

**AVAXIM 160 U**  
**Suspension for injection in a prefilled syringe**  
**Hepatitis A vaccine (inactivated, adsorbed)**

**Read all of this leaflet carefully before you start using this medicine 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. It may harm them.
- If you get 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 160 U is and what it is used for
2. What you need to know before you use AVAXIM 160 U
3. How to use AVAXIM 160 U
4. Possible side effects
5. How to store AVAXIM 160 U
6. Further information

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

AVAXIM 160 U is a vaccine.

Vaccines are used to protect you against infectious diseases.

This vaccine helps protect against the infection caused by the hepatitis A virus in people aged 16 years or more..

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 you receive an injection of AVAXIM 160 U, the natural defences of your 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 160 U**

**Do not use AVAXIM 160 U:**

- If you are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6).
- If you are allergic to neomycin (an antibiotic used during the manufacturing process of the vaccine and which may be present in it in small amounts).
- If you are allergic to AVAXIM 160 U.
- If you have a disease with a high temperature. Vaccination should be postponed until you have recovered.

**Warnings and precautions**

- If you have a weakened immune system due to:

- Corticosteroids, cytotoxic drugs, radiotherapy, or other treatments likely to weaken your immune system. Your doctor may wish to wait until treatment is over.
- Human immunodeficiency virus (HIV) infection or any other diseases that weaken your immune system. Vaccine administration will be possible but it may not protect you as well as it protects people whose immune system functions normally.
- If you have a liver disease.
- If you have haemophilia or if you are easily subject to bruises or bleeding.
- Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell your doctor or nurse if you fainted with a previous injection.
- This vaccine will not protect you against other viruses known to infect the liver (such as hepatitis B, hepatitis C or hepatitis E viruses).
- If you are already infected by the hepatitis A virus at the time of the administration of AVAXIM 160 U, the vaccination may not work properly.
- This vaccine cannot cause the infections against which it protects.
- As with all vaccines, not all people who receive AVAXIM 160 U will definitely be protected against hepatitis A.

### **Other medicines and AVAXIM 160 U**

As the vaccine is inactivated (it does not contain any bacteria or live virus), association with other inactivated vaccine(s) using a separate injection site should not induce any interactions.

This vaccine can be administered at the same time as any of the following vaccines but in separate injection sites, i.e. in another part of the body such as another arm or another leg, and must not be mixed in the same syringe:

- as a polysaccharide typhoid vaccine,
- as a yellow fever live vaccine.

This vaccine can be administered at the same time as immunoglobulins (antibodies obtained from blood donation) in two separate injection sites.

Avaxim 160 U may not work so well if it is given at the same time as the immunoglobulins. However, you 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 you are taking or have recently taken any other medicines, even one obtained without a prescription, please tell your doctor or pharmacist.

### **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 taking this medicine.

### **Driving or 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.

### **3. HOW TO USE AVAXIM 160 U**

The vaccine will be administered by a health professional trained to the use of vaccines and equipped to respond to any severe allergic reaction following the injection.

**Dosage** One 0.5 ml dose of AVAXIM 160 U is administered to subjects from the age of 16 years.

You will be protected against hepatitis A about 14 days after the first dose.

In order to obtain long-term protection against hepatitis A, you will need a second injection (booster) of hepatitis A vaccine. It is generally administered between 6 and 12 months after the first dose, and can be administered up to 36 months after the first dose. This booster will protect you against hepatitis A beyond 10 years.

AVAXIM 160 U can also be administered as a booster dose of the hepatitis A vaccination if you have received the first injection with the combined typhoid fever (Vi purified polysaccharide) and hepatitis A (inactivated) vaccine between 6 and 36 months earlier.

#### **Method of administration**

Your doctor or your nurse will avoid injecting the vaccine into your skin or into a blood vessel. This vaccine must not be administered into your buttock.

If you have bleeding problems or if you bruise easily, the vaccine can be administered under your skin.

AVAXIM 160 U must be administered into a muscle in the outer upper part of your arm.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like any medicines, this medicine can cause side effects in certain subjects, although not everybody gets them.

Serious allergic reactions:

Serious allergic reactions are only very rarely possible after vaccine injection.

These reactions may include:

- difficulty in breathing,
- bluish colouration of the tongue or lips,
- skin rash,
- swelling of the face or throat,
- low blood pressure which causes dizziness or fainting.

These signs or symptoms generally appear very soon after the injection, while you or your child are still at the clinic or the medical practice.

**If any of these symptoms appear after you or your child have left the place where you received the injection, you must IMMEDIATELY consult a doctor.**

Very common reactions (reported by more than 1 in 10 people)

- mild injection site pain,
- fatigue.

Common reactions (reported by less than 1 in 10 people but by more than 1 in 100 people)

- headache,
- nausea, vomiting,
- loss of appetite,
- diarrhoea, abdominal pain,
- muscle and joint pain,
- mild fever.

Uncommon reactions (reported by less than 1 in 100 people but by more than 1 in 1000 people)

- injection site redness.

Rare reactions (reported by less than 1 in 1000 people but by more than 1 in 10 000 people)

- injection site bump,
- slight and transient modifications of blood tests measuring liver activity.

Not known (cannot be estimated from the available data)

- fainting in response to injection.
- skin rash with or without itching.

### **Reporting of side effects**

If you get 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 160 U**

Keep out of the sight and reach of children.

Do not use AVAXIM 160 U after the expiry date which is stated on the box and on the syringe label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

Do not freeze.

If frozen, the vaccine should be discarded.

The vaccine should not be used if it contains 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 160 U contains**

- The active substance is:

The hepatitis A virus GBM strain\* (inactivated) \*\* (160 units\*\*\* for one 0.5-ml dose).

\*Cultured on MRC-5 human diploid cells

\*\*Adsorbed on hydrated aluminium hydroxide (0.3 milligrams of Al)

\*\*\*In the absence of an international standardized reference, the antigen content is expressed using an in-house reference.

- The other ingredients are:

2-phenoxyethanol, formaldehyde, and Hanks 199 medium without phenol red (a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins, and other components) supplemented with polysorbate 80 and diluted in water for injections, with a pH that adjusted with hydrochloric acid or sodium hydroxide.

**What AVAXIM 160 U looks like and contents of the pack**

This vaccine is presented as a suspension for injection in prefilled syringe (0.5 ml of inactivated hepatitis A vaccine) with or without attached needle (box of 1, 5, 10 or 20) or with one or 2 needles provided separately (box of 1 or 10).

Not all pack sizes are marketed.

The hepatitis A vaccine is a turbid and whitish suspension.

**Marketing authorisation holder**

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

**This leaflet was last approved on: November 2016**