ABRIDGED PRESCRIBING INFORMATION

AVAXIM®, suspension for injection in a prefilled syringe.

Hepatitis A vaccine (inactivated, adsorbed).

Refer to Summary of Product Characteristics for full product information.

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

Indications: For primary or booster immunisation against infection caused by hepatitis A virus in susceptible adults and adolescents aged 16 years and above. AVAXIM is to be used on the basis of official recommendations.

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.

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

Warnings and precautions: 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 also 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.

Pregnancy and lactation: AVAXIM should not be used during pregnancy unless clearly necessary and following an assessment of the risks and benefits. There are no data on the effect of administration of AVAXIM during lactation. AVAXIM is therefore not recommended during lactation.

Undesirable effects: 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.

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

Package quantities and basic NHS cost: Single dose prefilled syringes in single packs, basic NHS cost £18.10; packs of 10 single dose prefilled syringes, basic NHS cost £181.00.

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