For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory
Abridged Prescribing information

INACTIVATED HEPATITIS A VACCINE ADSORBED I.P.
Avaxim® 80U

QUALITATIVE & QUANTITATIVE COMPOSITION:
Hepatitis A virus GBM strain* (inactivated) **…….80 U***
For one dose of 0.5 mL.
Per container (for one 0.5 ml dose)

Component[1]	**Quantity (per container)**	**Function**
Hepatitis A virus, GBM strain (inactivated)	80 U	Active substance
Aluminium hydroxide, hydrated	0.15 milligrams Al^{3+}	Adjuvant
Phenoxyethanol – Ethanol (50% v/v solution) - 2-phenoxyethanol - ethanol anhydrous	 2.5 µL 2.5 µL	Preservative
Formaldehyde	12.5 µg	Preservative
1 x C Medium 199 Hanks (without phenol red)[2]	q.s. 0.5 mL	Stabilizer and buffer

* Cultured on MRC-5 human diploid cells.
** Adsorbed on hydrated aluminium hydroxide (0.15 milligrams of Al).
*** In the absence of an international standardised reference, the antigen content is expressed using an in-house reference
[1]- Hydrochloric acid and or sodium hydroxide can be used for pH adjustment. These components are only present in trace amount.

[2] - 1 x C Medium 199 Hanks (without phenol red) is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins and other substances (see detailed composition in section 6.1). It is supplemented with polysorbate 80 and is reconstituted in water for injections.

THERAPEUTIC INDICATIONS:
AVAXIM 80 U PEDIATRIC is a vaccine. Vaccines are used to protect you against infectious diseases. This vaccine helps protect your child aged from 12 months to 15 years inclusive against the infection caused by the hepatitis A virus. Hepatitis A infection is caused by a virus which attacks the liver. It can be transmitted by food or beverages containing the virus. Symptoms include yellowing of the skin (jaundice) and feeling generally unwell. When your child receives an injection of AVAXIM 80 U PEDIATRIC, the natural defences of his/her body develop a protection against the infection caused by the hepatitis A virus. This vaccine should be administered in accordance with official recommendations.

POSOLOGY AND ADMINISTRATION
Pediatric population
- Primary vaccination- Primary vaccination is achieved with one vaccine dose of 0.5 mL.
- Booster- One booster dose of 0.5 mL is recommended in order to provide long-term protection. This booster dose will preferably be administered 6 to 36 months following the primary

vaccination dose, but administration will be possible until 7 years after this primary vaccination.

Available data on vaccination with AVAXIM 80 U PEDIATRIC show that after the two doses of the initial vaccination schedule, no other booster vaccination is necessary in immunocompetent individuals, which is in agreement with the official recommendations.

Method and/or routes of administration
AVAXIM 80 U PEDIATRIC must be administered into a muscle (in order to minimise local reactions), in the outer upper part of your child's arm.
If your child has haemophilia or if he/she bruises or bleeds easily, the vaccine can exceptionally be administered under his/her skin.
This vaccine must never be administered into a blood vessel.
The doctor must not inject the vaccine into the skin.
The vaccine will not be administered into the buttock.

DOSAGE FORMS AND STRENGTHS: Suspension for injection in pre-filled syringe. The hepatitis A vaccine (inactivated, adsorbed) is a turbid and whitish suspension.

SAFETY RELATED INFORMATION

CONTRAINDICATIONS:

- If your child is allergic to the active substance or any of the other ingredients of AVAXIM 80 U PEDIATRIC (listed in section 2 and 6.1).
- If your child is allergic to neomycin (an antibiotic used during the manufacturing process of the vaccine, and which may be present in it in small amounts).
- If your child is allergic to AVAXIM 80 U PEDIATRIC.
- If your child has a disease with a high temperature. Vaccination should be postponed until he/she has recovered.

SPECIAL WARNING AND PRECAUTIONS FOR USE:

- Take special care
  - weakened immune system due to:
    - Corticosteroids, cytotoxic drugs, radiotherapy or other treatments
    - HIV (Human immunodeficiency virus) infection or any other diseases that weaken immune system. Vaccine administration is recommended although it may not protect him/her as well as it protects people with a normal immune system
  - liver disease.
  - haemophilia or is easily subject to bruises or bleeding.
  - Fainting can occur (especially in adolescents) following, or even before, any needle injection.

The vaccine does not protect against infection caused by hepatitis B virus, hepatitis C virus, hepatitis E virus or by other known liver pathogens. If your child is already infected by the hepatitis A virus at the time of the administration of AVAXIM 80 U Pediatric, the vaccination may not work properly.
The vaccine cannot cause the infections against which it protects.
As with all vaccines, not all people who receive AVAXIM 80 U Pediatric will definitely be

protected against hepatitis A.

USE IN SPECIFIC POPULATIONS

Pregnancy and breast-feeding: As a precautionary measure, it is preferable not to use this vaccine during pregnancy, except in case of a major contamination risk. The use of this vaccine is possible during breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Ask your doctor advice before using any medicinal product.

ADVERSE REACTIONS:

Common reactions (reported by less than 1 in 10 people but more than 1 in 100 people): appetite decrease, irritability, insomnia, headache, belly pain, diarrhea, nausea, vomiting, muscle and joint pain, local injection site reactions such as pain, redness, swelling or induration, fever, fatigue.
Uncommon reactions (reported by less than 1 in 100 people but more than 1 in 1000 people): skin eruptions (rash) with itching (urticaria).
Very rare reactions (reported by less than 1 in 10 000 people): Fainting in response to injection.

All undesirable effects were moderate and confined to the first few days following vaccination with spontaneous recovery.

For full prescribing information, please contact Sanofi Healthcare India Pvt. Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400 072, India

Date of update: May 2023
Source: EU-SMPC dated 10 Jul 2019 (CCDS version 11, 12, 13)