


Inactivated Hepatitis A vaccine, adsorbed I.P.


AVAXIM 80U

Pediatric

suspension for injection in prefilled syringe



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Read all of this leaflet carefully before you start using this medicine because it contains important information for your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This vaccine has been prescribed for your child only. Do not pass it on to others. It may harm them.
- If your child gets any side effects, talk to you doctor. This includes any possible side effects not listed in this leaflet. See Section 4.

Warning: To be sold by retail on the prescription of a Registered Medical Practitioner.

What is in this leaflet:

1. What AVAXIM 80 U Pediatric is and what it is used for
2. What you need to know before you use AVAXIM 80 U Pediatric
3. How to use AVAXIM 80 U Pediatric
4. Possible side effects
5. How to store AVAXIM 80 U Pediatric
6. Further information

1. What AVAXIM 80 U Pediatric is and what it is used for

AVAXIM 80 U PEDIATRIC is a vaccine. Vaccines are used to protect you against infectious diseases. This vaccine helps protect your child aged from 12 months to 15 years inclusive against the infection caused by the hepatitis A virus. Hepatitis A infection is caused by a virus which attacks the liver. It can be transmitted by food or beverages containing the virus. Symptoms include yellowing of the skin (jaundice) and feeling generally unwell. When

your child receives an injection of AVAXIM 80 U PEDIATRIC, the natural defences of his/her body develop a protection against the infection caused by the hepatitis A virus. This vaccine should be administered in accordance with official recommendations.

2. What you need to know before you use AVAXIM 80 U Pediatric

- Do not use AVAXIM 80U Pediatric:
- If your child is allergic to the active substance or any of the other ingredients of AVAXIM 80 U PEDIATRIC (listed in section 6).
 - If your child is allergic to neomycin (an antibiotic used during the manufacturing process of the vaccine and which may be present in it in small amounts).
 - If your child is allergic to AVAXIM 80 U PEDIATRIC.
 - If your child has a disease with a high temperature. Vaccination should be postponed until he/she has recovered.

Warnings and precautions

Inform your doctor:

- If your child has a weakened immune system due to:
 - o Corticosteroids, cytotoxic drugs, radiotherapy or other treatments likely to weaken his/her immune system. Your doctor may wait until treatment is over.
 - o HIV (Human immunodeficiency virus) infection
- or any other diseases that weaken his/her immune system. Vaccine administration is recommended although it may not protect him/her as well as it protects people with a normal immune system.
- If your child has a liver disease.
- If your child has haemophilia or is easily subject to bruises or bleeding.
- Fainting can occur (especially in adolescents) following, or even before, any needle injection. Therefore tell your doctor if your child fainted with a previous injection.

This vaccine will not protect your child against other viruses that infect the liver (such as hepatitis B, hepatitis C or hepatitis E viruses). 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.

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. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. *Ask for your doctor advice before using any medicinal product.*

Driving or using machines

The vaccine is unlikely to have any effects on the ability to drive and use machines. However no studies on this were performed.

Other medicines and AVAXIM 80 U PEDIATRIC

The immunological response may be diminished in case of immunosuppressive treatment.

The vaccine may be administered at the same time as at two different injection sites, with the routine booster vaccines given to children during the second year of life, i.e. the various vaccines against: diphtheria, tetanus, pertussis (acellular or whole cell), *haemophilus influenzae* type b and inactivated or oral poliomyelitis.

This vaccine can also be administered at the same time as a vaccine against measles, mumps and rubella.

All injections must be performed in separate injection sites, i.e. in another part of the body such as another arm or another leg, and the vaccines must not be mixed in the same syringe.

This vaccine can be administered at the same time as immunoglobulins (antibodies obtained from blood donation) but in two separate injection sites. AVAXIM 80 U PEDIATRIC may not work so well if it is given at the same time as the immunoglobulins. However your child will probably be protected against the hepatitis A infection.

This vaccine can be used as a booster dose in subjects who have received a first vaccination with another inactivated hepatitis A vaccine. If your child is taking or has recently taken any other medicines, even one obtained without a prescription, please tell your doctor.

3. How to use AVAXIM 80U Pediatric?

Dosage:

The recommended dose 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 your child against hepatitis A beyond 10 years.

Method and/or routes of administration

AVAXIM 80 U PEDIATRIC must be administered into a muscle (in order to minimise local reactions), in the outer upper part of your child's arm.

If your child has haemophilia or if he/she bruises or bleeds easily, the vaccine can exceptionally be administered under his/her skin. This vaccine must never be administered into a blood vessel. The doctor must not inject the vaccine into the skin. The vaccine will not be administered into the buttock. The doctor will shake the syringe immediately before the injection and will make sure the liquid is turbid and whitish and there are no foreign particles.

In case you forgot to take AVAXIM 80U Pediatric:

Your doctor will decide when to administer this missing dose. If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, AVAXIM 80 U PEDIATRIC can cause side effects, although not everybody gets them.

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.

Reporting of side effects

If your child gets any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store AVAXIM 80U 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. Do not use after the expiry date indicated on the label or on the box. The expiry date refers to the last day of that month. The vaccine should not be used in case of discolouration or presence of foreign particles. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What AVAXIM 80 U Pediatric contains

The active substance 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 hydrated aluminium hydroxide (0.15 milligrams of Al)
***Antigen units expressed using an in-house reference.

The 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.

What AVAXIM 80 U Pediatric looks like and contents of the pack

AVAXIM 80 U PEDIATRIC is a suspension for injection in pre-filled syringe (0.5 mL) with or without needle - box of 1, 10 or 20. All pack sizes may not be marketed. The hepatitis A vaccine (inactivated, adsorbed) is a turbid and whitish suspension.

The following information is intended for health care professionals only:
This vaccine must not be mixed with other vaccines in the same syringe.

Manufactured by :

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