PACKAGE LEAFLET: INFORMATION FOR THE USER

AVAXIM, Suspension for injection in a pre-filled syringe
Hepatitis A vaccine (inactivated, adsorbed)

Read all of this leaflet carefully before you are 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 vaccine has been prescribed for you only. Do not pass it on to others.
- 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.

In this leaflet:

1. WHAT AVAXIM IS AND WHAT IT IS USED FOR

Avaxim is a vaccine. Vaccines are used to protect you against infectious diseases. This vaccine helps to protect against hepatitis A infection in people 16 years of age and older.

Hepatitis A infection is due to a virus that attacks the liver. It may be caught from food or drink that contains the virus. Symptoms include yellowing of the skin (jaundice) and feeling generally unwell.

When you are given an injection of Avaxim, your body's natural defences will produce protection against hepatitis A infection.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AVAXIM

Do not use Avaxim:
- if you are allergic to:
  - the active ingredient or any ingredients of Avaxim (listed in section 6), or
  - neomycin, an antibiotic used during vaccine production, which may be present in the vaccine in small amounts, or
  - Avaxim,

- if you are ill with a high temperature, the vaccination will be delayed until you have recovered.

Warnings and precautions

Talk to your doctor or nurse before using Avaxim, if you have:

- liver disease.
- a poor or weakened immune system due to:
  - corticosteroids, cytotoxic drugs, radiotherapy or other treatments that can weaken your immune system. Your doctor or nurse may wait until the treatment has finished.
  - HIV (human immunodeficiency virus) infection or any disease that weakens your immune system. It is recommended that you are given the vaccine, although it may not protect as well as it protects people with a normal immune system.
- phenylketonuria as this vaccine contains phenylalanine and may be harmful to you
- haemophilia or any other condition where you bruise or bleed more easily

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell your doctor or nurse if you or your child fainted with a previous injection.

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

If you already have the hepatitis A virus when you are given Avaxim, the vaccination may not work properly.

The vaccine cannot cause the infection against which it protects.

As with any vaccine, not everyone who receives Avaxim will definitely be protected against hepatitis A infection.

Receiving other vaccines or medicines

This vaccine can be given at the same time as any of the following, providing they are given in different parts of the body (for example another arm or leg) and are not mixed in the same syringe:

- Typhoid polysaccharide vaccine
- Yellow fever vaccine
- Immunoglobulins (antibodies obtained from blood donors).

Avaxim may not work as well if it is given at the same time as immunoglobulins. However, it is likely that you will still be protected against hepatitis A infection.

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

Pregnancy and breast-feeding

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

The use of this vaccine is possible during breast-feeding.

Driving and using machines

This vaccine is unlikely to have any affect on your ability to drive or use machines.

However, no studies on this have been performed.

3. HOW TO USE AVAXIM

The vaccine will be given by a doctor or nurse who has been trained in the use of vaccines and who is equipped to deal with any uncommon severe allergic reaction to the injection.

Dosage
Avaxim is given as an injection of half a millilitre of the vaccine to people 16 years of age and older.

You will be protected against hepatitis A about 14 days after you receive the first, single dose of Avaxim. This protection will last for up to 36 months.

If you need longer term protection against hepatitis A, you will need a second dose (booster) of an inactivated hepatitis A vaccine. This is usually given between 6 and 12 months after the first dose but can be given up to 36 months later. This booster will protect you against hepatitis A beyond 10 years.
Avaxim can be given as a booster if you received a different hepatitis A vaccine for your first dose (including vaccines that protect you against hepatitis A and typhoid fever).

How the vaccine is administered
The doctor or nurse will shake the syringe immediately before use and check that the liquid is white and cloudy, and that there are no unexpected particles in it.

Avaxim should be injected into a muscle in the upper outer part of your arm.
If you suffer from a bleeding disorder, you may be given the injection under the skin. The doctor or nurse must not inject the vaccine into the skin or into a blood vessel.
Avaxim will not be given into your buttock.

4. POSSIBLE SIDE EFFECTS

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

<u>Possible serious allergic reactions</u>
Serious allergic reactions are always a very rare possibility after receiving a vaccine. These reactions may include:

- difficulty in breathing, blue discolouration of the tongue or lips,
- dizziness (low blood pressure) and collapse.
- swelling of the face and neck

If serious allergic reactions occur, they often do so very soon after the injection while still in the clinic or doctor's surgery. **If any of these symptoms occur after leaving the place where your injection was given, you must consult a doctor IMMEDIATELY.**

Very common reactions (reported by more than 1 in 10 people):
- mild pain at the injection site
- generally feeling weak (asthenia)

Common reactions (reported by less than 1 in 10 but more than 1 in a 100 people):
- headache
- feeling sick (nausea) or being sick (vomiting)
- loss of appetite
- diarrhoea and/or stomach ache (abdominal pain)
- pain in the muscles and joints (myalgia, arthralgia)
- mild fever

Uncommon reactions (reported by less than 1 in a 100 but more than 1 in a 1000 people):
- redness (erythema) at the injection site

Rare reactions (reported by less than 1 in a 1000 but more than 1 in 10,000 people):
- a lump formed at the injection site (injection site nodule)
- mild and temporary changes in blood tests that measure how the liver is working (transaminases increased)

Very rare reactions (reported by less than 1 in 10,000 people):
- fainting in response to injection
- rashes that have sometimes been lumpy and itchy (including urticaria)

Reporting of side effects in the UK
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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

Reporting of side effects in Ireland
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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AVAXIM

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.
The vaccine must not be used 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.
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. FURTHER INFORMATION

What Avaxim contains
The active ingredient is:

- Hepatitis A virus GBM strain (inactivated)[1,2], 160 U
  [1] produced in human diploid (MRC-5) cells
  [2] adsorbed on aluminium hydroxide hydrated (0.3 milligram Al)

The other ingredients are:
- 2-phenoxyethanol
- formaldehyde
- Medium 199 Hanks (a mixture of amino acids including phenylalanine, mineral salts, vitamins and other components)
- water for injections
- hydrochloric acid and sodium hydroxide for pH adjustment

What Avaxim looks like and contents of the pack
The inactivated hepatitis A vaccine is a cloudy, white suspension.
The vaccine is presented as a suspension for injection in a pre-filled syringe (0.5 ml of inactivated hepatitis A virus) with or without an attached needle (pack size of 1, 5, 10 or 20) or with 1 or 2 needles provided separately (pack size of 1 or 10). Not all pack sizes are marketed.

Marketing Authorisation Holder

Marketing Authorisation Holder:
Sanofi Pasteur Europe
14 Espace Henry Vallée
69007 Lyon
France

Distributed by:
United Kingdom:
Sanofi
One Onslow Street
Guildford

Surrey
GU1 4YS
UK
Tel: 0845 372 7101

Ireland:
sanofi-aventis Ireland T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland
Tel: +353 (0) 1 4035 600

Manufacturer
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

This medicinal product is authorised in the Member States of the EEA under the following names:
AVAXIM - Austria, Belgium, Germany, Denmark, Greece, Spain, Finland, Ireland, Italy, Luxembourg, Netherlands, Portugal, Sweden, United Kingdom.

This leaflet was last approved in 05/2018.