

Registration No. : 1C.109/46 (N)

Importer / Manufacturer: Sanofi Pasteur Ltd., Thailand/Sanofi Pasteur S.A., France

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT : AVAXIM 80U PEDIATRIC, Inactivated hepatitis A vaccine, adsorbed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hepatitis A virus (GBM strain)*, inactivated**80U***
For one 0.5 ml dose

* cultured on MRC-5 human diploid cells

** adsorbed on aluminium hydroxide (quantity equivalent to 0.15 mg of aluminium)

*** antigen units expressed using an in-house reference.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection in prefilled syringe

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The vaccine is recommended for the prevention of infection caused by hepatitis A virus in children from 12 months to 15 years inclusive.

4.2 Posology and method of administration

Posology:

The recommended dose is 0.5 ml for each injection.

The vaccination schedule includes a primary vaccination dose. A booster injection is recommended 6 to 18 months later.

Method and/or routes of administration:

Intramuscular route, muscle in the upper arm.

Shake before injection, until a homogenous suspension is obtained.

In case you forgot to take AVAXIM 80U Pediatric:

Your doctor will decide when to administer this missing dose.

4.3 Contraindication

Do not use AVAXIM 80U Pediatric if your child has:

- allergy to the active substance to one of excipients, to neomycin, to polysorbate or shown hypersensitivity following a previous injections of this vaccine,
- a febrile illness, acute infection or progressive chronic disease (it is preferable to postpone vaccination).

4.4 Special warnings and precautions for use

Inform your doctor if your child suffers from:

- immunodepression

This vaccine should never be administered by the intravascular or intradermal route.

4.5 Interaction with other medical products and forms of interaction

The immunological response may be diminished in case of immunosuppressive treatment. The vaccine may be administered simultaneously, at two different injection sites, with the routine booster vaccines given to children during the second year of life, i.e. the various vaccines containing one or more of the following valences: diphtheria, tetanus, pertussis (acellular or whole cell), haemophilus influenzae type b and inactivated or oral poliomyelitis.

Please inform your doctor or your pharmacist of any ongoing treatment, or if other medicinal products, even if non-prescription, have been taken recently.

4.6 Pregnancy and lactation

This vaccine should be used in pregnant women on medical advice only.

The vaccine can be used during lactation.

Ask your doctor or pharmacist for advice before using any medicinal product.

4.7 Effects on the ability to drive and use machines

The vaccine is unlikely to produce an effect on the ability to drive and use machines.

4.8 Undesirable effects

As with all medicinal product, Avaxim 80U Pediatric may cause undesirable effects:

The most common reaction are:

- local reactions at the injection site, such as pain, redness, oedema or induration,
- systemic reactions such as headaches, gastrointestinal tract disorders (abdominal pain, diarrhoea, nausea, vomiting), muscular or joint pain, transitory behaviour changes (appetite decrease, insomnia, irritability), fever, asthenia.

Cutaneous manifestations (rash, urticaria) have been observed on rare occasions.

All adverse reactions were moderate and confined to the first few days following vaccination, with spontaneous recovery.

Please inform your doctor or pharmacist if you notice any other undesirable effects not mentioned in this package insert.

List of excipients with known effect:

Formaldehyde

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

phenoxyethanol, formaldehyde, Hanks medium 199 which is a complex mixture of amino acids, mineral salts, vitamins, hydrochloric acid or sodium hydroxide for pH adjustment and water for injections.

6.2 Incompatibilities

6.3 Shelf life

3 years

6.4 Special precautions for storage

The product should be stored at + 2 °C to + 8 °C (in a refrigerator) and protected from light. Do not freeze.

6.5 Nature and contents of container

0.5 ml of suspension in a prefilled syringe (Type I glass) with needle in a box of 1

6.6 Special precautions for disposal and other handling

Do not use after the expiry date indicated on the label or on the box.

The vaccine should not be used in case of discolouration or presence of foreign particles.

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur Ltd., Bangkok, Thailand

8. MARKETING AUTHORISATION NUMBER(S)

1C 109/46 (N)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31 December 2003

10. DATE OF REVISION OF THE TEXT

December 2003

Date of local approval: 10 January 2005

(The above information is based on the currently approved leaflet)