Prescribing Information: AVAXIM JUNIOR, suspension for injection in pre-filled syringe Hepatitis A vaccine (inactivated, adsorbed)

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

Presentation: Suspension for injection in pre-filled syringe. Available as a 0.5 millilitre single dose prefilled 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 millilitre dose should be administered intramuscularly in the deltoid area in older children and adolescents, and anterolateral area of the thigh in young children. Immediately before use, the syringe should be shaken well to obtain a homogenous suspension. The vaccine should be visually inspected before administration for any foreign particulate matter. 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. The vaccine should not be administered into the buttocks.

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 illness.

Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Precautions and Warnings: As with all vaccines, appropriate medical treatment and supervision should be readily available for immediate use in case of rare anaphylactic reaction following vaccination. As a psychogenic response to the needle injection, Syncope (fainting) can occur, especially in adolescents. This can be accompanied by several neurological signs and symptoms. 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. The effect of AVAXIM JUNIOR on individuals during the late stage of the incubation period of hepatitis A has not been documented. 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. It does not provide protection against infection caused by hepatitis B virus, hepatitis C virus, hepatitis E virus or by other liver pathogens. It 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. AVAXIM JUNIOR contains 2 mg of alcohol (ethanol) in each 0.5 ml dose. It contains less than 1mmol of potassium (39 mg) and sodium (23 mg) per dose. In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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.

Pregnancy: Limited data are available on the use of AVAXIM vaccines in pregnant women. No animal reproductive studies have been conducted. 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 foetus.

Breast-feeding: AVAXIM JUNIOR can be used during breastfeeding.

Fertility: AVAXIM JUNIOR has not been evaluated for impairment of male or female fertility.

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 erythema, asthenia or drowsiness, injection site induration or oedema, injection site haematoma.

Not Known: anaphylactic reactions, convulsions with or without fever. Please refer to the SPC for full list of adverse events.

List price: £16.77 for single dose pre-filled syringe. **Legal Category:** POM. **Marketing Authorisation Number**: PL 46602/0023. **Marketing Authorisation Holder:** Sanofi Pasteur, 14 Espace Henry Vallée, 69007 Lyon, France. **Further information is available from:** Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire RG6 1PT 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