

## **Package leaflet: Information for the user**

### **AVAXIM Junior, suspension for injection in pre-filled syringe** Hepatitis A vaccine (inactivated, adsorbed)

**Read all of this leaflet carefully before you or your child is 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 or your child only. Do not pass it on to others. It may harm them.
- If you or your child gets any side effects, talk to your 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 Junior is and what it is used for
2. What you need to know before you use AVAXIM Junior
3. How to use AVAXIM Junior
4. Possible side effects
5. How to store AVAXIM Junior
6. Contents of the pack and other information

#### **1. What AVAXIM Junior is and what it is used for**

##### **What AVAXIM Junior is**

Avaxim Junior is a vaccine. Vaccines are used to protect against infectious diseases.

##### **What AVAXIM Junior is used for**

This vaccine helps to protect against hepatitis A infection.

- It is used in children aged from 1 year up and including 15 years of age.

Hepatitis A infection is caused by a virus that attacks the liver.

- It may be caught from food or drink that contains the virus.
- Symptoms include yellowing of the skin and eyes (jaundice) and feeling generally unwell.

##### **How AVAXIM Junior works**

- When an injection of Avaxim Junior is given, the body's natural defenses produce protection (antibodies) against hepatitis A infection.
- This vaccine protects against hepatitis A - but it cannot cause a hepatitis A infection.
- This vaccine will not protect against other viruses that attack the liver (such as hepatitis B, hepatitis C or hepatitis E viruses).

#### **2. What you need to know before you use AVAXIM Junior**

##### **Do not use AVAXIM Junior if you or your child have:**

- an allergy to the active ingredient or any ingredients of Avaxim Junior (listed in section 6)
- an allergy to neomycin. This is an antibiotic used when the vaccine is made – it may be present in the vaccine in small amounts.
- had an allergic reaction after a previous dose of Avaxim Junior
- an illness with a high temperature. The vaccination should be delayed until you or your child are better.

## Warnings and precautions

Talk to your doctor or nurse before Avaxim Junior is given, if you or your child have:

- a poor or weakened immune system due to:
  - steroid medicines, medicines for cancer, radiotherapy or other treatments that can weaken the immune system. Your doctor or nurse may wait until the treatment has finished before giving the vaccination.
  - HIV (human immunodeficiency virus) infection or any disease that weakens the immune system. Vaccination is still recommended, but it may not protect as well as it protects people without such diseases.
- haemophilia or any other condition which causes bruising or bleeding more easily.
- had jaundice in the past (yellowing of skin and eyes) or lived in an area where hepatitis A is common. You or your child may need to have a test to check if you have previously had hepatitis A virus infection.
- fainted with a previous injection.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection.

The vaccine may not work properly if you are already infected with the hepatitis A virus at the time of vaccination.

As with all vaccines, Avaxim Junior may not fully protect all people who are vaccinated.

## Other medicines and AVAXIM Junior

Please tell your doctor, nurse or pharmacist if you or your child is taking or has recently taken any other medicines, including medicines obtained without a prescription.

You or your child can be given this vaccine at the same time as any of the below. However, they must be given in different parts of the body (for example another arm or leg). They must not be mixed in the same syringe:

- vaccines (such as against diphtheria, tetanus, pertussis, *Haemophilus influenzae* of type b, poliomyelitis, measles, mumps and rubella).
- antibodies from blood donors (immunoglobulins) – the vaccine may not work as well if it is given at the same time as antibodies. However, it is likely that you will still be protected against hepatitis A infection.

## Pregnancy and breast-feeding

If there is any chance that you or your child is pregnant, tell your doctor or nurse. They will advise whether to delay the vaccination.

You or your child can be given this vaccine during breast-feeding.

## Driving and using machines

This vaccine is unlikely to have any effect on the ability to drive or use machines. However, no studies on this have been performed.

## AVAXIM Junior contains phenylalanine, ethanol, potassium and sodium

- Avaxim Junior contains 10 micrograms phenylalanine in each 0.5 ml dose which is equivalent to 0.17 microgram/kg for a 60 kg person. Phenylalanine may be harmful for people who have phenylketonuria (PKU). PKU is a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- Avaxim Junior contains 2 mg of alcohol (ethanol) in each 0.5 ml dose. The small amount of alcohol in this medicine will not have any noticeable effects.
- Avaxim Junior contains less than 1mmol of potassium (39 mg) and sodium (23 mg) per dose, that is to say it is essentially 'potassium-free' and 'sodium-free'.

### 3. How to use AVAXIM Junior

The vaccine will be given by a doctor or nurse who has been trained to give vaccines. They will also be able to deal with any very rare severe allergic reaction to the injection.

#### When protection starts

Protection against hepatitis A will start within 2 weeks after injection of the first dose of vaccine.

#### Long-term protection

If you need long-term protection against hepatitis A, you might need a second dose depending on official recommendations. This is called a booster injection.

- This second injection should be given between 6 months to 10 years after the first dose of vaccine.
- Avaxim Junior can be given as a booster if you or your child received a different hepatitis A vaccine for your first dose.

#### How the vaccine is given

- The vaccine is injected into a muscle in the upper outer part of the arm. In young children, it can be injected in the outer part of the thigh.
- If you or your child has a bleeding disorder, the injection may be given under the skin.
- Avaxim Junior will not be given into your or your child's buttock.

### 4. Possible side effects

Like all medicines, Avaxim Junior can cause side effects, although not everybody gets them.

#### Serious allergic reactions

Serious allergic reactions (anaphylactic reactions, including shock) can always happen, even if it is very rare.

**Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away** if you or your child experience allergic reactions that can be life-threatening. The symptoms usually appear very soon after the injection and may include:

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

#### Other side effects

People who have had the side effects below had them during the first few days after the vaccination and did not need treatment. The side effects happen less often after the second dose than after the first dose.

**Very common:** may affect more than 1 in 10 people

- pain where the injection is given
- abnormal crying (in babies)
- generally feeling unwell
- headache.

**Common:** may affect up to 1 in 10 people

- lower appetite
- irritability, difficulty sleeping (insomnia)
- belly pain, diarrhoea, nausea, vomiting
- muscle or joint pain
- reactions where the injection is given, such as redness, swelling, bruising
- fever

- feeling tired or very sleepy.

**Uncommon:** may affect up to 1 in 100 people

- rashes with or without itching.

**Not known:** frequency cannot be estimated from the available data

- fainting in response to injection
- Fits (convulsions) with or without fever.

### **Reporting of side effects**

If you or your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store AVAXIM Junior**

Keep out of the sight and reach of children.

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

Do not use the vaccine if there are unexpected particles in it.

- The vaccine must be stored in a refrigerator between 2°C and 8°C.
- Do not freeze. If frozen, discard the vaccine.
- Store in the original package in order to protect from light.

Do not dispose of vaccines via wastewater or household waste. Ask your pharmacist how to dispose of vaccines no longer required. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What AVAXIM Junior contains**

The active ingredient is:

Hepatitis A virus GBM strain (inactivated)<sup>1,2</sup>, 80 EU<sup>3</sup>

<sup>1</sup> produced in human diploid (MRC-5) cells

<sup>2</sup> adsorbed on aluminium hydroxide hydrated (0.15 milligram Al<sup>3+</sup>)

<sup>3</sup> ELISA Unit.

The other ingredients are:

- 2-phenoxyethanol
- ethanol anhydrous
- formaldehyde
- Medium 199 Hanks\*
- water for injections
- polysorbate 80
- hydrochloric acid and sodium hydroxide for pH adjustment

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

### **What AVAXIM Junior looks like and contents of the pack**

The inactivated hepatitis A vaccine is a cloudy and whitish suspension.

The vaccine is presented as a suspension for injection in pre-filled syringe (0.5 ml of inactivated hepatitis A virus) with or without an attached needle (pack size of 1 or 10) or with 1 or 2 needles provided separately. All pack sizes may not be marketed.

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation Holder:  
[To be completed nationally]

The manufacturer responsible for batch release is Sanofi Pasteur at one of the following manufacturing sites:

Sanofi Pasteur, Campus Mérieux, 1541 avenue Marcel Mérieux, 69280 Marcy l’Etoile, France	or	Sanofi Pasteur, Parc Industriel D’Incarville, 27100 Val de Reuil, France
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**This medicinal product is authorised in the Member States of the EEA under the following names:**

AVAXIM Junior – Sweden, Denmark, Germany, Greece, Italy, Spain, and United Kingdom.

**This leaflet was last revised in**  
MM/YYYY.

**<Other sources of information>**

<Detailed information on this medicine is available on the website of { name of MS Agency (link)}>

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<The following information is intended for healthcare professionals only:>