

HAVRIX 1440 and HAVRIX Junior

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor, nurse or pharmacist.

1. Why am I being given HAVRIX?

HAVRIX is used to prevent hepatitis A infection. In this leaflet, HAVRIX refers to the use of both HAVRIX 1440 for adults, and HAVRIX Junior for children. HAVRIX contains inactivated hepatitis A virus.

For more information, see Section [1. Why am I being given HAVRIX?](#) in the full CMI.

2. What should I know before I am given HAVRIX?

Do not receive this vaccine if you/your child has ever had an allergic reaction to HAVRIX or any of the ingredients listed at the end of the CMI.

You should not be given HAVRIX if you have/your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.

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 am given HAVRIX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HAVRIX 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 is HAVRIX given?

- HAVRIX will be injected into the upper arm muscle in adults and older children, and into the thigh muscle in infants. For some people with bleeding problems, the dose may need to be given under the skin (subcutaneously).
- HAVRIX is generally given as a single dose on an elected date. If travelling overseas, HAVRIX should be given at least 2 weeks before departure. After one dose of HAVRIX, protection from hepatitis A lasts for at least 1 year. A second booster dose, given 6 to 12 months after the first dose, gives longer term protection.

More instructions can be found in Section [4. How is HAVRIX given?](#) in the full CMI.

5. What should I know when being given HAVRIX?

Things you should do	<ul style="list-style-type: none">• Keep your visits with the doctor or clinic. It is important HAVRIX doses are given at the correct times.• Remind any doctor, nurse or pharmacist you visit that you have been given HAVRIX.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how HAVRIX affects you.• HAVRIX may cause dizziness or lightheadedness in some people.
Looking after your vaccine	<ul style="list-style-type: none">• HAVRIX will normally be stored at the doctor's surgery or in the pharmacy.• If you need to store HAVRIX, store in the refrigerator between 2°C and 8°C. Do not freeze.

For more information, see Section [5. What should I know when being given HAVRIX?](#) in the full CMI.

6. Are there any side effects?

Side effects which have been reported include redness, swelling, a hard lump, soreness, bruising or itching around the injection site, headache, irritability, drowsiness, diarrhoea, vomiting, loss of appetite, stiff joints, aching muscles, headache, tiredness, fever, and feeling generally unwell.

As with all vaccines given by injection there is a very small risk of serious allergic reaction. 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.

HAVRIX 1440 and HAVRIX Junior

Active ingredients: *Inactivated Hepatitis A Virus*

Consumer Medicine Information (CMI)

This leaflet provides important information about HAVRIX. In this leaflet, HAVRIX refers to the use of both HAVRIX 1440 for adults, and HAVRIX Junior for children. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using HAVRIX.**

Where to find information in this leaflet:

- [1. Why am I being given HAVRIX?](#)
- [2. What should I know before I am given HAVRIX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is HAVRIX given?](#)
- [5. What should I know when being given HAVRIX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given HAVRIX?

HAVRIX contains inactivated hepatitis A virus.

HAVRIX is a vaccine used to prevent hepatitis A infection.

The vaccine works by causing the body to produce its own protection (antibodies) against this disease.

HAVRIX cannot give you hepatitis A when you receive it as the virus in the vaccine has been killed.

Hepatitis A is an infectious disease, which can affect the liver. This disease is caused by the hepatitis A virus.

The hepatitis A virus can be passed from person to person in food and drink, or by swimming in water contaminated by sewage. Symptoms of hepatitis A begin 3 to 6 weeks after coming into contact with the virus. These consist of nausea (feeling sick), fever and aches and pains. After a few days the whites of eyes and skin may become yellowish (jaundice). The severity and type of symptoms can vary. Young children may not develop jaundice. Most people recover completely but the illness is usually severe enough to keep people off work for about a month.

Hepatitis A is very common in many parts of the world, and the risk of infection is greatest in those areas where hygiene and sanitation are poor. Such areas include Asia, India, Africa, Central and South America, the Pacific Islands, the Middle East, and the Mediterranean basin. HAVRIX is recommended for all travellers to these areas, including people in the armed forces.

Hepatitis A occurs in Australia, but is not common. Some groups of people however, are at risk of exposure to the disease and should be vaccinated. Vaccination is recommended for:

- healthcare workers
- day-care centre staff
- staff and residents of homes for the intellectually disabled
- sewage workers

- food handlers
- abusers of injectable drugs
- homosexual men
- people in contact with an infected person
- and people with some types of liver or blood disorders.

There is no specific treatment for hepatitis A. Therefore, vaccination is the best way to protect against infection in the longer term.

HAVRIX will not protect against hepatitis caused by other agents or viruses (such as hepatitis B, hepatitis C or hepatitis E). If a person is already infected with the hepatitis A virus at the time of vaccination, HAVRIX may not prevent the disease in these people.

2. What should I know before I am given HAVRIX?

Warnings

You should not be given HAVRIX if:

- you/your child are allergic to **HAVRIX**, or any of the ingredients listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. Always check the ingredients to make sure you can use this vaccine
- you have/your child has had HAVRIX before and became unwell. Tell your doctor or nurse before the first dose is given
- you have/your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.

Check with your doctor if you/your child:

- has any other medical conditions such as:
 - a bleeding disorder, or
 - an immune deficiency condition (e.g. are HIV positive)
- take any medicines for any other condition
- you have/your child has allergies to any other medicines or substances, such as dyes, foods or preservatives
- has fainted with a previous injection. Fainting can occur following, or even before, any needle injection.

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

Check with your doctor if you are pregnant or intend to become pregnant.

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

Your doctor or nurse can discuss with you the risks and benefits involved.

Children

HAVRIX Junior is recommended for use in children 2 to 15 years of age.

HAVRIX is not recommended in children under 2 years of age, as information on use is limited.

Elderly

Information on use of HAVRIX in the elderly is limited.

3. What if I am taking other medicines?

Tell your doctor, nurse 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.

Some medicines may interfere with HAVRIX and affect how it works such as:

- steroids, ciclosporin – medicines used to suppress the immune system.

Having other vaccines

Tell your doctor, nurse or pharmacist if you/your child have received another vaccine recently.

Some vaccines may be affected by other vaccines.

HAVRIX can be given at the same time as other vaccines including: hepatitis B, typhoid, yellow fever, cholera (injectable) and tetanus.

It can also be given at the same time as human immunoglobulin. HAVRIX will always be given separately from other injections.

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

4. How is HAVRIX given?

The doctor or nurse will give HAVRIX as an injection.

If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.

How it is given

- For adults and children aged 16 years and over: HAVRIX 1440 is given as a 1 mL injection into the upper arm muscle.
- For adolescents and children aged 2 to 15 years: HAVRIX Junior is given as a 0.5 mL injection into the upper arm muscle in older children and into the thigh muscle in infants.
- For some people with bleeding problems, the dose may need to be given under the skin (subcutaneously).

The vaccine should never be given into a vein (intravenously).

When it is given

- HAVRIX is generally given as a single dose on an elected date.
- If travelling overseas, HAVRIX should be given at least 2 weeks before departure.
- After one dose of HAVRIX, protection from hepatitis A lasts for at least 1 year. A second booster dose, given 6 to 12 months after the first dose, gives longer term protection. It is predicted that protection could last for 20 years. Your doctor will advise on the need for booster dosing.

If there is a risk of hepatitis A infection occurring before immunity develops, human immunoglobulin may need to be given at the same time as HAVRIX.

If a dose is missed

If a scheduled dose is missed, talk to your doctor or nurse and arrange another visit as soon as possible.

If you/your child are given too much HAVRIX

If you think that you/your child has been given too much HAVRIX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know when being given HAVRIX?

Things you must do

Keep your visits with the doctor or clinic. It is important that HAVRIX doses are given at the correct times. This will ensure the best effect of the vaccine in protecting you/your child against hepatitis A.

Remind any doctor, nurse or pharmacist you visit that you have/your child has been given HAVRIX.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how HAVRIX affects you.

HAVRIX may cause dizziness or lightheadedness in some people.

Looking after your vaccine

HAVRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy.

If you need to store HAVRIX:

- store in the refrigerator between 2°C and 8°C
- THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE
- store in the original pack.

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

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

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

Do not use this vaccine after the expiry date.

6. Are there any side effects?

All vaccines 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
Nervous system disorders: <ul style="list-style-type: none">• headache• irritability• drowsiness• dizziness. Gastrointestinal disorders: <ul style="list-style-type: none">• diarrhoea• vomiting• abdominal pain• loss of appetite. Musculoskeletal and connective tissue disorders: <ul style="list-style-type: none">• stiff joints• aching muscles• pain in the joints or muscles. General disorders and administration site conditions: <ul style="list-style-type: none">• redness, swelling, a hard lump, soreness, bruising or itching around the injection site• feeling generally unwell• fever• feeling sick• tiredness• influenza like illness• chills. Respiratory, thoracic and mediastinal disorders: <ul style="list-style-type: none">• runny or blocked nose. Skin and subcutaneous tissue disorders <ul style="list-style-type: none">• pins and needles• numbness of the skin• rash.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Immune system disorders and allergic reactions: <p>As with all vaccines given by injection there is a very small risk of serious allergic reaction.</p> <ul style="list-style-type: none">• swelling of limbs, face, eyes, inside of nose, mouth or throat• shortness of breath, breathing or swallowing difficulties• hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions• unusual tiredness or weakness that is sudden and severe• convulsions. <p>Allergy to HAVRIX is rare. Any such severe reactions will usually occur within the first few hours of vaccination.</p>	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, nurse 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. By reporting side effects, you can help provide more information on the safety of this vaccine.

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

7. Product details

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

What HAVRIX contains

Active ingredient (main ingredient)	Inactivated hepatitis A virus
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• aluminium hydroxide hydrate• aluminium (HAVRIX Junior only)• neomycin sulphate (trace amounts)• formaldehyde (trace amounts)• polysorbate 20 and amino acid supplement in a

	phosphate buffered saline solution <ul style="list-style-type: none"> • dibasic sodium phosphate heptahydrate • monobasic potassium phosphate • sodium chloride • potassium chloride • water for injections.
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You should not be given this vaccine if you are allergic to any of these ingredients.

HAVRIX does not contain human blood or blood products, or any other substances of human origin.

The manufacture of this vaccine 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.

What HAVRIX looks like

HAVRIX is a turbid liquid suspension in a glass pre-filled syringe. Upon storage, a fine white deposit with a clear colourless supernatant may be observed.

HAVRIX 1440 - 1 mL of suspension in a pre-filled syringe (AUST R 147331)

HAVRIX Junior - 0.5 mL of suspension in a pre-filled syringe (AUST R 147335)

Who distributes HAVRIX

GlaxoSmithKline Australia Pty Ltd

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Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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