

HAVRIX[®] 1440 and HAVRIX[®] Junior

Inactivated Hepatitis A Virus Vaccine

CONSUMER MEDICINE INFORMATION LEAFLET

In this leaflet, HAVRIX refers to the use of both HAVRIX 1440 for adults, and HAVRIX Junior for children.

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about HAVRIX vaccine. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of you or your child having HAVRIX against the expected benefits.

If you have any concerns about HAVRIX talk to your doctor, nurse or pharmacist.

Keep this leaflet with this vaccine. You may need to read it again.

WHAT IS HAVRIX USED FOR

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.

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.

BEFORE RECEIVING HAVRIX

DO NOT HAVE HAVRIX IF:

- you have/your child has had an allergic reaction to HAVRIX, or any ingredient contained in this vaccine. The ingredients are 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.

If 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.
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering
- you have/your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- you have/your child has received another vaccine. 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.

If you are not sure whether HAVRIX should be given, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for you/or your child.

BEFORE HAVING HAVRIX TELL YOUR DOCTOR IF

- you are or think you may be pregnant or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of having HAVRIX during pregnancy.
- you are breast feeding. It is not known if HAVRIX passes into breast milk, however the vaccine is not expected to cause problems in breast-fed babies.
- you have/your child has any medical conditions, such as:
 - a bleeding disorder. Sometimes HAVRIX may need to be given differently in people with bleeding problems.
 - or an immune deficiency condition (eg. are HIV positive)

Some vaccines may be affected by other vaccines or medicines. Your doctor, nurse or pharmacist will be able to tell you what to do if HAVRIX is to be given with another vaccine or medicine.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you/your child fainted with a previous injection.

USE IN 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.

USE IN THE ELDERLY

Information on use of HAVRIX in the elderly is limited.

HOW HAVRIX IS 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 MUCH IS GIVEN

For adults and children aged 16 years and over: the HAVRIX 1440 dose is 1mL.

For adolescents and children aged 2 to 15 years: the HAVRIX Junior dose is 0.5mL

HOW IS IT 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).

The vaccine should never be given intravenously.

WHEN IT WILL BE 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. This is so the body has time to respond to the vaccine. 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.

After one dose of HAVRIX, protection from hepatitis A lasts for at least 1 year. A second boosting 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 A DOSE IS MISSED

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

WHILE YOU ARE USING HAVRIX

THINGS YOU MUST DO:

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

THINGS TO BE CAREFUL OF:

Be careful driving or operating machinery until you know how HAVRIX affects you. HAVRIX should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or lightheadedness. Make sure you know how you react to HAVRIX before you drive a car or operate machinery, or do anything that could be dangerous if you are dizzy or lightheaded.

SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if you (or your child) do not feel well during or after having had a dose of HAVRIX.

HAVRIX helps protect most people from hepatitis A, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious; most of the

time they are not. Some side effects may need medical treatment.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Most unwanted effects with HAVRIX are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

MILD EFFECTS

- **Tell your doctor if you notice any of the following that are troublesome or ongoing after vaccination:**
 - redness, swelling, a hard lump, soreness, bruising or itching around the injection site
 - feeling generally unwell, fever, or headache
 - loss of appetite, or feeling sick
 - tiredness, diarrhoea, vomiting abdominal pain
 - influenza like illness, chills
 - runny or blocked nose
 - stiff joints, aching muscles
 - irritability, drowsiness, dizziness
 - pins and needles, numbness of the skin, rash

SERIOUS EFFECTS

As with all vaccines given by injection there is a very small risk of serious allergic reaction. Contact your doctor immediately or go to the casualty department of your nearest hospital if any of the following happens:

- 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

Allergy to HAVRIX is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Other events that have been reported with HAVRIX include:

- pain in the joints or muscles, convulsions

Other side effects not listed above, can also occur during or soon after a dose of HAVRIX.

Check with your doctor or nurse if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

STORAGE

HAVRIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store HAVRIX always:

- Keep HAVRIX in the refrigerator stored between +2°C and +8°C. **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- Keep the vaccine out of the reach of children.

- Keep HAVRIX in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over HAVRIX that has expired or has not been used.

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

HAVRIX comes in glass vials or prefilled syringes. It is a white, slightly milky liquid.

INGREDIENTS:

The active ingredient of HAVRIX is the killed hepatitis A virus. Two different vaccine strengths are available:

- HAVRIX 1440: 1440 ELISA units of killed hepatitis A virus in 1mL of liquid
- HAVRIX Junior: 720 ELISA units of killed hepatitis A virus in 0.5mL of liquid

Inactive ingredients in the vaccine are: aluminium hydroxide, 2-phenoxyethanol, polysorbate 20, amino acids for injection, phosphate salts, sodium chloride, and water. Very small amounts of neomycin sulfate and formaldehyde may also be present.

The vaccine is not infectious, and will not give you hepatitis A.

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

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.

FURTHER INFORMATION

HAVRIX is only available if prescribed by a doctor.

The vaccine comes in the following:

HAVRIX 1440 - monodose vials in packs of 1 and 10 (AUST R 53163) and prefilled syringes in packs of 1 (AUST R 53628)
 HAVRIX Junior - monodose vials in packs of 1 and 10 (AUST R 57802) and prefilled syringes in packs of 1 (AUST R 57801)

MANUFACTURER

GlaxoSmithKline Biologicals s.a.
 rue de l'Institut 89,
 1330 Rixensart, Belgium.

DISTRIBUTED IN AUSTRALIA BY

GlaxoSmithKline Australia Pty Ltd
 1061 Mountain Highway
 Boronia 3155 VIC

Date of Preparation:
 16 May 2011
 Version 3.0