Product Monograph

Including Patient Medication Information

HAVRIX

Hepatitis A virus, inactivated

720 ELISA units per 0.5 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain) or 1440 ELISA units per 1 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain)

Suspension for injection, Intramuscular

Active immunizing agent against infection by hepatitis A virus

ATC Code: J07BC02

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Recent Major Label Changes

Section	Date
4 Dosage and Administration, 4.4. Administration	MAY 2025

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1. Indications

HAVRIX (hepatitis A virus, inactivated) is indicated for active immunization against disease caused by hepatitis A virus (HAV). HAVRIX is approved for use in persons 12 months of age and older. Primary immunization should be administered at least 2 weeks prior to anticipated exposure to HAV.

Please refer to the National Advisory Committee on Immunization (NACI) and the Canadian Immunization Guide for recommendations of use.

1.1 Pediatrics

Pediatrics (12 months of age and older): HAVRIX is approved for use in persons 12 months of age and older (see 14 CLINICAL TRIALS).

1.2 Geriatrics

Geriatrics: Limited data are available to Health Canada (see 7 WARNINGS AND PRECAUTIONS and 14 CLINICAL TRIALS).

2. Contraindications

HAVRIX (hepatitis A virus, inactivated) should not be administered to subjects with known hypersensitivity to any component of the vaccine preparation or component of the container, or to subjects having shown signs of hypersensitivity after previous HAVRIX administration. For a complete listing, see the 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

As with other vaccines, the administration of HAVRIX should be postponed in subjects with severe febrile illness. The presence of a minor infection however, is not a contraindication.

4. Dosage and Administration

4.2 Recommended Dose and Dosage Adjustment

Primary Immunization

Adults from 19 years onwards
A single dose of HAVRIX 1440 (hepatitis A virus, inactivated) (1 mL suspension) is used for primary immunization.

Children and adolescents from 1 year up to and including 18 years of age
A single dose of HAVRIX 720 Junior (0.5 mL suspension) is used for primary immunization.

Booster Dose

A booster dose is recommended at any time between 6 and 12 months after a single dose of HAVRIX 1440 or HAVRIX 720 Junior in order to ensure long-term protection.

Long-term persistence of serum antibodies to hepatitis A virus after vaccination with HAVRIX is under evaluation. Nevertheless, data available after 5 years show persistence of antibodies which is consistent with a projected 20 years persistence (based on mathematical calculations).

Concomitant administration with immune globulin (human)

Concomitant administration of HAVRIX and immune globulin (human) may be considered when a subject is at risk of being exposed to hepatitis A before adequate anti-HAV antibody titres can be reached.

4.4 Administration

Check the expiry date of the vaccine carefully. Do not use vaccine beyond its expiry date.

The vaccine should be inspected visually for any foreign particulate matter and/or colouration prior to administration.

Upon storage, a fine white deposit with a clear colourless layer above may be observed.

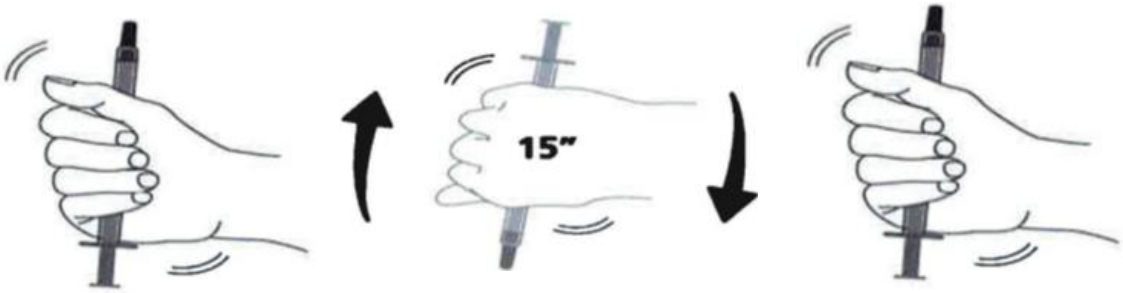
The vaccine should be re-suspended before use. When re-suspended, the vaccine will have a uniform hazy white appearance. Discard if the content appears otherwise.

Re-suspension of the vaccine to obtain a uniform hazy white suspension.

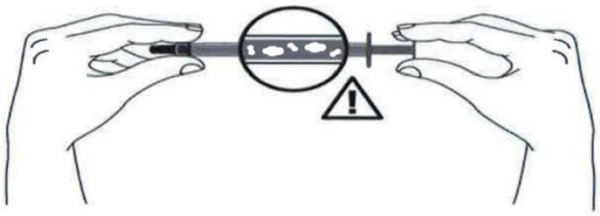
The vaccine can be re-suspended following the steps below:

1. Hold the syringe upright in a closed hand.
2. Shake the syringe by tipping it upside down and back again.
3. Repeat this action vigorously for at least 15 seconds.
4. Inspect the vaccine again:
    a. If the vaccine appears as a uniform hazy white suspension, it is ready to use – the appearance should not be clear.
    b. If the vaccine still does not appear as a uniform hazy white suspension - tip upside down and back again for at least another 15 seconds - then inspect again.

Figure 1. Instructions for Use



1. Grasp the syringe in the palm of the hand shake vigorously by rotating the syringe upside down with a tip over movement, for at least 15 seconds.

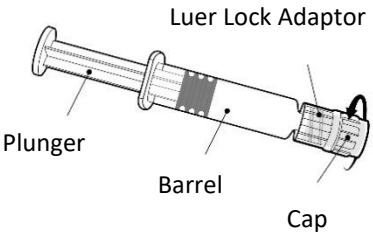


2. Inspect the vaccine and if you still observe clouds or white agglomerates, repeat this action for another 15 seconds.

HAVRIX should be injected **intramuscularly** in the deltoid region in adults and children, in the antero-lateral part of the thigh in young children up to 2 years of age. The vaccine **should not** be administered intramuscularly in the gluteal region or subcutaneously/intradermally since administration by these routes may result in a less than optimal anti-HAV antibody response.

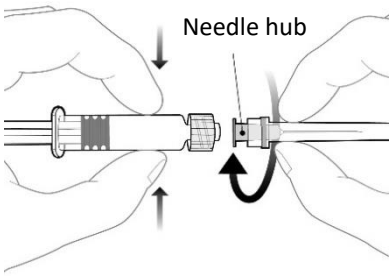
HAVRIX should never be administered intravenously.

Figure 2. Pre-Filled Syringe Instructions



Hold the syringe by the barrel, not by the plunger.

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

5. Overdose

Cases of overdose have been reported during post-marketing surveillance. Adverse events reported following overdosage were similar to those reported with normal vaccine administration.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

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 – Route of Administration, Dosage Forms, Strengths, and Non-medicinal Ingredients

Route of Administration	Dosage Form / Strength	Non-medicinal Ingredients
Intramuscular Injection	Sterile suspension for injection/ HAVRIX 1440 contains: 1440 ELISA units per 1 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain); HAVRIX 720 Junior contains: 720 ELISA units per 0.5 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain).	Aluminium (as aluminium hydroxide), amino acids for injection, disodium phosphate, monopotassium phosphate, polysorbate 20, potassium chloride, sodium chloride, water for injection. Residue*: neomycin sulphate.

*From the manufacturing process

Dosage Forms

HAVRIX (hepatitis A virus, inactivated) is available as HAVRIX 1440 (1440 ELISA Units/mL) and HAVRIX 720 Junior (720 ELISA Units/0.5 mL) suspension for injection.

Composition

HAVRIX is a sterile suspension containing formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain) adsorbed onto aluminium hydroxide.

The virus is propagated in MRC_5 human diploid cells. Before viral extraction, the cells are extensively washed to remove culture medium constituents. A virus suspension is then obtained by lysis of the cells followed by purification using ultrafiltration techniques and gel chromatography. Inactivation of the virus is assured by treatment with formalin.

The viral antigen content of HAVRIX is determined by an ELISA test. Each dose is standardized to ensure a viral antigen content of not less than:

	ELISA Units	Dose Volume
HAVRIX 1440	1440	1 mL
HAVRIX 720 Junior	720	0.5 mL

The virus is adsorbed on aluminium (0.5 mg/1 mL adult dose, 0.25 mg/0.5 mL pediatric dose) in the form of aluminium hydroxide. Residue from the manufacturing process: neomycin sulphate (less than 10 ng for HAVRIX 720 Junior; less than 20 ng for HAVRIX 1440).

HAVRIX meets the World Health Organization requirement for biological substances including those for final vaccine residual bovine serum albumin.

Packaging

HAVRIX 1440:

Single Dose 1 mL Prefilled Syringes: in packages of 1 prefilled syringe.

HAVRIX 720 Junior:

Single Dose 0.5 mL Prefilled Syringes: in packages of 1 prefilled syringe.

Description

HAVRIX (hepatitis A virus, inactivated) is a sterile suspension containing formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain) adsorbed onto aluminium hydroxide.

7. Warnings and Precautions

General

As with other injectable vaccines, appropriate medication (e.g., adrenaline) should be readily available for immediate use in case of anaphylaxis or anaphylactoid reactions following administration of the vaccine. For this reason, the vaccinee should remain under medical supervision for 30 minutes after immunization.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

Driving and Operating Machinery

HAVRIX (hepatitis A virus, inactivated) is unlikely to produce an effect on the ability to drive and use machines.

Hematologic

HAVRIX (hepatitis A virus, inactivated) should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Immune

It is possible that subjects may be in the incubation period of hepatitis A infection at the time of immunization. It is not known whether HAVRIX will prevent hepatitis A in such cases.

Since there is a possibility that the vaccine may contain trace amounts of neomycin, the possibility of an allergic reaction in individuals sensitive to this substance should be kept in mind when considering the use of this vaccine (see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING).

As with other vaccines, subjects with an impaired immune system may not obtain adequate antibody titres after the primary immunization course. Such patients may require administration of additional doses of HAVRIX. However, no specific dosing recommendations can be made at this time.

Renal

As with other vaccines, hemodialysis patients may not obtain adequate antibody titres after the primary immunization course. Such patients may require administration of additional doses of HAVRIX. However, no specific dosing recommendations can be made at this time.

7.1 Special Populations

7.1.1 Pregnancy

Animal reproduction studies and adequate human data on use during pregnancy are not available. However, as with all inactivated viral vaccines, the risks to the fetus are considered to be negligible. HAVRIX should be used during pregnancy only when clearly needed.

7.1.2 Breastfeeding

Animal reproduction studies and adequate human data on use during lactation are not available. Therefore, caution should be exercised if HAVRIX is to be administered to breast feeding women.

7.1.3 Pediatrics

Pediatrics (12 months of age and older): HAVRIX is approved for use in persons 12 months of age and older.

7.1.4 Geriatrics

Geriatrics: Clinical studies of HAVRIX did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently from younger subjects. Other reported clinical experience from Hepatitis A vaccines has not identified differences in overall safety between these subjects and younger adult subjects.

8. Adverse Reactions

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reactions observed in the clinical trials may not reflect frequencies observed in clinical practice and should not be compared to frequencies reported in clinical trials of another drug.

The safety profile presented below is based on data from more than 5,300 subjects.

Table 2 – Safety Profile of Subjects

AE Frequency	System/Organ Class	Adverse Event (AE)
Very Common: ≥ 10%	General disorders and administration site conditions	Pain and redness at the injection site, fatigue
	Nervous system disorders	Headache
	Psychiatric disorders	Irritability
Common: ≥ 1% and < 10%	Gastrointestinal disorders	Gastrointestinal symptoms (such as nausea, vomiting, diarrhea)
	General disorders and administration site conditions	Malaise, injection site reaction (such as swelling or induration), fever (≥ 37.5°C)
	Metabolism and nutrition disorders	Appetite lost
	Nervous system disorders	Drowsiness
Uncommon: ≥ 0.1% and < 1%	General disorders and administration site conditions	Influenza-like illness
	Infections and infestations	Upper respiratory tract infection, rhinitis
	Musculoskeletal and connective tissue disorders	Myalgia, musculoskeletal stiffness
	Nervous system disorders	Dizziness
	Skin and subcutaneous tissue disorders	Rash
Rare: ≥ 0.01% and < 0.1%	General disorders and administration site conditions	Chills
	Nervous system disorders	Hypoaesthesia, paraesthesia
	Skin and subcutaneous tissue disorders	Pruritus

Administration of HAVRIX with measles-mumps-rubella (MMR) and varicella (V) vaccines

In a co-administration study (HAV 231) evaluating immune response in toddlers receiving HAVRIX 720 Junior (N=324) or HAVRIX 720 Junior plus measles-mumps-rubella (MMR) plus varicella vaccines (N=462) or MMR plus varicella plus HAVRIX 720 Junior (N=455), the primary analysis of safety (N=1,241) demonstrated that all the three vaccines, HAVRIX, MMR and varicella, whether co-administered or administered alone, were well tolerated. Reactogenicity and safety of HAVRIX when co-administered with MMR/V vaccines is consistent with the known safety profile of HAVRIX.

8.3 Less Common Clinical Trial Adverse Reactions

See Uncommon and Rare adverse events above for the safety information on Less Common Clinical Trials Adverse Reactions.

8.5 Post-Market Adverse Reactions

Because post marketing reporting of adverse events is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions or establish a causal relationship to drug exposure. Evaluation and interpretation of these post marketing events is confounded by underlying diagnosis, concomitant medications, preexisting conditions, and inherent limitations of passive surveillance.

The following adverse reactions have been reported with HAVRIX (see **Table 2**).

Table 2 – Post-Market Adverse Reactions

System/Organ Class	Adverse Event
Immune system disorders	Anaphylaxis, allergic reactions including anaphylactoid reactions and mimicking serum sickness
Musculoskeletal and connective tissue disorders	Arthralgia
Nervous system disorders	Convulsions
Skin and subcutaneous tissue disorders	Angioneurotic oedema, urticaria, erythema multiforme, Stevens-Johnson syndrome
Vascular disorders	Vasculitis

9. Drug Interactions

9.2 Drug Interactions Overview

Since HAVRIX is an inactivated vaccine, its concomitant use with other inactivated vaccines is unlikely to result in interference with immune responses. When concomitant administration of other vaccines is considered necessary, the vaccines must be given with different syringes and at different injection sites.

Clinical experiences with the concomitant administration of HAVRIX and the hepatitis B virus surface antigen (recombinant) vaccine, ENGERIX-B, has been satisfactory. No interference in the respective immune responses to both antigens has been observed.

HAVRIX can be given concomitantly with any of the following vaccines: typhoid, yellow fever, cholera (injectable), tetanus, or with monovalent and combination vaccines comprised of measles, mumps, rubella and varicella. See also 14 CLINICAL TRIALS.

HAVRIX must not be mixed with other vaccines.

9.4 Drug-Drug Interactions

The concomitant administration of HAVRIX (hepatitis A virus, inactivated) and immune globulin (human) does not influence the seroconversion rate, but may result in a relatively lower anti-HAV antibody titre than when the vaccine is given alone. HAVRIX and immune globulin (human) should be administered at separate injection sites.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology

10.1 Mechanism of Action

HAVRIX (hepatitis A virus, inactivated) confers immunity against hepatitis A virus (HAV) infection by inducing the production of specific anti-HAV antibodies.

10.2 Pharmacodynamics

Immune response

In clinical studies involving subjects of 18 – 50 years of age, specific humoral antibodies against HAV were detected in more than 88% of vaccinees at day 15 and 99% at month 1 following administration of a single dose of HAVRIX 1440 (hepatitis A virus, inactivated).

In clinical studies involving subjects of 1 – 18 years of age, specific humoral antibodies against HAV were detected in more than 93% of vaccinees at day 15 and 99% of vaccinees one month following administration of HAVRIX 720 Junior.

The mean titre of anti-HAV antibodies induced by HAVRIX is at least 3 times higher than the maximum observed after passive immunization using immune globulin (human). In a randomly selected subset of subjects, vaccine induced anti-HAV antibodies were shown to be qualitatively indistinguishable from immune globulin (human) anti-HAV antibodies.

To obtain long-term immunity a booster dose is recommended at any time between 6 and 12 months after primary vaccination with HAVRIX 1440 Adult or HAVRIX 720 Junior, to induce long-term antibody titres.

Long-term persistence of serum antibodies to hepatitis A virus after vaccination with HAVRIX is under evaluation. Nevertheless, data available after 5 years show persistence of antibodies which is consistent with a projected 20 years persistence (based on mathematical calculations).

Primates exposed to the virulent heterologous hepatitis A strain were vaccinated 2 days after exposure. This post exposure vaccination resulted in total protection of the animals.

Efficacy of HAVRIX for outbreak control

Results of hepatitis A outbreak control program showed a substantial drop in symptomatic cases in 4,930 vaccinees within 3 weeks of receiving 1 dose of hepatitis A vaccine. In villages where more than 70% of estimated susceptible individuals were vaccinated, a dramatic drop in the number of symptomatic cases of disease was observed within 8 weeks of vaccination.

Immunization Recommendations (see also Canadian Immunization Guide)

Active immunization with HAVRIX is indicated for the following individuals: Armed Forces personnel who travel to higher endemicity areas or to areas where hygiene is poor have an increased risk of HAV infection, close contacts of infected persons since virus shedding of infected persons may occur for a prolonged period, individuals with chronic liver disease or who are at risk of developing chronic liver disease such as hepatitis B (HB) and hepatitis C (HC) chronic carriers and alcohol abusers and susceptible individuals in areas of intermediate to high prevalence of hepatitis A.

Immunization with HAVRIX is particularly recommended in subjects who are, or will be, at increased risk of infection such as: travellers (i.e., to areas where the prevalence of hepatitis A is high), persons for whom hepatitis A is an occupational hazard (i.e., employees in day-care centres, nursing, medical and paramedical personnel in hospitals and institutions, especially gastroenterology and pediatric units, sewage workers, and food handlers), persons for whom there is an increased risk of transmission of Hepatitis A (i.e., homosexuals, persons with multiple sexual partners, abusers of injectable drugs, hemophiliac patients), specific population groups known to have higher incidence of Hepatitis A (i.e., North American Indians, Inuits, recognized community-wide HAV epidemics).

11. Storage, Stability, and Disposal

The vaccine should not be used beyond the expiry date stamped on the syringe.

Store HAVRIX (hepatitis A virus, inactivated) in the original package in order to protect from light. The vaccine must be stored at 2 to 8°C.

Do not freeze; discard if vaccine has been frozen.

Stability data indicate that HAVRIX is stable at temperatures up to 25°C for 3 days. These data are intended to guide healthcare professionals in case of temporary temperature excursion only.

Dispose any unused product or waste material accordingly.

Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

Proper name: hepatitis A virus, inactivated

Product Characteristics

HAVRIX (hepatitis A virus, inactivated) is a sterile suspension containing formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain) adsorbed onto aluminium hydroxide.

14. Clinical Trials

14.1 Clinical Trials by Indication

For active immunization against disease caused by hepatitis A virus

Clinical studies have been conducted in Asia, Europe, Latin America, USA and Canada to evaluate the immunogenicity and reactogenicity of HAVRIX.

Table 3 – Summary of Study Demographics, Trial Design and Efficacy Results

Study No.	Trial design	Dosage and route of administration	No. of subjects	Patient Demographics	Immunogenicity Results[1]	
					SC Rate (%)	GMT (mIU/ml)
HAV-104	Double-blind, randomized, multi-country, multi-centre	Intramuscular injection (into deltoid region) 1440 EL.U/1 mL dose 0, 6 month dosing schedule	Enrolled: 150	Healthy adults aged 18 to 50 years	97.6[2]	577[2]
HAV-107	Double-blind, randomized, multi-country, multi-centre	Intramuscular injection (into deltoid region) 1440 EL.U/1 mL dose 0, 6 month dosing schedule	Enrolled: 150	Healthy adults aged 18 to 40 years	99.3[2]	490[2]
HAV-112	Double-blind, randomized, multi-country, multi-centre	Intramuscular injection (into deltoid region) 1440 EL.U/1 mL dose 0, 12 month dosing schedule	Enrolled: 194	Healthy adults aged 21 to 40 years	99.4[3]	387[3]

Study No.	Trial design	Dosage and route of administration	No. of subjects	Patient Demographics	Immunogenicity Results[1]	
					SC Rate (%)	GMT (mIU/ml)
HAV-115	Open randomized, multi-country, multi-centre	Intramuscular injection (into deltoid region) Group 1: 720 EL.U/0.5 mL dose Group 2: 1440 EL.U/1 mL dose 0, 6 month dosing schedule	Enrolled: 202	Healthy adolescents aged 12 to 19 years	Group 1: 99.0 Group 2: 100	Group 1: 249 Group 2: 349
HAV-117B	Open study, multi-country, multi-centre	Intramuscular injection (into deltoid region) 720 EL.U/0.5 mL dose 0, 6 month dosing schedule	Enrolled: 60	Healthy children aged 2 to 13 years	100	305
HAV-118	Open prospective study, multi-country, multi-centre	Intramuscular injection (into deltoid region, and sometimes the thigh muscle) 720 EL.U/0.5 mL dose 0, 12 month dosing schedule	Enrolled: 54	Healthy children aged 2 to 11 years	95.5	184
HAV-122	Open randomized study, multi-country, multi-centre	Intramuscular injection (into deltoid region) 720 EL.U/0.5 mL dose 0, 6 month dosing schedule	Enrolled: 81	Healthy children aged 2 to 15 years	96.8	194
HAV-129	Open study, multi-country, multi-centre	Intramuscular injection (into deltoid region) 720 EL.U/0.5 mL dose 0, 6 month dosing schedule	Enrolled: 120	Healthy adolescents aged 9 to 18 years	100	256
Alaskan Outbreak Control Programme	Independent study, multi-country, multi-centre	Children/teenagers received dose level of 720 EL.U/0.5 mL Adults received dose level of 1440 EL.U/1 mL	Enrolled: 4,930	Mean age (±standard deviation): 16.47 ± 14.9 years Male: 51% Female: 49%	92[4]	Children / teenagers: 269[5] Adults: 254[6]
HAV-231	Open randomized study, USA, multi-centre	Toddlers 15 months of age Group 1: HAVRIX 720 EL.U/0.5 mL dose 0, 6 month dosing schedule	Enrolled: 1474	Mean age (±standard deviation): 15 months ± 0.21 months	Group 1: 99 Group 2: 99.7 Group 3: 100	Group 1: 1390 Group 2: 1895 Group 3: 1770

Study No.	Trial design	Dosage and route of administration	No. of subjects	Patient Demographics	Immunogenicity Results[1]	
					SC Rate (%)	GMT (mIU/ml)
		Group 2: HAVRIX 720 EL.U/0.5 mL + MMR + varicella vaccines 0, 6-9 month dosing schedule Group 3: MMR + varicella vaccines + HAVRIX 720 EL.U/0.5 mL 0, day 42 (1st dose HAVRIX 720 EL.U/0.5 mL), month 7.5-10.5 (2nd dose HAVRIX 720 EL.U/0.5 mL)		Male: 53%. Female: 47%	(SC rates post-dose 2)[7]	(GMCs post-dose 2)[8]

1. Results at 1 month after initial dose
2. Average of 3 lots
3. Average of 2 lots
4. Results at 3-4 weeks after initial dose
5. Average for 3 different age groups (1-2 years, 3-9 years and 10-19 years)
6. 20-40 years age group
7. Seroconversion rates for anti-HAV antibodies
8. GMCs for anti-HAV antibodies

Efficacy

Clinical studies performed in Europe (HAV 104, 107, 112) evaluated immune response in adults to primary vaccination with HAVRIX 1440. Antibodies were measured at screening, day 15, and at month 1 and 6.

In an overall analysis of immunogenicity following vaccination the seroconversion rate was 98.9% at month 1 and the Geometric Mean Titre was 466 mIU/mL.

Clinical studies performed in Asia, Europe, Latin America, and Alaska (HAV 115, 117B, 118, 122, 129 and Alaskan outbreak program) evaluated immune response in subjects between 2 and 18 years receiving 720 EL.U.

The overall analysis of immunogenicity following vaccination showed that the seroconversion rate was 99.3% at month 1 and the Geometric Mean Titre was 253 mIU/mL.

Administration of HAVRIX with measles-mumps-rubella (MMR) and varicella (V) vaccines

A co-administration study (HAV 231) evaluated immune response in toddlers receiving HAVRIX 720 Junior (group 1) or HAVRIX 720 Junior + MMR + V vaccines (group 2) or MMR + V + HAVRIX 720 Junior (group 3). Study HAV 231 demonstrated non-inferiority of anti-HAV immune response 31 days after the 2nd dose of HAVRIX when the 1st dose had been co-administered with MMR + V compared to HAVRIX alone (1st co-primary objective). HAV 231 also demonstrated non-inferiority of the MMR + V immune responses 42 days after the first dose of MMR co-administered with varicella and HAVRIX vaccines

compared to MMR + V alone (2nd co-primary objective). All antigens in study HAV 231, including anti-measles, anti-rubella and anti-varicella antibodies, had similar immune responses in the co-administration group (HAV+MMR+V) and control groups (HAV Group and the MMR+V – HAV group). Thus, co-administration of HAVRIX with MMR and varicella vaccines does not impact the immunogenicity of either of these vaccines.

15. Microbiology

No microbiological information is required for this drug product.

16. Non-Clinical Toxicology

Not applicable.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

HAVRIX

hepatitis A virus, inactivated

This Patient Medication Information is written for the person who will be taking **HAVRIX**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this vaccine. If you have more questions about this vaccine or want more information about **HAVRIX**, talk to a healthcare professional.

What HAVRIX is used for:

HAVRIX is a vaccine used to prevent hepatitis A disease. Vaccination is the best way to protect against this disease.

HAVRIX is approved for use in persons 12 months of age and older. The first dose of the vaccine should be given at least 2 weeks prior to anticipated exposure to hepatitis A disease.

How HAVRIX works:

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

The ingredients in HAVRIX are:

Medicinal ingredients: The medicinal ingredient in HAVRIX is inactivated hepatitis A virus. None of the components of the vaccine are infectious.

Non-medicinal ingredients: Aluminium (as aluminium hydroxide), amino acids for injection, disodium phosphate, monopotassium phosphate, polysorbate 20, potassium chloride, sodium chloride and water for injection. Residue from the manufacturing process: neomycin sulphate.

HAVRIX comes in the following dosage forms:

HAVRIX is available as a suspension for injection.

Do not use HAVRIX if:

- you or your child have a known allergy to any component of the vaccine (see What are the ingredients in HAVRIX? above).
- you or your child have shown signs of a serious allergic reaction after a previous dose of this vaccine or any vaccine intended to protect against hepatitis A infection. Signs of an allergic reaction may include skin rash, shortness of breath and swelling of the face or tongue.

Immunization should be postponed if you or your child has a severe fever or infection.

To help avoid side effects and ensure proper use, talk to your healthcare professional before HAVRIX is given to you. Talk about any health conditions or problems you or your child may have, including if:

- you or your child has a severe infection with a high temperature (over 38°C).
- you or your child have any known allergies.
- you or your child is on dialysis for kidney disease.
- you or your child have a poor immune system due to illness or drug treatment.
- you are pregnant or breastfeeding.
- you or your child have a bleeding problem or bruise easily.

Please tell your healthcare professional if you are taking or have recently taken any other medicines. You can be given other vaccines at the same time as HAVRIX, however these vaccines will be given at different injection sites.

Fainting can occur following, or even before, any needle injection; therefore, tell the healthcare professional if you or your child fainted with a previous injection.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

HAVRIX and immune globulin (human) should be administered at separate injection sites.

When administration of other vaccines with HAVRIX is considered necessary, the vaccines must be given with different syringes and at different injection sites.

How to take HAVRIX:

HAVRIX is injected into the muscle in your upper arm or in the front of the thigh in young children.

Usual dose:

Primary Immunization

The first dose of the vaccine should protect you or your child with normal immunity from infection with hepatitis A virus within 2-4 weeks after the injection.

Booster Dose

To ensure that you or your child is protected long-term you or your child should have a second (booster) dose of the vaccine 6 to 12 months after the first injection.

Overdose:

If you think you, or a person you are caring for, have received too much HAVRIX, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you or your child misses a scheduled injection, talk to your healthcare professional to arrange another visit.

Possible side effects from using HAVRIX:

Like all vaccines, HAVRIX can have side effects. These are not all the possible side effects you may have when taking HAVRIX. If you experience any side effects not listed here, tell your healthcare professional.

Side effects that may occur are the following:

Very common (more than 10% of doses):

- Irritability.
- Headache.
- Pain and redness at the injection site, fatigue.

Common (between 1% and 10% of doses):

- Loss of appetite.
- Drowsiness.
- Diarrhea, nausea, vomiting.
- Swelling or hard lump at the injection site.
- Generally feeling unwell, fever.

Uncommon (between 0.1% and 1% of doses):

- Upper respiratory tract infection, runny or blocked nose.
- Dizziness.
- Rash.
- Aching muscles, muscular stiffness not caused by exercise.
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills.

Post-market side effects include: abnormal sensation (such as of burning, prickling, tickling or tingling, pins and needles), itching, chills, fits or seizures, narrowing or blockage of blood vessels, hives (red, often itchy spots which starts on the limbs and sometimes on the face and the rest of the body), joint pain.

Other post-market sides include: allergic reactions. These may be local or widespread rashes that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness. These reactions may occur before leaving the doctor's surgery. However, if your child gets any of these symptoms you should contact a doctor urgently.

If any of the side effects get serious or if you notice any side effects not mentioned above, please tell your healthcare professional.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (PHAC), Health Canada (HC) and GSK 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 (Reporting Adverse Events Following Immunization (AEFI) in Canada) and send it to your local Health Unit.

Storage:

HAVRIX must be stored in a refrigerator between 2 and 8°C. **Do not freeze.** Discard if the vaccine has been frozen.

Do not use after expiration date shown on the label. The date for last use corresponds to the last day of the month mentioned.

Store in the original package in order to protect from light.

Store all vaccines out of the sight and reach of children.

If you want more information about HAVRIX:

- 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 Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website www.gsk.ca, or by calling 1-800-387-7374.

This leaflet was prepared by GlaxoSmithKline Inc.

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