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
COMPOSITION
The active substance is:-
Hepatitis A virus (GBM strain)* inactivated**. . . . . .80U*** For one dose of 0.5 ml
* cultured on MRC-5 human diploid cells
** Adsorbed on hydrated aluminum hydroxide (0.15 milligrams of Al) ***
Antigen units expressed using an in-house reference
Other components are 2-Phenoxyethanol, formaldehyde, Hanks Medium 199 without phenol red (a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins, and other components) supplemented with polysorbate 80 and diluted into water for injections with a pH adjusted with hydrochloric acid or sodium hydroxide.

THERAPEUTIC INDICATIONS
This vaccine is recommended for the prevention of the infection caused by the hepatitis A virus in children aged from 12 months to 15 years inclusive.
DOSAGE AND ADMINISTRATION
This medicinal product is a vaccine in the form of a suspension for injection. The recommended dosage is 0.5 mL for each injection.
The vaccination schedule includes a single primary vaccination dose. A booster injection is recommended 6 to 36 months later in order to obtain long-term protection. This booster will protect child against hepatitis A beyond 10 years.

Method and/or routes of administration
This vaccine must be administered by the intramuscular route. In exceptional cases, the vaccine may be administered by the subcutaneous route in patients suffering from thrombocytopaenia or in patients at risk of haemorrhage. Do not inject intravascular or intradermal route. Do not inject into buttock.

CONTRAINDICATIONS
- An allergy to the active substance, to any of the other ingredients of vaccine, to neomycin or shown hypersensitivity following a previous injection of this vaccine.
- A febrile illness, acute infection or progressive chronic disease (it is preferable to postpone vaccination).

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.

WARNING AND PRECAUTIONS
- 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.

- 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.

SAFETY RELATED INFORMATION

Common reactions (reported by less than 1 in 10 people but more than 1 in 100 people): appetite decrease, irritability, insomnia, headache, belly pain, diarrhoea, 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 Pasteur 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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