

AVAXIM 80 U

Pediatric

INACTIVATED ADSORBED
HEPATITIS A VACCINE



Please study this leaflet carefully before receiving AVAXIM 80U Pediatric.

Keep this leaflet for reference purposes until you have completed the vaccination schedule. You should follow your doctor's or nurse's advice attentively. If you need further information or advice, please contact your doctor or nurse. Make sure you complete the full vaccination schedule, or you may not be fully protected. This vaccine has been prescribed specifically to your child. Do not give it to anyone else.

COMPOSITION

The active ingredient is inactivated** hepatitis A virus (GBM strain)* 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).

*** antigenic units measured according to the manufacturer's internal method

The other ingredients are phenoxyethanol, formaldehyde, Hanks medium 199 containing, among others, a complex mixture of amino acids, mineral salts, vitamins, hydrochloric acid or sodium hydroxide to maintain pH between 6.8 and 7.8 water for injections.

MARKETING AUTHORIZATION HOLDER

AVENTIS PASTEUR SA
2, avenue Pont Pasteur
69007 Lyon – France

I. WHAT IS AVAXIM 80U Pediatric AND WHAT IS IT USED FOR?

AVAXIM 80U Pediatric comes in the form of a suspension for injection in a prefilled syringe (0.5 ml) or multi-dose vial (ten 0.5 ml doses).

This vaccine is recommended in the prevention of infection induced by hepatitis A virus in children from ~~12 months~~ to 15 years inclusive.

2. WHAT INFORMATION IS REQUIRED BEFORE USING AVAXIM 80U Pediatric?

Do not use AVAXIM 80U Pediatric if you are/your child is:

- allergic to the active ingredient, to any of the excipients, to neomycin, or to polysorbate or if you have / your child has already experienced an allergic reaction following a previous vaccine administration,
- suffering from a febrile disease, acute disease, progressive chronic disease (it is preferable to postpone vaccination).

Be particularly careful to AVAXIM 80U Pediatric:

Inform your doctor if you are/your child is:

- immunocompromised.

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

Pregnancy and lactation: ~~not recommended~~

Pregnant women should ~~only~~ use this medicinal product on their doctor's advice.

Vaccination with this vaccine is not a ~~contra~~ indication to breastfeeding.

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

Rancangan Leaflet

Driving and using machinery:

It is improbable that vaccination will induce an effect on the ability to drive or operate machinery.

List of excipients with a well-known effect:

Formaldehyde

Use of other medicinal products:

The immunological response may be diminished in the event of immunosuppressive treatment. Please inform your doctor or your pharmacist if you are taking recently taken any other medicinal product, even without a prescription.

3. HOW TO USE AVAXIM 80U Pediatric

Posology:

The recommended dose is 0.5 mL for each injection.

The vaccination schedule includes a primary vaccination dose. It is recommended to administer a booster 6 months later.

Method of administration:

Intramuscular route, into the upper arm muscle.

Shake before use until you obtain a homogeneous suspension.

If you miss a vaccination with AVAXIM 80U Pediatric:

Your doctor will decide when to administer the missing dose.

4. WHAT ARE THE POSSIBLE UNDESIRABLE EFFECTS?

As for any medicinal product, Avaxim 80U Pediatric is liable to have undesirable effects:

The most frequent reactions are:

-local reactions at the injection site, such as pain, redness, swelling or induration,

-Systemic reactions such as headaches, gastrointestinal disorders (abdominal pain, diarrhoea, nausea, vomiting), muscle and joint pain, transient behavioural disorders (loss of appetite, insomnia, irritability), fever, asthenia.

Skin symptoms (rash, urticaria) have been more rarely reported.

All the undesirable effects were moderate and limited to the first days following the vaccination, with spontaneous regression.

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

5. HOW TO STORE AVAXIM 80U Pediatric?

Keep out of the reach and sight of children.

The vaccine should be stored away from light, between +2°C and +8°C (in a refrigerator).

The vaccine should not be frozen.

PACKAGES:

Prefilled syringe 0.5 mL
vial 5 mL

Imported by:

PT Aventis Pharma, Jakarta, Indonesia



Harus dengan resep dokter

Aventis Pasteur

*Aventis