

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

AVAXIM®

Hepatitis A Vaccine Inactivated

Read this carefully before you receive AVAXIM®. This leaflet is a summary and will not tell you everything about this product. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about taking AVAXIM®.

What is AVAXIM® used for?

AVAXIM® [Hepatitis A Vaccine Inactivated] is a vaccine that is used to prevent hepatitis A infection. This vaccine may be given to persons 12 years of age or older. Geriatrics: Limited data are available to Health Canada.

Hepatitis A is a contagious liver disease that is spread from person to person through drinking water or eating food with the hepatitis A virus (HAV) in it. It is also spread by close personal contact. It is more common in areas of the world with poor sanitation. Hepatitis A can cause a mild illness, but about 1 person in 5 has to be hospitalized and sometimes people die as a result of hepatitis A.

The majority of persons who are vaccinated with AVAXIM® will produce enough antibodies to help protect them against this disease. However, as with all vaccines, 100% protection cannot be guaranteed. Clinical studies of AVAXIM did not include subjects aged 65 years and older to determine whether they respond differently from younger subjects. Clinical experience from Hepatitis A vaccines has not identified differences in overall safety between these subjects and younger adult subjects

How does AVAXIM® work?

AVAXIM® causes the body to produce its own natural protection against hepatitis A infection. After you receive the vaccine, your body begins to make substances called antibodies. Antibodies help the body to fight disease. If a vaccinated person comes into contact with the germ that causes this disease, the body is usually ready to destroy it.

What are the ingredients in AVAXIM®?

Medicinal ingredients: inactivated hepatitis A virus.

Non-medicinal ingredients: aluminum hydroxide, ethanol anhydrous, formaldehyde, Medium 199 Hanks, neomycin, and 2-phenoxyethanol.

AVAXIM® comes in the following dosage forms:

AVAXIM® is a suspension for injection (160U/0.5mL), supplied in prefilled syringes.

Do not use AVAXIM® if:

- You have a known severe allergy to any ingredient in AVAXIM® or its container, or have had a severe allergic reaction after receiving a vaccine that contained similar ingredients.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive AVAXIM®. Talk about any health conditions or problems you may have, including if you:

- **Have a high fever or serious illness.** Wait until the person is better to receive the vaccination.
- **Have an allergy to any component of the vaccine or the container.** As each dose may contain traces of formaldehyde, caution should be exercised when the vaccine is administered to subjects with hypersensitivity to this product. As each dose may contain undetectable traces of neomycin, which is used during vaccine production, caution should be exercised when the vaccine is administered to subjects with hypersensitivity to this antibiotic (and other antibiotics of the same class).
- **Have liver disease.** No studies have been performed with Avaxim in subjects with liver disease. The use of this vaccine in such subjects should be considered with care.
- **Have a weakened immune system.** The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.
- **Have a bleeding disorder or taking blood thinning medications.** Tell the person giving you the injection about your condition. The injection must be done carefully to prevent excessive bleeding.
- **Are pregnant or breast-feeding.** It is important that you understand the risks and benefits of vaccination. AVAXIM® should be given to a pregnant or nursing woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.
- **Have fainted with a previous injection.** Fainting can occur following vaccination. Appropriate measures should be taken to prevent falling injury.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with AVAXIM®:

- DO NOT mix AVAXIM® with other vaccines or medicinal products in the same syringe.

How to take AVAXIM®:

Usual dose:

A single dose of 0.5 mL is recommended for immunization in persons 12 years of age and older.

For long-term protection against hepatitis A, a booster vaccination will be required 6 to 36 months after vaccination with AVAXIM®.

The vaccination should be given in the muscle, preferably in the deltoid (shoulder) region.

Overdose:

If you think you, or a person you are caring for, have taken too much AVAXIM, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss the second dose, contact your doctor to schedule a visit.

What are possible side effects from using AVAXIM®?

These are not all the possible side effects you may feel when taking AVAXIM®. If you experience any side effects not listed here, contact your healthcare professional

A vaccine, like any medicine, may cause serious problems. Serious or even life-threatening allergic reactions (anaphylactic reactions, including shock) can always happen, even if they are very rare. If you experience an allergic reaction, **contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away.**

The risk of AVAXIM® causing serious harm is extremely small. The risks associated with AVAXIM® are much less than the risks associated with getting the diseases.

Serious side effects are very rare.

Some people who receive AVAXIM® may have mild side effects such as mild pain at the injection site, associated with redness or a lump at the injection site. They may also have fever, weakness, headache, fainting, muscle or joint ache or gastro-intestinal tract disorders such as nausea, vomiting, diarrhea and abdominal pain or hives and rash (with or without itching). Mild and temporary changes in blood tests that measure how the liver is working may also occur. These side effects usually go away within a few days.

| Serious side effects and what to do about them | | |
|---|--------------------------------------|--------------|
| Symptom / effect | Talk to your healthcare professional | |
| | Only if severe | In all cases |
| Anaphylaxis and Hypersensitivity (serious or even life-threatening allergic reaction with symptoms that can include: difficulty in breathing; blue colour of the tongue or lips; dizziness (low blood pressure) and possibility of fainting; fast heart rate and weak pulse, cold skin; swelling of the face or neck; itching and skin rash) | | ✓ |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store AVAXIM® in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze.** Throw the product away if it has been exposed to freezing.

Do not use after the expiration date. Store protected from light.

Keep out of reach and sight of children.

If you want more information about AVAXIM®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug->

product-database.html); the Sanofi Canada website (<http://www.sanofi.ca>), or by calling the Sanofi Pasteur Limited Vaccine Information Service at 1-888-621-1146 (no charge.)

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