HCP-MEPPO
Publishers of MEPPO and MODERN MEDICINE

AVAXIM 80 U
Sanofi-Pasteur

Pediatric
INACTIVATED HEPATITIS A VACCINE, ADSORBED
Please read all the package insert instructions carefully before vaccination.

Keep this leaflet until completion of the vaccination schedule.

You may need to read it again.

Follow carefully the advice of your doctor or nurse. If you need further information and advice, contact your doctor or nurse.

Ensure that the whole immunization schedule has been completed. Otherwise, the protection may be insufficient.

This vaccine has been prescribed for your child personally. Do not pass it on to others.

COMPOSITION

The active ingredient is: Hepatitis A virus (GBM strain)*, inactivated** 80 U***

For one dose of 0.5 ml

* cultured on MRC-5 human diploid cells
** adsorbed on aluminium hydroxide (quantity corresponding to 0.15 mg of aluminium)
*** antigen units expressed using an in-house reference

The other components are 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 injection.

MARKETING AUTHORIZATION HOLDER

SANOFI PASTEUR SA 2, avenue Pont Pasteur
69007 Lyon, France

1.WHAT IS AVAXIM 80 U Pediatric AND WHEN SHOULD IT BE USED?

AVAXIM 80 U Pediatric is a suspension for injection in a prefilled syringe (0.5 ml) or in a multidose vial (10 doses of 0.5 ml).

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.

2. INFORMATION YOU SHOULD HAVE BEFORE USING AVAXIM 80 U Pediatric

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

- an allergy to the active substance, to one of the excipients, to neomycin, to polysorbate, 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).

Take special care with AVAXIM 80 U Pediatric

Inform your doctor if your child suffers from:

- immunodepression.

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

Pregnancy and lactation:

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

The vaccine can be used during lactation.

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

Driving vehicles and operating machines

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

List of excipients with known effect:

Formaldehyde

Use with other medicinal products:

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 pharmacist of any

ongoing treatment, or if any other medicinal products, even if non-prescription, have been taken recently.

3.HOW TO USE AVAXIM 80 U Pediatric?

Posology:

The recommended dose is 0.5 ml for each injection.

The vaccination schedule includes one 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 80 U Pediatric:

Your doctor will decide when to administer this missing dose.

4.WHAT ARE THE POSSIBLE UNDESIRABLE EFFECTS?

As with all medicinal products, AVAXIM 80 U Pediatric may cause undesirable effects:

The most common reactions 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.

5.HOW TO STORE AVAXIM 80 U Pediatric?

Keep out of the reach and sight of children.

The product should be stored at +2°C to +8°C (in a refrigerator) and protected from light.

Do not freeze.

Multidose vials presentation: after opening, the vaccine should be used immediately.

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.

Date of last revision of this leaflet: 12/2003

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AVAXIM 160 U

Sanofi-Pasteur

HEPATITIS A VACCINE
(INACTIVATED, ADSORBED)

Suspension for intramuscular injection in a pre-filled syringe

The active substance is the inactivated** hepatitis A virus (GBM strain)* (160 units***/for one 0.5 ml dose).

* cultured on MRC-5 human diploid cells.
** adsorbed on aluminium hydroxide (quantity corresponding to 0.3 mg of aluminium).
*** antigen units measured using an in-house reference.

Read all of this leaflet carefully before you are vaccinated.

Keep this leaflet until you have completed the vaccination schedule. You may need to read it again.

Follow carefully the advice of your doctor or nurse. Ask your doctor or your nurse if you need more information or advice.

Make sure you complete the full vaccination schedule. Otherwise you may not be fully protected.

The other ingredients are phenoxyethanol, formaldehyde, and Hanks 199 Medium (containing a complex mixture of amino acids, mineral salts, vitamins, hydrochloric acid, or sodium hydroxide for adjusting the pH and water for injections).

Marketing Authorization Holder and Manufacturer:
SANOFI PASTEUR SA 2, avenue Pont Pasteur 69007 Lyon - France

1.WHAT AVAXIM 160 U IS AND WHAT IT IS USED FOR

This medicinal product is a VACCINE in a 0.5 ml prefilled syringe,

– This vaccine is recommended for the prevention of infection caused by the hepatitis A virus in adolescents from 16 years of age and in adults.

- Vaccination against viral hepatitis A is recommended for subjects at risk of exposure to hepatitis A virus including:

- non-immunized adolescents from 16 years of age and adults travelling in endemic areas,
- adults at risk of contamination through their work: nursery personnel, personnel in residential institutions and homes for handicapped children and young people, sewage and water treatment personnel, food industry and catering personnel,
- adolescents from 16 years of age living in residential institutions and homes for handicapped children and young people,
- adolescents from 16 years of age and adults exposed to specific risks: haemophilia, multiple transfusions, IV drug addiction, homosexual practices,
- adolescents from 16 years of age and adults chronically infected by hepatitis B virus.

- It does not protect against infection due to other types of hepatitis virus or other known pathogens of the liver.

2. BEFORE YOU USE AVAXIM 160 U

Do not use AVAXIM 160 U:

– in the event of fever, acute illness, chronic progressive disease (it is preferable to postpone vaccination),
– hypersensitivity to one of the vaccine components or following a previous injection.

Take special care with AVAXIM 160 U:

– do not inject by the intravascular route: ensure that the needle does not penetrate a blood vessel,
– this vaccine is not to be injected into the buttocks (due to the presence of varying amounts of adipose tissue), nor administered intradermally, since these routes of administration may result in a weaker immune response,
– immunosuppressant treatment or a state of immune deficiency may lead to a diminished immune response to the vaccine,
– vaccination may have no effect on the development of hepatitis A if administered during the incubation period of the disease,

– in subjects with a liver disease,
– in subjects who are hypersensitive to neomycin (each dose of vaccine contains trace amounts of neomycin).

Pregnancy and breast-feeding:
As a precautionary measure, this vaccine is not recommended in pregnant women except in case of a major contamination risk.

The use of this vaccine is possible during breast-feeding.

List of excipients with known effect:
Formaldehyde

Taking or using other medicines:
This vaccine may be administered simultaneously with immunoglobulins provided two different injection sites are used.

As the vaccine is inactivated, its use in association with other inactivated vaccine(s) at different injection sites does not generally result in any interaction.

This vaccine can be administered at the same time, but at separate sites, as a polysaccharide typhoid vaccine or a recombinant hepatitis B vaccine.

This vaccine can also be administered at the same time, but at separate sites, as a live yellow fever vaccine.

This vaccine can be used as a booster dose in subjects who have received primary vaccination with another inactivated hepatitis A vaccine.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3.HOW TO USE AVAXIM 160 U
Posology:

The recommended dosage is 0.5 ml for each injection.

The primary vaccination consists of one single dose of vaccine followed by a booster injection 6 to 12 months later.

Method and route of administration:
It is recommended that this vaccine be administered by the intramuscular route (IM) in order to minimize local reactions.

The recommended injection site is the deltoid region (upper arm muscle).

Do not inject by intravascular route: make sure that the needle does not enter a blood vessel.

This vaccine is not to be injected into the buttocks (due to the presence of varying amounts of adipose tissue), nor administered intradermally, since these routes of administration may induce a weaker immune response.

In exceptional cases, the vaccine may be administered by the subcutaneous route in patients suffering from thromocytopaenia (inadequate amount of platelets, a specific blood component with an important role in blood clotting) or in patients at risk of haemorrhage.

This vaccine must not be mixed with other vaccines in the same syringe.

Shake before injection, until a homogenous suspension is obtained.

Any unused product or waste material should be disposed of in accordance with local requirements.

4. POSSIBLE SIDE EFFECTS
Like any medicines, AVAXIM 160 U can have side effects in certain subjects:
– local pain sometimes combined with redness. The appearance of a nodule at the injection site has been observed in very rare cases,
– moderate fever, fatigue, headache, muscle or joint pains, and gastrointestinal disorders have been the most commonly observed side effects,
– a mild reversible rise in liver enzymes (transaminases) has been observed on rare occasions,
– exceptional cutaneous reactions such as pruritus, rash (cutaneous eruption), or urticaria have been observed.

Inform your doctor if these symptoms persist or worsen.

5. STORING AVAXIM 160 U
Keep out of the reach and sight of children.
Store in a refrigerator (2°C - 8°C). Do not freeze.

Do not exceed the expiry date stated on the external packaging.

This package leaflet was last approved on: November 2004