ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicine

Avaxim 160 U suspension for injection in prefilled syringe

Hepatitis A vaccine (inactivated, adsorbed)

Boxed text

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 suspension for injection in prefilled syringe IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Vaccine against hepatitis A, ATC code: J07BC02.

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 and over.

Hepatitis A infection is caused by a virus that 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 suspension for injection in prefilled syringe

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

Talk to your doctor, pharmacist or nurse before using Avaxim 160 U.

- 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.

Children

Not applicable.

Other medicines and Avaxim 160 U

As this 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. 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.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Avaxim 160 U with food and drink

Not applicable.

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.

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 160 U contains ethanol, phenylalanine, potassium and sodium

Avaxim 160 U 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 160 U 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 if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Avaxim 160 U contains less than 1 mmol of potassium (39 mg) and less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'potassium-free' and 'sodium-free'.

3. HOW TO USE Avaxim 160 U suspension for injection in prefilled syringe

The vaccine will be administered by a health professional trained in 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 6 to 36 months earlier.

Method of administration

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

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

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 use more Avaxim 160 U than you should

Not applicable.

If you forget to use Avaxim 160 U

Not applicable.

If you stop using Avaxim 160 U

Not applicable.

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, which can even be fatal (anaphylactic reaction, including shock), while very rare, can still occur after the vaccine.

If you have an allergic reaction, immediately contact your doctor or a healthcare professional, or go to the emergency department of the nearest hospital.

Allergic reactions can occur immediately or in the days following the vaccination, and symptoms may include:

- difficulty in breathing, bluish colouration 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 throat,
- itching and skin rash.

Other adverse reactions

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

- mild injection site pain,
- fatigue.

Common reactions (reported by fewer 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 fewer than 1 in 100 people but by more than 1 in 1 000 people)

- injection site redness.

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

- injection site bump,
- slight and transient modification 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. You can also report side effects directly via the national reporting system: "*Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance*" - Site internet: www.signalement-sante.gouv.fr.

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

5. HOW TO STORE Avaxim 160 U suspension for injection in prefilled syringe

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.

Keep in the original packaging, protected from light.

Do not use this medicine if you notice that it contains 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 160 U contains

- The active substance is:

  The hepatitis A virus GBM strain* (inactivated) ** ..... 160 ELISA units***

  for one 0.5 mL dose

  * Cultured on MRC-5 human diploid cells

  ** Adsorbed on hydrated aluminium hydroxide (0.3 milligrams of Al^{3+})

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

- The other ingredients are:

  2-phenoxyethanol, ethanol, formaldehyde, Hanks 199 medium*, water for injections, polysorbate 80, hydrochloric acid and sodium hydroxide for pH adjustment.

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

What Avaxim 160 U is 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 two 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
14 ESPACE HENRY VALLÉE
69007 LYON
FRANCE

Marketing Authorisation Distributor

SANOFI PASTEUR EUROPE
14 ESPACE HENRY VALLÉE
69007 LYON
FRANCE

Manufacturer

SANOFI PASTEUR
1541 AVENUE MARCEL MERIEUX
69280 MARCY L'ETOILE
FRANCE

Names of the medicinal product in the Member States of the European Economic Area

Not applicable.

This leaflet was last revised in:

[to be completed later by the holder]

Other

Detailed information on this medicine is available on the website of ANSM (France).

The following information is intended for healthcare professionals only:

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

Shake the syringe immediately before the injection and make sure the liquid is turbid and whitish.

Parenteral products must be visually inspected to reveal the presence of particles and/or a change in colouration before administration. In either case, the product must not be administered.