PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

AVAXIM® - Pediatric

Hepatitis A Vaccine Inactivated

Suspension for Injection

80U/0.5mL

For active immunization against Hepatitis A infection

ATC Code: J07BC02

Sanofi Pasteur Limited

Toronto, ON Canada

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

AVAXIM® - Pediatric is indicated for active immunization against infection caused by hepatitis A virus (HAV) in persons 12 months to 15 years of age inclusive. AVAXIM® - Pediatric can be used for primary immunization or as a booster following primary immunization with AVAXIM® - Pediatric or other similar hepatitis A vaccines.

1.1 Pediatrics

AVAXIM® - Pediatric is not indicated for immunization of persons under the age of 12 months or persons 16 years of age and older.

2 CONTRAINDICATIONS

AVAXIM® - Pediatric 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 , see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- **Administration Route Related Precautions:**
  Do not administer AVAXIM® - Pediatric by intravascular injection.
  Do not administer intradermally.
  AVAXIM® - Pediatric 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

Primary immunization:

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

Booster immunization:

After primary vaccination, a booster dose of 0.5 mL is recommended in order to confer long-term protection. This booster dose should be given preferably 6 months to 36 months after the primary vaccination, but can be given up to 7 years after primary vaccination.

The need for another booster dose is not fully established. However, long-term antibody persistence data showed that anti-HAV antibodies persist up to 14-15 years in healthy individuals after a two-dose vaccination schedule with AVAXIM® - Pediatric (See 10 CLINICAL PHARMACOLOGY, 10.3 Pharmacokinetics).

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® - Pediatric 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.

Use a separate sterile needle and syringe, or a sterile disposable unit for each individual patient to prevent disease transmission. When administering a dose from a stoppered vial, do not remove either the stopper or the metal seal holding it in place. Aseptic technique must be used for withdrawal of each dose. 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 Ingredients:** Hepatitis A Virus, GBM strain (inactivated): 80 antigen units (U)	aluminum hydroxide (expressed as aluminum), ethanol anhydrous, formaldehyde, Medium 199 Hanks, 2-phenoxyethanol Manufacturing process residuals: neomycin

Description

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

Each dose (0.5 mL) is formulated to contain: 80 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 0.15 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 is used for pH adjustment; these components are only present in trace amount. Neomycin is also present in trace amounts.

Packaging:

The plunger stoppers and needle shield for the syringes do not contain latex (natural rubber).

AVAXIM® - Pediatric 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® - Pediatric, 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® - Pediatric will prevent hepatitis A in this case.

Seropositivity against HAV is not a contraindication.

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® - Pediatric 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® - Pediatric 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® - Pediatric does not provide protection against infection caused by hepatitis B virus, hepatitis C virus, hepatitis D virus, hepatitis E virus, or by other liver pathogens, other than HAV.

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

7.1 Special Populations

7.1.1 Pregnant Women

Animal reproduction studies have not been conducted with AVAXIM® - Pediatric.

Data on the use of this vaccine in pregnant woman are limited. Therefore, the administration of the vaccine during pregnancy is not recommended. AVAXIM® - Pediatric 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® - Pediatric is administered to a nursing mother.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The most commonly reported adverse reactions in pediatrics (aged 12 months to 15 years) were injection site pain (13.4%) and crying abnormal (13.0%) after the first dose, injection site pain (9.8%) and malaise (6.3%) after the second dose.

8.2 Clinical Trial Adverse Reactions

Because clinical trials are conducted under very specific 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.

8.2.1 Clinical Trial Adverse Reactions – Pediatrics

More than 6,200 children aged 12 months to 15 years were vaccinated with AVAXIM® - Pediatric during clinical trials. A pooled analysis was performed by integrating data from 5,458 subjects included in 15 clinical trials conducted between 1996 and 2014, who received at least one dose of AVAXIM® - Pediatric. The mean age of the subjects was 5.80 years (ranging from 11.8 months to 16.0 years) at the time of the first injection, and 6.69 years (ranging from 17.2 months to 16.8 years) at the second

injection. The proportion of male and female subjects was balanced with 51.4% male subjects. The subjects were from 12 countries in Europe, Asia and Latin America.

Adverse events were usually mild and confined to the first few days after vaccination with spontaneous recovery. Younger children experienced fewer reactions than older children. Reactions were reported less frequently after the booster dose than after the first dose.

Mild transient elevation of serum transaminases has been reported on rare occasions.

Table 2 summarizes the percentage of subjects from this pooled analysis experiencing at least one solicited adverse reaction within 7 days post-vaccination with AVAXIM® - Pediatric.

Table 2: Solicited Adverse Reactions Within 7 Days Following AVAXIM® - Pediatric

Adverse Reaction	After the First Dose (%)* N† = 5,458	After the Second Dose (%)* N† = 4,777
Injection site reaction		
Injection site pain	13.4	9.8
Injection site erythema	4.6	2.3
Injection site induration/edema	2.5	1.3
Injection site hematoma	1.5	0.7
Systemic Reaction		
Crying abnormal	13.0	0.9
Malaise	8.9	6.3
Headache	8.6	4.6
Myalgia	6.7	4.7
Decreased appetite	6.1	2.2
Pyrexia	5.5	2.4
Irritability	5.1	1.4
Abdominal pain	4.6	2.4
Asthenia/Drowsiness	4.5	1.4
Diarrhea	3.6	1.6
Vomiting	3.5	1.4
Nausea	3.0	1.0
Arthralgia	1.8	0.8

Insomnia	1.7	1.0
Urticaria	0.9	0.0
Rash	0.0	0.5

*For each reaction, the frequency has been defined by the number of subjects experiencing the reaction divided by the number of subjects with available data; the number of subjects with available data ranges from 50 to 5,353.

† N: the number of subjects who received AVAXIM® - Pediatric

In subjects seropositive against HAV, AVAXIM® - Pediatric, was as well tolerated as in seronegative subjects.

The safety results of clinical trial HAF65 studying concomitant administration of AVAXIM® - Pediatric and Sanofi Pasteur's MMR vaccine were consistent with the safety profile of each individual vaccine and showed a tendency towards a greater number of subjects experiencing at least one systemic reaction when AVAXIM® - Pediatric and Sanofi Pasteur's MMR vaccine were administered concomitantly.

8.5 Post-Market Adverse Reactions

The following additional adverse reactions have been spontaneously reported during the post-marketing use of AVAXIM® - Pediatric. 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 events, 2) frequency of reporting, or 3) strength of causal connection to AVAXIM® - Pediatric.

Immune system disorders

- Anaphylactic reaction

Nervous system disorders

- Vasovagal syncope
- Convulsions with or without fever

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). No interaction with other medication is currently known.

Separate injection sites and separate syringes must be used in case of concomitant administration with

other medicinal products.

Concomitant Vaccine Administration:

AVAXIM® - Pediatric 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.

AVAXIM® - Pediatric may be administered concomitantly with trivalent live attenuated vaccine for combined immunization against measles, mumps and rubella (MMR).

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

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

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.

AVAXIM® - Pediatric 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 95% 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 clinical studies for immunogenicity in 656 children aged 12 months to 15 years (inclusive), seroconversion rates 2 weeks following vaccination ranged from 95.4% to 99.1% depending on the study. One hundred percent of those tested at 24 and 28 weeks following vaccination had protective antibody levels.

10.3 Pharmacokinetics

Duration of Effect

A descriptive, prospective, mono-centre, antibody persistence study conducted in 546 Argentinean children provided long-term antibody persistence data on two groups; one group who received a single dose of AVAXIM® - Pediatric and another group who received the standard two-dose schedule. It was shown 7 years after vaccination that the group who received a single dose of AVAXIM® - Pediatric (N=204) had a similar seroprotective level of anti-HAV antibodies as the group who received two doses (N=53).

Data relative to long-term persistence of anti-HAV antibodies following booster vaccination with AVAXIM® - Pediatric indicate that anti-HAV antibodies persist up to 14-15 years in healthy individuals. According to NACI, protective levels of anti-HAV antibody will likely persist for at least 20 years, possibly for life, following immunization with two doses of hepatitis A-containing vaccine.

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® - Pediatric [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 80 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 Pivotal Trials with AVAXIM® - Pediatric

Study #	Trial Design	Dosage, Route of Administration and Duration	Study Subjects	Age Range	Gender
HAF11395	Unicentre, open, non-controlled study with three age groups and direct individual benefit	0.5 mL I.M. 1 Dose + Booster	N = 189	18 months – 15 years 18 months – 4 years (N = 42) 4 – 9 years (N = 59) 9 – 15 years (N = 88)	Males N = 103 Females N = 86
HAF17396	Multicentre, open, non-controlled, descriptive with direct individual benefit.	0.5 mL I.M. 1 Dose + Booster	N = 1244	18 months – 15 years 18 months – 4 years (N = 353) 4 – 9 years (N = 463) 9 – 15 years (N = 428)	Males N = 652 Females N = 592

Study #	Trial Design	Dosage, Route of Administration and Duration	Study Subjects	Age Range	Gender
HAF19396	Multicentre, open, non-controlled, with direct individual benefit.	0.5 mL I.M. 1 Dose + Booster	N = 597	18 months – 15 years 18 months – 4 years (N = 200) 4 – 9 years (N = 197) 9 – 15 years (N = 200)	Males N = 301 Females N = 296
HAF20396	Unicentre, open, non-controlled, with direct individual benefit.	0.5 mL I.M. 1 Dose + Booster	N = 537	12 months – 15 years 12 months – 4 years (N = 257) 4 – 9 years (N = 163) 9 – 15 years (N = 117)	Males N = 292 Females N = 245
HAF82	Unicentre descriptive prospective cohort study (epidemiological trial).	Not applicable	N = 546	24 – 39 months	Males N = 271 Females N = 275
HAF65	Multi-center, randomized, blind observer, controlled study.	0.5 mL I.M. 1 Dose + Booster (concomitant or separately 1 dose MMR)	N = 470	12 – 13 months	Males N = 261 Females N = 209

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 for immunogenicity in 656 children aged 12 months to 15 years (inclusive), seroconversion rates 2 weeks following vaccination ranged from 95.4% to 99.1% depending on the

study. One hundred percent of those tested at 24 and 28 weeks following vaccination had protective antibody levels. A second dose given 6 months following the initial dose resulted in a marked booster response (increase in antibody titres of 22.6-fold and 35.5-fold).

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. Immunity persisted for at least 36 months and was reinforced after a booster dose.

In comparative trials with another hepatitis A vaccine, AVAXIM® - Pediatric demonstrated a superior immunogenicity profile. Although seroconversion rates at 14 days were similar to that of the other hepatitis A vaccine, GMTs were significantly higher following AVAXIM® - Pediatric. 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.

A descriptive, prospective, mono-centre, antibody persistence study was conducted in a cohort of 546 Argentinean subjects who received 1 or 2 doses of AVAXIM® - Pediatric before inclusion and were 11 to 23 months old at the time of the first vaccine dose administration. The subjects were followed-up on a yearly basis and blood samples were collected to determine the concentration of anti-HAV antibody up to 7 years after hepatitis A vaccination course. This study showed that the seroprotection rate remained high 3, 5 and 7 years after hepatitis A vaccination course, including in subjects who received only a single dose of AVAXIM® - Pediatric. At Year 7, the seroprotection rate (defined as the proportion of subjects with anti-HAV IgG concentrations ≥3 mIU/mL, using electrochemiluminescence immunoassay) was 100.0% in subjects who received 1 dose (N=204) or 2 doses (N=53) of AVAXIM® - Pediatric. Anti-HAV IgG titers were well above the seroprotective thresholds up to 7 years after hepatitis A vaccination course, including in subjects who received only a single dose of AVAXIM® - Pediatric, but tended to decrease all along the 7 years after vaccination.

A randomized, blind-observer, controlled trial was conducted in Turkey to compare the immunogenicity of AVAXIM®-Pediatric administered alone or concomitantly but at different sites with Sanofi Pasteur's MMR vaccine, in HAV seronegative children, 12 to 13 months of age. A total of 470 subjects were randomly assigned to one of three groups and received a dose of either AVAXIM® - Pediatric or MMR vaccine alone, or both vaccines concomitantly (at separate sites) on D0. All groups received one booster dose of AVAXIM® - Pediatric vaccine on Day 213.

	D0		**D28**		**Booster D213**
Group	AVAXIM® - Pediatric	MMR	AVAXIM® - Pediatric	MMR	AVAXIM® - Pediatric
A	X			X	X
B		X	X		X
C	X	X			X

The primary parameter was the difference in seroprotection rates (anti-HAV antibody titer ≥20 mIU/mL on D28) between the Group C and Group A. Non-inferiority was defined as the lower limit of the 95% CI of this difference being ≥-5%. As shown in Table 4, when AVAXIM® - Pediatric was administered alone

or concomitantly with Sanofi Pasteur's MMR vaccine, high anti-HAV antibody titers were induced and seroprotection was achieved in 92.7% to 93.6% of subjects.

Table 4: Anti-HAV Seroprotection Rates on Day 28

	Group A N=172		Group C N=164		Group C - Group A
	n	%	n	%	Difference with 95% CI
Anti-HAV ≥20 mIU/mL	161	93.60	152	92.68	-0.92 [-6.68;4.69]

Previous concomitant AVAXIM® - Pediatric and MMR did not impact the anamnestic response to a booster dose of AVAXIM® - Pediatric.

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® - Pediatric

Hepatitis A Vaccine Inactivated

Read this carefully before you start taking AVAXIM® - Pediatric. 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® - Pediatric.

What is AVAXIM® - Pediatric used for?

AVAXIM® - Pediatric [Hepatitis A Vaccine Inactivated] is a vaccine that is used to prevent hepatitis A infection. This vaccine may be given to persons 12 months to 15 years of age inclusive.

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. Although young children usually are not very ill, they can continue to spread the virus to others for several months.

The majority of persons who are vaccinated with AVAXIM® - Pediatric will produce enough antibodies to help protect them against this disease. However, as with all vaccines, 100% protection cannot be guaranteed.

How does AVAXIM® - Pediatric work?

AVAXIM® - Pediatric 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® - Pediatric?

Medicinal ingredients: inactivated hepatitis A virus.

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

AVAXIM® - Pediatric comes in the following dosage forms:

AVAXIM® - Pediatric is a suspension for injection (80U/0.5mL)-supplied in 0.5 mL prefilled syringes.

Do not use AVAXIM® - Pediatric if:

- You have a known severe allergy to any ingredient in AVAXIM® - Pediatric or its container, or who 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 or your child take AVAXIM® - Pediatric. 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® - Pediatric 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® - Pediatric with other vaccines or medicinal products in the same syringe.

How to take AVAXIM® - Pediatric:

Usual dose:

A single dose of 0.5 mL is recommended for immunization in persons 12 months to 15 years of age inclusive.

For long-term protection against hepatitis A, a booster dose of 0.5 mL will be required. This booster dose should be given preferably 6 to 36 months after the first dose of AVAXIM® - Pediatric but can be given up to 7 years after the first dose.

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® - Pediatric, 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® - Pediatric?

These are not all the possible side effects you may feel when taking AVAXIM® - Pediatric. 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® - Pediatric causing serious harm is extremely small. The risks associated with AVAXIM® - Pediatric are much less than the risks associated with getting the diseases.

Serious side effects are very rare.

Some children who receive AVAXIM® - Pediatric may have mild side effects such as mild pain at the injection site, associated with redness and swelling and injection site bruising.

Other common side effects include abnormal crying, headache, gastro-intestinal tract disorders such as abdominal pain, diarrhea, nausea and vomiting, muscle or joint ache, hives or rash, behavioural changes such as decreased appetite and nervousness, fever, difficulty sleeping, weakness and generally feeling unwell. These side effects usually go away within a few days.

Some children may also experience fainting or fits (convulsions) with or without fever.

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)		✓
Convulsions with or without fever		✓

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® - Pediatric 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® - Pediatric:

- 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 (www.sanofi.ca), or by calling the vaccine producer at 1-888-621-1146 (no charge).

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