AVAXIM 80 U PEDIATRIC, suspension for injection in pre-filled syringe

Hepatitis A vaccine (inactivated, adsorbed)

Read all of this leaflet carefully before you have your child vaccinated because it contains important information for you.

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

What is in this leaflet

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 80 U 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

Talk to your doctor, pharmacist or nurse before using AVAXIM 80 U PEDIATRIC.

Children and adolescents

- If your child has a weakened immune system due to:

- Corticosteroids, cytotoxic drugs, radiotherapy or other treatments likely to weaken his/her immune system. Your doctor may wait until treatment is over.
- 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 or nurse 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.

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 routine booster vaccines of the child during the second year of life, i.e. the various vaccines against diphtheria, tetanus, pertussis, *Haemophilus influenzae* of type b and poliomyelitis.

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

All injections must be perfomed 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.

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

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 or pharmacist for advice before receiving this vaccine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

AVAXIM 80 U PEDIATRIC contains phenylalanine, ethanol, potassium and sodium

AVAXIM 80 U PEDIATRIC contains 10 micrograms of phenylalanine in each 0.5 mL dose, which is equivalent to 0.17 micrograms/kg for a 60 kg person. Phenylalanine may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

AVAXIM 80 U PEDIATRIC contains 2 mg of alcohol (ethanol) per dose of 0.5 mL. The quantity for 1 dose of this medicinal product is equivalent to less than 0.1 mL of beer or less than 0.1 mL of wine. The small quantity of alcohol contained in this medicinal product is not likely to cause any notable effects.

AVAXIM 80 U PEDIATRIC contains less than 1 mmol (39 mg) of potassium and less than 1 mmol (23 mg) of sodium per dose, that is to say essentially “potassium-free” and “sodium-free”.

3. HOW TO USE AVAXIM 80 U PEDIATRIC

Dosage

- Primary vaccination (first dose):

Primary vaccination is ensured with a 0.5 mL dose of vaccine.

- Booster :

After primary vaccination, a 0.5 mL booster dose is recommended in order to obtain long-term protection. This booster dose will preferably be administered 6 to 36 months after the first dose, but may be administered up to 7 years after this first dose.

Method 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 or the nurse must not inject the vaccine into the skin.

The vaccine will not be administered into the buttock.

The doctor or the nurse will shake the syringe immediately before the injection and will make sure the liquid is turbid and whitish and there are no foreign particles.

If your child forgets to use AVAXIM 80 U 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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious allergic reactions

Serious allergic reactions (anaphylactic reaction, including shock), though very rare, may occur after vaccination.

Contact your doctor or a healthcare professional immediately, or go to the emergency department of the nearest hospital immediately if you or your child has allergic reactions that could be life-

threatening. These signs or symptoms will generally appear very quickly after the injection and may include:

- difficulty breathing, blue colouring of the tongue or lips,
- vertigo (low blood pressure) and possible fainting,
- fast heart rate and weak pulse, cold skin,
- swelling of the face or neck,
- itching and skin rash.

Other side effects

Side effects have been reported after the first dose (primary vaccination) and the second dose (booster dose) with the following frequencies:

Very common side effects (reported in more than 1 in 10 people):

- pain at the injection site (1),
- abnormal crying (1) .

Common side effects (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 (1),
- local injection site reactions such as pain (2), redness, swelling or induration, haematoma (1),
- malaise, fever, fatigue or somnolence.

Uncommon side effects (reported in less than 1 in 100 people but more than 1 in 1000 people):

- abnormal crying (2),
- skin eruptions (2),itching (urticaria) (1),
- joint pain (2),
- haematoma at the injection site (2),

Side effects with a not known frequency (cannot be estimated based on the available data):

- fainting in response to injection.
- seizures with or without fever.

(1) Frequency after the first dose

(2) Frequency after the second dose

Overall, side effects were reported less frequently after the second dose than after the first dose.

All undesirable effects were moderate and limited 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, pharmacist or nurse. 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 80 U PEDIATRIC

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and on the label of the syringe after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

Do not freeze.

Keep in the original packaging, protected from light.

Do not use this medicine if you notice a colouration or the presence of foreign particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What AVAXIM 80 U PEDIATRIC contains

- The active substance is:
  Hepatitis A virus GBM strain* (inactivated) ** ..... 80 ELISA units***

  For one dose of 0.5 mL.

  * Cultured on MRC-5 human diploid cells.

  ** Adsorbed on hydrated aluminium hydroxide (0.15 milligrams of Al^{3+}).

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

- The other components are:
  2-Phenoxyethanol, ethanol, formaldehyde, Hanks Medium 199*, water for injections, polysorbate 80, hydrochloric acid and sodium hydroxide for pH adjustment.

* Hanks Medium 199 (without phenol red) is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins, and other components, including potassium.

What AVAXIM 80 U PEDIATRIC is 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.

Marketing Authorisation Holder

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This leaflet was last revised in:

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The following information is intended for healthcare professionals only:

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