antigen units of inactivated hepatitis A virus.

Indication: Active immunisation against infection caused by hepatitis A virus in susceptible adults and adolescents aged 16 years and above. The use of AVAXIM should be based on official recommendations.

Dosage and Administration: A single 0.5 mL dose should be administered by intramuscular (IM) injection in the deltoid region. Protective levels of antibody may not be reached until 14 days after administration of the vaccine. To provide long term protection, a second dose (booster) should be given, preferably between 6 and 12 months later, but may be administered up to 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. AVAXIM may be administered subcutaneously under exceptional circumstances (e.g. in patients with thrombocytopenia or in patients at risk of haemorrhage). Do not inject intradermally or intravascularly. Also avoid administration into buttocks.

Special Populations: Paediatric population: AVAXIM is not recommended for use in children ≤15 years of age due to insufficient data on safety and efficacy.

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

Warnings and Precautions: AVAXIM does not provide protection against infection caused by hepatitis B virus, hepatitis C virus, hepatitis E virus or by other liver pathogens. As with any vaccine, vaccination may not result in a protective response in all susceptible vaccinees. Prior to immunisation: As with all vaccines, appropriate medical treatment and supervision should be readily available for immediate use in case of rare anaphylactic reaction following vaccination. The effect of AVAXIM on individuals late in the incubation period of hepatitis A has not been documented. Because of the incubation period of hepatitis A, infection may be present but not clinically apparent at the time of vaccination. 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. Administration precautions: AVAXIM has not been studied in patients with impaired immunity. The immune response to AVAXIM could be impaired by immunosuppressive treatment or in immunodeficiency states. Caution is advised for the use of AVAXIM in patients with liver disease. 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: AVAXIM is essentially 'potassium-free' and 'sodium-free' as it contains less than 1 mmol 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 µg phenylalanine in each 0.5 mL dose which is equivalent to 0.17 µg/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.

Interactions: 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. When concurrent administration is considered necessary, 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.

Fertility, pregnancy and lactation: There are no adequate data from the use of hepatitis A vaccine (inactivated, adsorbed) in pregnant women. 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.

Adverse Reactions: Very common: asthenia and mild injection site pain. Common: myalgia, arthralgia, headache, nausea, vomiting, decreased appetite, diarrhoea, abdominal pain and mild fever. Other Serious Adverse Drug Reactions (frequency not known): anaphylactic reaction, vasovagal syncope in response to injection, urticaria and rashes associated or not with pruritus. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List price: Single dose pre-filled syringes in single packs: £21.72; Packs of 10 single dose prefilled syringes: £217.20.

Legal Category: POM.

Marketing Authorisation Number: PL 23228/0006

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