Prescribing Information: AVAXIM JUNIOR suspension for injection in pre-filled 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 80 ELISA units of inactivated hepatitis A virus, GBM strain.

Indication: Active immunisation against infection caused by hepatitis A virus in children from 1 year up and including 15 years of age. The use of AVAXIM JUNIOR should be based on official recommendations.

Dosage and Administration: A single 0.5 mL dose should be administered intramuscularly (IM) in the deltoid area in older children and adolescents, and anterolateral area of the thigh in young children. The vaccine should not be administered into the buttocks. Initial protection starts within 2 weeks after administration. To provide long term protection, a second dose (booster) of vaccine is recommended. This booster dose should be given between 6 months to 10 years after the first dose. In line with WHO recommendation, in a setting transitioning from high to intermediate endemicity, in childhood immunization programmes either a single-dose or two-dose schedule (primary vaccination and booster) can be used. This vaccine can be used as a booster in subjects previously vaccinated with another inactivated hepatitis A vaccine. AVAXIM JUNIOR must not be administered intradermally or intravascularly – ensure that the needle does not penetrate a blood vessel. In exceptional circumstances (e.g., in patients with thrombocytopenia or in patients at risk of haemorrhage), the vaccine may be injected by the subcutaneous route.

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 illness.

Warnings and Precautions: AVAXIM JUNIOR 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 JUNIOR on individuals during the late stage of 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. In such a case, vaccination may not modify the course of infection. Individuals who have grown up in areas of high hepatitis A endemicity and/or with a history of jaundice may be immune to hepatitis A, in which case vaccine is unnecessary. Testing for antibodies to hepatitis A prior to a decision on immunisation could be considered in such situations. In the absence of testing, seropositivity against hepatitis A is not a contraindication to vaccination. Administration precautions: Syncope (fainting) can occur as a psychogenic response to the needle injection, especially in adolescents. This can be accompanied by several neurological signs and symptoms 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 JUNIOR has not been studied in patients with impaired immunity. The immune response to the vaccine could be impaired by immunosuppressive treatment or in immunodeficiency states. Excipients of known effect: It 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. AVAXIM JUNIOR contains 2 mg of alcohol (ethanol) in each 0.5 mL dose. It contains less than 1 mmol of potassium (39 mg) and sodium (23 mg) per dose.

Interactions: Separate injection sites and separate syringes must be used in case of concomitant administration with other medicinal products. The vaccine may be administered simultaneously with vaccines containing one or more of following valences: diphtheria, tetanus, pertussis (acellular or whole cells), *Haemophilus influenzae* of type b, inactivated or oral poliomyelitis, measles, mumps and rubella.

Fertility, pregnancy and lactation: Limited data are available on the use of AVAXIM vaccines in pregnant women. However, no conclusions can be drawn regarding whether AVAXIM JUNIOR is safe for use during pregnancy. AVAXIM JUNIOR should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus. AVAXIM JUNIOR can be used during breast-feeding.

Adverse Reactions: Very common: abnormal crying, headache, injection site pain and malaise. Common: appetite decrease, irritability, insomnia, abdominal pain, diarrhoea, nausea, vomiting, arthralgia, myalgia, pyrexia, injection site reactions (erythema, induration or oedema, haematoma), asthenia or drowsiness. Other Serious Adverse Drug Reactions (frequency not known): anaphylactic reaction, vasovagal syncope in response to injection, convulsions with or without fever. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List price: Single dose pre-filled syringe: £16.77

Legal Category: POM.

Marketing Authorisation Number: PL 23228/0007

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