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 Pediatric
Suspension for injection in pre-filled syringe

QUALITATIVE & QUANTITATIVE COMPOSITION:

Each dose of 0.5 ml PFS contains:
Inactivated Hepatitis A antigen…… 80 Elisa Unit (EU)
[G.B.M (Village of Gomaringen + Name of the patient B.M) strain cultured on MRC-5 human diploid cells]
Aluminium hydroxide expressed as Aluminium….. 0.15mg Al^{3+}
Phenoxyethanol Ethanol (50%v/v) solution
- 2-phenoxyethanol, Ph. Eur …….. 2.5 µL
- Ethanol anhydrous, Ph. Eur…….. 2.5 µL

Formaldehyde……..12.5 µg
1x C Medium 199 Hanks (without Phenol Red)…… q.s. to 0.5mL
2.5 M Sodium hydroxide……. Up to pH 7.0±0.1
10% Hydrochloric acid…… Up to pH 7.0±0.1

THERAPEUTIC INDICATIONS:

For prevention of infections caused by Hepatitis A virus in children in the age group of 12 months to 15 years.

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
This vaccine must be administered by the intramuscular route.
The recommended injection site is the deltoid region.
In exceptional cases, the vaccine may be administered by the subcutaneous route in patients suffering from thrombocytopaenia or in patients at risk of haemorrhage.

The vaccine should not be administered into the buttocks because of the varying amount of fat tissue in this region, that may contribute to variability in effectiveness of the vaccine.
Do not inject by the intravascular route: ensure that the needle does not penetrate a blood vessel.
Do not inject by the intradermal route.

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:

- Hypersensitivity to the active substance, to one of the excipients, to neomycin (that may be present as traces in each dose due to its use during the manufacturing process).
- Hypersensitivity following a previous injection of this vaccine.
- Vaccination should be postponed in case of severe acute febrile illness.

SPECIAL WARNING AND PRECAUTIONS FOR USE:

As with all injectable vaccines, available appropriate medical treatment and subject monitoring are recommended in case of an anaphylactic reaction after vaccine administration.
Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection, especially in adolescents. This may be accompanied by several neurological signs such as transient sight disorders, paraesthesia and tonic-clonic limb movements during the recovery phase. It is important that procedures be in place to avoid any injury from faints.
AVAXIM 80U PEDIATRIC has not been studied in patients with impaired immunity.
The immune response to the vaccine may be impaired by immunosuppressive treatment or immunodeficiency. In such cases it is recommended to wait for the end of treatment before vaccinating or to make sure the subject is well protected. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even though the antibody response might be limited.
Because of the incubation period of hepatitis A, infection may already be present, although asymptomatic, at the time of vaccination.
The effect of administering AVAXIM 80U PEDIATRIC during the incubation period of hepatitis A has not been documented.
In such a case, vaccination may have no effect on the development of hepatitis A.
The use of this vaccine in subjects with liver disease should be considered with caution, as no studies have been performed in such subjects.
As with all vaccines, vaccination may not induce a protective response in some vaccinees.
The vaccine does not protect against infection caused by hepatitis B virus, hepatitis C virus, hepatitis E virus or by other known liver pathogens.

USE IN SPECIFIC POPULATIONS

Pregnancy and breast-feeding:
No relevant teratogenic data on animal are available.
In humans, up to now, the data is inadequate to assess teratogenic or foetotoxic risk of the vaccine against Hepatitis A when administered during pregnancy.
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.

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.
Not known- Anaphylactic reaction, Seizures with or without fever

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

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