

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

AVAXIM®

Hepatitis A Vaccine Inactivated

Suspension for Injection

160U/0.5mL

For active immunization against Hepatitis A infection

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

AVAXIM® is indicated for active immunization against infection caused by hepatitis A virus (HAV) in persons 12 years of age and older. AVAXIM® can be used for primary immunization or as a booster following primary immunization with AVAXIM® or other similar hepatitis A vaccines.

1.1 Pediatrics

AVAXIM® is not indicated for immunization of persons below the age of 12 years. AVAXIM® Pediatric is used for children aged 12 months to 15 years of age inclusive. Either vaccine may be used for persons between 12 through 15 years of age.

1.2 Geriatrics

AVAXIM® is indicated for immunization of persons 12 years of age or older.

2 CONTRAINDICATIONS

AVAXIM® is contraindicated in patients who are hypersensitive to this vaccine after previous administration or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing [6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING](#).

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- **Administration Route Related Precautions:**
Do not administer AVAXIM® by intravascular injection.
Do not administer intradermally.
AVAXIM® should not be administered into the buttocks.
- For more information, refer to the National Advisory Committee on Immunization and the Canadian Immunization Guide for current recommendations on the use of vaccines in Canada.

4.2 Recommended Dose and Dosage Adjustment

AVAXIM® should be administered as a single injection of 1 dose (0.5 mL) by the intramuscular route.

Primary immunization consists of one dose of vaccine, followed by a booster dose 6 to 36 months later in order to confer long term protection.

4.4 Administration

Inspect for extraneous particulate matter and/or discolouration before use. If these conditions exist, the product should not be administered.

Shake the pre-filled syringe well until a uniform, cloudy suspension results.

AVAXIM® may be packaged in one of two presentations: a pre-filled syringe with a choice of two needles, or a pre-filled syringe with attached needle.

If two needles are present, select a needle of appropriate length to ensure that the vaccine will be delivered intramuscularly. Remove the tip cap from the syringe, take the chosen needle from the blister pack and fix to the tip of the pre-filled syringe.

If a syringe with attached needle is present, the vaccine is ready to administer.

Aseptic technique must be used. Use a separate sterile needle and syringe, or a sterile disposable unit for each individual patient to prevent disease transmission. Needles should not be recapped and should be disposed of according to biohazard waste guidelines.

Administer the vaccine **intramuscularly** (I.M.). The preferred site of injection is the deltoid muscle.

Give the patient a permanent personal immunization record. In addition, it is essential that the physician or nurse record the immunization history in the permanent medical record of each patient. This permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

5 OVERDOSAGE

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

Table 1: Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	Suspension for injection Each 0.5 mL dose is formulated to contain: Active Ingredient: Hepatitis A Virus Inactivated (GBM strain): 160 antigen units (U)	2-phenoxyethanol, aluminum hydroxide (expressed as aluminum), ethanol anhydrous, formaldehyde, Medium 199 Hanks, Manufacturing process residuals: neomycin

Description

AVAXIM® is supplied as a sterile, whitish, cloudy suspension in a pre-filled syringe.

Each dose (0.5 mL) is formulated to contain: 160 EU (ELISA Unit) of Hepatitis A Virus, GBM strain (inactivated). In the absence of an international standardized reference, the antigen content is expressed in EU using an in-house reference.

The non-medicinal ingredients are as follows: Phenoxyethanol-Ethanol (50% v/v solution) with 2 phenoxyethanol (2.5 µL) and ethanol anhydrous (2.5 µL); Formaldehyde (12.5 mcg); Aluminum hydroxide, hydrated (expressed as aluminum 0.3 mg); 1 x C Medium 199 Hanks (up to 0.5 mL). 1 x C Medium 199 Hanks (without phenol red) is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins and other components supplemented with polysorbate 80 and is reconstituted in water for injection. Hydrochloric acid and or sodium hydroxide can be used for pH adjustment; these components are only present in trace amounts. Neomycin is also present in trace amounts.

Packaging:

AVAXIM® is supplied in pre-filled single dose syringes.

The syringes are made of Type 1 glass. The plunger stoppers and needle shield for the syringes do not contain latex (natural rubber).

AVAXIM® is supplied in packages of:

1 x 0.5 mL (single dose) syringe with attached needle.

1 x 0.5 mL (single dose) syringe with choice of two needles (1 x 25G x 16 mm and 1 x 25G x 25 mm).

7 WARNINGS AND PRECAUTIONS

General

Before administration of AVAXIM®, health-care providers should inform the recipient or the parent or guardian of the recipient of the benefits and risks of immunization, inquire about the recent health status of the recipient, review the recipient's history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindications to immunization and comply with any local requirements with respect to information to be provided to the recipient, parent or guardian before immunization.

Because of the incubation period of hepatitis A disease, infection may be present but not clinically apparent at the time of vaccination. It is not known whether AVAXIM® will prevent hepatitis A in this case.

Seropositivity against HAV is not a contraindication.

As with any vaccine, AVAXIM® may not protect 100% of vaccinated individuals.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent falling injury and manage syncopal reactions.

Febrile or Acute Disease:

Vaccination should be postponed in cases of an acute or febrile disease. However, a disease with a low-grade fever should not usually be a reason to postpone vaccination.

Hematologic

Because any intramuscular injection can cause an injection site hematoma in persons with any bleeding disorders, such as hemophilia or thrombocytopenia, or in persons on anticoagulant therapy, intramuscular injections with AVAXIM® should not be administered to such persons unless the potential benefits outweigh the risk of administration. If the decision is made to administer any product by intramuscular injection to such persons, it should be given with caution, with steps taken to avoid the risk of hematoma formation following injection.

In exceptional circumstances (e.g., in patients with thrombocytopenia or in patients at risk of hemorrhage), the vaccine may be administered by the subcutaneous route, however, this may be associated with a higher risk of local reaction including injection site nodule.

Immune

The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated. Hypersensitivity reactions may occur following the use of AVAXIM® even in persons with no prior history of hypersensitivity to the product components (See [6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING](#)).

As with all other products, epinephrine hydrochloride solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. Health-care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management.

Immunocompromised persons (whether from disease or treatment) may not obtain the expected immune response. If possible, consideration should be given to delaying vaccination until after the completion of any immunosuppressive treatment. Nevertheless, vaccination of persons with chronic immunodeficiency such as HIV infection is recommended even if the antibody response might be limited.

Protection

AVAXIM® does not provide protection against infection caused by hepatitis B virus, hepatitis C virus, delta virus, hepatitis E virus, or by other liver pathogens, other than hepatitis A virus.

7.1 Special Populations

7.1.1 Pregnant Women

Animal reproduction studies have not been conducted with AVAXIM®.

Data on the use of this vaccine in pregnant woman are limited. Therefore, the administration of the vaccine during pregnancy is not recommended. AVAXIM® should be given to pregnant women only if clearly needed and following an assessment of its risks and benefits.

7.1.2 Breast-feeding

It is not known whether this vaccine is excreted in human milk. Caution must be exercised when AVAXIM® is administered to a nursing mother.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The most commonly reported adverse reactions were asthenia (13.5%), injection site pain occasionally associated with redness (0.5% over 3 cm) (11.7%), muscle or joint ache (10.3%) and headache (9.7%). Mild fever (5.2%) and gastrointestinal tract disorders (6.1%) such as nausea, vomiting, diarrhea, or pain, were also reported.

8.2 Clinical Trial Adverse Reactions

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect rates observed in practice. The adverse reaction information from clinical trials does however, provide a basis for identifying the adverse events that appear to be related to vaccine use and for approximating rates of those events.

In six clinical trials conducted which involved over 2,200 participants, adverse events were usually mild and confined to the first few days after vaccination with spontaneous recovery.

Table 2: Frequency (%) of Reactions Observed After One Dose of AVAXIM®

Reaction	% of Persons with a Reaction (N = 2,204)
Local Reactions	
Pain	11.7
Redness	0.5
Systemic Reactions	
Asthenia (weakness)	13.5
Myalgia/Arthralgia (muscle or joint ache)	10.3
Headache	9.7
Gastrointestinal Tract Disorders (nausea, vomiting, diarrhea, pain)	6.1
Mild Fever ($\geq 38.0^{\circ}\text{C}$ to $\leq 38.4^{\circ}\text{C}$)	5.2

Mild transient elevation of serum transaminases has been reported on rare occasions. The appearance of a nodule at the injection site was observed in very rare cases.

Adverse reactions were less frequently reported after the booster dose than after the first dose.

In subjects seropositive to HAV, AVAXIM® was as well tolerated as in seronegative subjects. The reactions observed in haemophilic children were identical to those observed in adults.

In comparative trials with another hepatitis A vaccine, in a total of 423 adults, AVAXIM® demonstrated significantly fewer local reactions after each injection.

8.5 Post-Market Adverse Reactions

The following additional adverse reactions have been spontaneously reported during the post-marketing use of AVAXIM®. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Decisions to include these events in labelling were based on one or more of the following factors: 1) severity of the event, 2) frequency of reporting, or 3) strength of causal connection to AVAXIM®.

Immune system disorders

- Anaphylactic reaction

Nervous system disorders

- Vasovagal syncope, headache

Gastrointestinal disorders

Nausea, diarrhea, vomiting, abdominal pain

Skin and subcutaneous tissue disorders

Urticaria, rashes with or without pruritus

Musculoskeletal and connective tissue disorders

Arthralgia, myalgia

General disorders and administration site condition

Injection site pain, injection site rash, injection site nodule, pyrexia, asthenia

Investigations

Transaminases increased (mild and reversible)

Physicians, nurses and pharmacists should report any adverse reaction temporally related to the administration of the product in accordance with local requirements (See [PATIENT MEDICATION INFORMATION](#), Reporting Side Effects for Vaccines).

9 DRUG INTERACTIONS

9.4 Drug-Drug Interactions

Vaccine-Drug Interactions:

Immunosuppressive treatments, may interfere with the development of the expected immune response. (See 7 WARNINGS AND PRECAUTIONS).

Separate injection sites and separate syringes must be used in case of concomitant administration with other medicinal products.

Concomitant Vaccine Administration:

AVAXIM® may be administered simultaneously with immune globulin at separate sites with separate syringes. Seroconversion rates are not modified, but antibody titres could be lower than after vaccination with the vaccine alone.

As the vaccine is inactivated, concomitant administration of other vaccine(s) given at other injection sites is unlikely to interfere with immune responses. No interaction with other medication is currently known. AVAXIM® has been shown to be safe and immunogenic when concomitantly administered with TYPHIM Vi® and live yellow fever vaccine using separate syringes at different sites.

Vaccines administered simultaneously must be given using separate syringes at separate sites.

10 CLINICAL PHARMACOLOGY

HAV is a single serotype, ribonucleic acid (RNA) virus of the Picornaviridae family. HAV is transmitted via the fecal-oral route, which can occur from direct person-to-person contact, from contamination of the environment or objects, or through contaminated food or water.

10.1 Mechanism of Action

AVAXIM® confers immunity against HAV infection by inducing the production of specific anti-HAV antibodies.

10.2 Pharmacodynamics

In clinical studies involving over 1,000 adult volunteers, specific humoral antibodies against hepatitis A were elicited after the first injection and more than 90% of immunocompetent subjects were protected (titres above 20 mIU/mL) 14 days after vaccination. One month after the first injection, 100% of the subjects were protected.

In a clinical trial, an assessment of the persistence of HAV antibodies showed more than 99% (n = 103) of subjects were still protected (titre \geq 20 mIU/mL) 3 years after the initial dose of AVAXIM®.

10.3 Pharmacokinetics

Duration of Effect

Data relative to long-term persistence of anti-HAV antibodies following vaccination with AVAXIM® are not currently available. Published data suggest that anti-HAV antibodies persist beyond 10 years after the booster vaccination in healthy individuals. According to NACI, kinetic models of antibody decline suggest that protective levels of anti-HAV antibody will likely persist for at least 20 years.

11 STORAGE, STABILITY AND DISPOSAL

Store at 2° to 8°C (35° to 46°F). **Do not freeze.** Discard product if exposed to freezing. Store protected from light.

12 SPECIAL HANDLING INSTRUCTIONS

Do not use the vaccine after the expiration date.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Hepatitis A Vaccine Inactivated

Product Characteristics:

AVAXIM® [Hepatitis A vaccine Inactivated] is a sterile, cloudy, whitish suspension of inactivated hepatitis A.

The active ingredient is a purified and formaldehyde-inactivated hepatitis A virus (HAV) obtained from the GBM strain cultured on MRC-5 human diploid cells. HAV is adsorbed onto aluminum. Each dose (0.5 mL) of inactivated hepatitis A vaccine contains 160 antigen units (in the absence of an international standardized reference, the antigen content is expressed using an in-house reference).

14 CLINICAL TRIALS

14.1 Trial Design and Study Demographics

Table 3: Summary of Demographics and Study Design of the Trials with AVAXIM®

Study #	Trial Design	Dosage, Route of Administration and Duration	Study Subjects	Age Range	Gender
HAF03293	Randomized, open, multicentre, controlled, comparative study on administration routes.	0.5 mL I.M., S.C., Jet Injector 1 Dose + Booster	N = 147	19 – 60 Years	Males N = 58 Females N = 89
HAF05392	Randomized, open, multicentre, controlled, comparative study between AVAXIM® and another HAV vaccine.	AVAXIM® 0.5 mL I.M. HAV vaccine 1 mL I.M. 1 Dose + Booster	N = 840	18 – 60 Years	Males N = 275 Females N = 565
HAF06393	Randomized, double-blinded, /multicentre, descriptive study for HAV antibody titres and immunogenicity.	0.5 mL I.M. 1 Dose + Booster	N = 243	16 – 60 Years	Males N = 213 Females N = 30
HAF07393	Monocentre, open, controlled, comparative	0.5 mL I.M.	N = 80	18 – 60 Years	Males N = 50

Study #	Trial Design	Dosage, Route of Administration and Duration	Study Subjects	Age Range	Gender
	study on immunogenicity	1 Dose + Booster			Females N = 30
HAF08393	Multicentre, open, non-controlled trial descriptive study on local and systemic reactions.	0.5 mL I.M. 1 Dose + Booster	N = 2159	18 – 60 Years	Males N = 2065 Females N = 94
AVi01398	Multicentre, open, randomized comparison study between HA/Vi vaccine and concomitant administration of hepatitis A and typhoid fever vaccines	1 Dose, 1.0 mL I.M. of HA/Vi Vaccine or 1 Dose, 0.5 mL I.M. each of Hepatitis A and Typhoid Fever Vaccine	N = 360	16 – 65 Years	Males N = 144 Females N = 216

14.4 Immunogenicity

Clinical studies indicate that the vaccine confers immunity against HAV by inducing antibody titres greater than those obtained after passive immunization with immunoglobulin. Immunity appears shortly after the first injection.

In clinical studies involving over 1,000 volunteers, specific humoral antibodies against hepatitis A were elicited after the first injection and more than 90% of immunocompetent subjects were protected (titres above 20 mIU/mL) 14 days after vaccination. One month after the first injection, 100% of the subjects were protected. Immunity persisted for at least 36 months and was reinforced after a booster dose.

In comparative trials with another hepatitis A vaccine, AVAXIM® demonstrated a superior immunogenicity profile. Additionally, seroconversion rates at 14 days showed that the immune responses occur more rapidly with AVAXIM®. This prompt immune response may be an important consideration when travellers must be vaccinated immediately prior to departure or when post-exposure prophylaxis cannot be done immediately after exposure.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

Available data in animals revealed no unexpected findings and no target organ toxicity.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

AVAXIM®

Hepatitis A Vaccine Inactivated

Read this carefully before you start taking 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.

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.

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 take 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.**
- **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® - Pediatric:

- 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/ae-fi-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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