AVAXIM™

Hepatitis A Virus (inactivated, adsorbed)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AVAXIM It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you having AVAXIM against the benefits they expect it will have for you.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What AVAXIM is used for

AVAXIM is a vaccine used to help prevent Hepatitis A infection.

Hepatitis A is an infection caused by a virus which is usually transmitted in unclean food or drink. It may also be transmitted by sharing needles and some sexual practices.

The vaccine contains inactivated virus and is injected into the body. The body then produces its own protection by making disease-fighting substances (antibodies) to fight the virus. The vaccine cannot cause the infection. If a vaccinated person comes into contact with live virus the body is usually ready to destroy it. However, as with all vaccines, 100% protection against hepatitis A cannot be guaranteed. Avaxim will not protect against hepatitis caused by other agents or viruses (such as hepatitis B, hepatitis C, or hepatitis E).

As with most vaccines, AVAXIM may not protect every person.

AVAXIM is recommended in adults and children aged 2 years and older.

Before you are given AVAXIM

When you must not be given it

You have had a severe reaction to a previous injection of this vaccine.

Do not have AVAXIM if you have an allergy to:

- **AVAXIM or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include:

- Shortness of breath, wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Skin rash, itching or hives

Do not give AVAXIM to children under 2 years of age.

The safety and efficacy of AVAXIM in these children has not been established.

Do not have AVAXIM after the expiry date printed on the pack.

If the vaccine is used after the expiry date has passed, it may not work.

Do not have AVAXIM if the packaging is torn or shows signs of tampering.

Talk to your doctor or pharmacist if you are not sure whether you should have AVAXIM.

Before you are given it

Tell your doctor if you have ever had a serious allergic reaction to a vaccine.

Tell your doctor if you have an illness with a high temperature or any acute illness

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- Lowered immunity due to diseases such as some blood disorders, leukaemia, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer
- Lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)

If you have lowered immunity then the vaccine may not work as well as it would in healthy individuals.

Tell your doctor if you have allergies to:

- Neomycin
- Any other medicines
- Any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

AVAXIM is not recommended for use during pregnancy. If there is a need to consider AVAXIM during your pregnancy, your doctor will discuss with you the benefits and risks of having it.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having AVAXIM during breastfeeding.

Having other vaccines

As AVAXIM does not contain any live bacteria or viruses, it can generally be given at the same time as other inactivated vaccines, but at a different injection site.

AVAXIM can be given at the same time as yellow fever vaccine or polysaccharide typhoid vaccine at different injection sites.

Other medicines should be taken as usual after the vaccination.

How AVAXIM is given

AVAXIM is given as an injection into your upper arm muscle by a doctor or nurse.

For some people with bleeding disorders, the dose may need to be given under the skin.

AVAXIM should not be injected directly into the veins or into the buttocks.

The dose is the same for adults and children, 0.5 mL of vaccine. The first injection is followed by a second injection 6 to 36 months later in order to give long-term protection. AVAXIM may be given as a second injection to those who have previously been vaccinated with another inactivated hepatitis A vaccine.

It is important to return at the scheduled date for the second dose. If you miss a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

Because hepatitis A infection can go undetected for a long period of time, it is possible that an individual may already be infected at the time the vaccine is given. The vaccine may not prevent hepatitis A in these individuals.

How much is injected

Your doctor will usually give you one injection, followed by another injection 6 to 36 months later.

After having AVAXIM

Things you must do

- Keep an updated record of your vaccinations
- Attend any other appointments made by your doctor or nurse
- Report any side effects to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after having AVAXIM

AVAXIM may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Local reaction around the injection site such as pain sometimes associated with redness. The appearance of a nodule at the injection site has been observed in very rare cases
- Bruising
- Mild fever
- Headaches
- Unusual weakness
- Aching muscles, muscle tenderness or weakness (not caused by exercise)
- Painful, swollen joints
- Stomach upsets such as nausea, diarrhoea, vomiting or abdominal pain
- Fainting
- Severe allergic reaction
- Seizures

These are the more common side effects of AVAXIM. Mostly these are mild and short-lived.

Less common side effects include rash sometimes associated with itchiness of skin, or pinkish, itchy swelling on the skin. Very rarely some patients experience a mild reversible rise in liver enzyme but this can only be found when your doctor does tests.

Hence tell your doctor as soon as possible if you notice anything that is making you feel unwell after you have been given AVAXIM.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storing AVAXIM

AVAXIM is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store AVAXIM

- **Keep it where children cannot reach it.**
- **Keep AVAXIM in the original pack until it is time for it to be given.**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze AVAXIM.**

Freezing destroys the vaccine.

Product description

What it looks like

Each pack of AVAXIM contains one syringe filled with inactivated Hepatitis A vaccine.

Ingredients

Active ingredients:

- 160 antigen units hepatitis A virus (inactivated, adsorbed)

Other ingredients:

- Aluminium hydroxide hydrate
- Phenoxyethanol
- Ethanol absolute
- Formaldehyde
- Medium 199 (Hanks) supplemented with Polysorbate 80
- Neomycin (trace)
- Bovine serum albumin (trace)

The hepatitis A virus that this vaccine contains was grown in a cell line derived from human embryonic lung in the 1960s.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

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