AVAXIM™

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using AVAXIM?

AVAXIM contains the active ingredient Hepatitis A Virus (inactivated, adsorbed). AVAXIM is a vaccine used to help prevent Hepatitis A infection.

For more information, see Section 1. Why am I using AVAXIM? in the full CMI.

2. What should I know before I use AVAXIM?

Do not use if you have ever had an allergic reaction to AVAXIM or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use AVAXIM? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AVAXIM and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use AVAXIM?

- AVAXIM is given as an injection into your upper arm muscle by a doctor or nurse.
- Your doctor will usually give you one injection, followed by another injection 6 to 36 months later

More instructions can be found in Section 4. How do I use AVAXIM? in the full CMI.

5. What should I know while using AVAXIM?

Things you should 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.
Things you should not do	• Do not have AVAXIM if you have had a severe reaction to a previous injection of this vaccine.
Looking after your medicine	• AVAXIM is usually stored in the doctor's surgery or clinic, or at the pharmacy • It should be kept in the original pack until it is time for it to be given • It must be kept it in the refrigerator, between 2°C and 8°C. Do not freeze.

For more information, see Section 5. What should I know while using AVAXIM? in the full CMI.

6. Are there any side effects?

The more common side effects of AVAXIM include local reaction around the injection site, bruising, mild fever, headaches, unusual weakness, aching muscles, muscle tenderness or weakness (not caused by exercise), painful, swollen joints, nausea, diarrhoea, vomiting or abdominal pain, fainting, severe allergic reaction and seizures. Mostly these are mild and short-lived.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

AVAXIM™

Active ingredient: *Hepatitis A Virus (inactivated, adsorbed)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AVAXIM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AVAXIM.**

Where to find information in this leaflet:

1. Why am I using AVAXIM?
2. What should I know before I use AVAXIM?
3. What if I am taking other medicines?
4. How do I use AVAXIM?
5. What should I know while using AVAXIM?
6. Are there any side effects?
7. Product details

1. Why am I using AVAXIM?

AVAXIM contains the active ingredient Hepatitis A Virus (inactivated, adsorbed). 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.

2. What should I know before I use AVAXIM?

Warnings

Do not use AVAXIM if:

- you are allergic to AVAXIM, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have had a severe reaction to a previous injection of this vaccine.
- the child is under 2 years of age. The safety and efficacy of AVAXIM in these children has not been established.

Check with your doctor if you:

- have any other medical conditions that may cause lowered immunity as the vaccine may not work as well as it would in healthy individuals especially
    - 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)
- take any medicines for any other condition.
- have allergies to neomycin, any other medicines or any other substances such as foods, preservatives or dyes.
- have ever had a serious allergic reaction to a vaccine.
- Have an illness with a high temperature or any acute illness. Your doctor may decide to delay vaccine until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AVAXIM.

4. How do I use AVAXIM?

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.**
- 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.

If you forget to use AVAXIM

If you miss a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

If you use too much AVAXIM

Overdose is unlikely as your doctor is giving you the injection.

If you have any concerns, ask your doctor.

5. What should I know while using AVAXIM?

Things you should 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.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using AVAXIM.

Looking after your medicine

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

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Skin-related: • 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 • Rash sometimes associated with itchiness of skin, or pinkish, itchy swelling on the skin **General body:** • Mild fever • Bruising **Neurological-related:** • Headaches • Unusual weakness • Fainting • Seizures **Musculoskeletal-related:** • Aching muscles, muscle • tenderness or weakness (not caused by exercise) • Painful, swollen joints **Gastrointestinal-related:** • Stomach upsets such as nausea, diarrhoea, vomiting or abdominal pain **Liver-related:** • Mild reversible rise in liver enzyme that can only be found when your doctor does tests **Lymphatic-related:**	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• Swollen lymph nodes	

Serious side effects

Serious side effects	What to do
Allergy-related: • Severe allergic reaction. Symptoms may include: o Shortness of breath, wheezing or difficulty breathing o Swelling of the face, lips, tongue or other parts of the body o Skin rash, itching or hives	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or in New Zealand at https://pophealth.my.site.com/carmreportnz/s/. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What AVAXIM contains

Active ingredient **(main ingredient)**	160 antigen units hepatitis A virus (inactivated, adsorbed) The hepatitis A virus that this vaccine contains was grown in a cell line derived from human embryonic lung in the 1960s.
Other ingredients **(inactive ingredients)**	• Aluminium hydroxide hydrate • Phenoxyethanol • Ethanol absolute • Formaldehyde • Medium 199 (Hanks) supplemented with Polysorbate 80 • Neomycin (trace) • Bovine serum albumin (trace)
	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.

Do not take this medicine if you are allergic to any of these ingredients.

What AVAXIM looks like

Each pack of AVAXIM contains one syringe filled with inactivated Hepatitis A vaccine. (Aust R 194815).

Who distributes AVAXIM

Distributed in Australia by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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