

Hepatitis A Vaccine

BIOLOGICAL PAGE

Section 7	Biological Product Information	Standard # 07.230	
Created and approved by	Provincial Immunization Program		
Approval date	March 1, 2013	Published	March 31, 2026

	Havrix	Vaqta			
Manufacturer	GlaxoSmithKline Inc.	Merck Canada Inc.			
Classification	Non-live: inactivated				
Indications for Provincially Funded Vaccine	Pre-exposure for individuals 6 months of age and older:				
	- Individuals with chronic liver disease from any cause. - Individuals who will undergo or have had liver transplantation and individuals who have developed liver chronic graft versus host disease following hematopoietic stem cell transplant (HSCT). See: Immunization for Adult HSCT Transplant Recipients Immunization for Child HSCT Transplant Recipients Immunization of Adult Solid Organ Transplant Candidates and Recipients Immunization of Children Expecting Solid Organ Transplant Before 18 Months of Age Immunization for Children Expecting Solid Organ Transplant After 18 Months of Age - Individuals receiving repeated replacement of plasma-derived clotting factors. - Individuals with lifestyle risks of infection such as: - Illicit drug use (injectable and non-injectable) - Men having sex with men. - Individuals who live in communities with high rates of hepatitis A infection (includes inmates of provincial correctional facilities). - Residents and staff of institutions for the developmentally challenged in which there is evidence of sustained hepatitis A transmission. - Workers involved in hepatitis A research or production of hepatitis A vaccine who may be exposed to hepatitis A virus. - Specific occupational groups who handle non-human primates (includes zookeepers, veterinarians and researchers). - Household or close contacts of children adopted from hepatitis A endemic countries. - Hepatitis A endemic countries are all countries other than those listed below.				
	The following countries are NOT endemic:				
	Aland Islands	Andorra	Australia	Austria	Belgium
	Canada	Denmark	Faeroe Islands	Finland	France
Germany	Greece	Greenland	Iceland	Ireland	
Italy	Japan	Liechtenstein	Luxembourg	Monaco	
Netherlands	New Zealand	Norway	Portugal	San Marino	
Spain	Sweden	Switzerland	United Kingdom	USA	

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	Note: - Use Hepatitis A and Hepatitis B Combined Vaccine for individuals who are eligible for both pre-exposure hepatitis A and hepatitis B vaccines and who do not require double-strength hepatitis B vaccine. See Hepatitis A and Hepatitis B Combined Vaccine Biological Page. Post-exposure prophylaxis for individuals 6 months of age and older: Administer post-exposure prophylaxis (PEP) to susceptible contacts as soon as possible within 14 days of the last exposure to the case (when the exposure occurred while the case was in the infectious period). This may include hepatitis A vaccine, immune globulin or both. See specific recommendations below. - Give both hepatitis A vaccine (two-dose series) and immune globulin to contacts at risk of developing severe complications (such as those with chronic liver disease; hepatitis B carriers; individuals who are anti-HCV positive; candidates and recipients of liver transplant) and individuals who are immune compromised (congenital and acquired immunodeficiency; immunosuppressive therapy and HIV infection). See Immune Globulin Biological Page. Both doses of hepatitis A vaccine will be provincially funded. - Give immune globulin only to contacts younger than 6 months of age and individuals in whom hepatitis A vaccine is contraindicated. See Immune Globulin Biological Page. - Give hepatitis A vaccine only to all other contacts. - Only one dose of hepatitis A vaccine is provincially funded for PEP. Encourage individuals to receive the 2nd dose for long term protection. - Both doses of hepatitis A vaccine will be provincially funded for individuals eligible to receive hepatitis A vaccine as outlined in pre-exposure indications. Note: - Consult with the Medical Officer of Health on a case-by-case basis if more than 14 days have elapsed since the last exposure. - Hepatitis A vaccine PEP may be considered if more than 14 days have elapsed since the last exposure, as there is no data on the outer limit of efficacy. - For further information related to post-exposure follow-up, refer to Alberta public health disease management guidelines: hepatitis A.	
Serology	Pre-immunization serology (HAV IgG) is recommended for the following individuals: - Individuals born prior to 1945 - Individuals from a hepatitis A endemic country (all countries other than those listed in the Indications Section above are considered endemic for hepatitis A) - Individuals with a history of jaundice that may have been caused by hepatitis A - Adults who are diagnosed with hepatitis B - Adults who are diagnosed with hepatitis C. Post-immunization serology: - Serological testing after receiving hepatitis A containing vaccine is not routinely recommended. Refer to Appendix A: Hepatitis A Serology Interpretation for information on serology results and interpretation.	

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Schedule	- Dose 1: day 0 - Dose 2: 6 to 12 months after dose 1 Note: - No reinforcing doses required. - If the second dose in the hepatitis A vaccine series is missed, it can be administered at a later time without repeating the first dose. - Infant candidates or recipients of SOT. See Immunization of Children Expecting Solid Organ Transplant Before 18 Months of Age (Accelerated). - See Standard for Recommended Immunization Schedules for further information regarding alternate, rapid or combined schedules.	
Preferred Use	None. - Both vaccines are safe and immunogenic in individuals for whom the vaccines are recommended. - Individuals with medical contraindications to one product should be offered the alternate product if supply is available.	
Dose	Individuals 6 months up to and including 18 years of age Havrix 720 Junior 0.5 mL Adults 19 years of age and older Havrix 1440 Adult 1 mL	Individuals 6 months up to and including 17 years of age Pediatric/Adolescent Presentation 0.5 mL Adults 18 years of age and older Adult Presentation 1 mL
Route	Intramuscular injection (IM)	
Contraindications/Precautions	Contraindications: - Known severe hypersensitivity to any component of hepatitis A containing vaccine or its packaging. - Anaphylactic or other allergic reactions to a previous dose of vaccine containing similar components. Precautions: - It is possible that clients may be in the incubation period of hepatitis A infection at the time of immunization. It is not known whether or not hepatitis A vaccine will prevent hepatitis A infection in such cases.	
Possible Reactions	Common: - Pain, redness, swelling, tenderness, warmth and induration at the injection site - Headache, fever, irritability, loss of appetite, drowsiness, malaise, myalgia, stiffness, fatigue, dizziness - Rhinitis, pharyngitis - Rash - Nausea, vomiting, diarrhea and abdominal pain. Rare: - Anaphylaxis - Allergic reactions - As with any immunization, unexpected or unusual side effects can occur. Refer to the Product Monograph for more detailed information.	

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Pregnancy	- Consider giving hepatitis A vaccine to pregnant individuals in high-risk situations when benefits outweigh risks. - A retroactive cohort study published in 2019 of Vaccine Safety Datalink (VSD) data from 2004 through 2015 did not identify any concerning pattern of adverse events in pregnant individuals or their infants following hepatitis A immunization during pregnancy. - Risk to the fetus is considered to be low or non-existent because the vaccine contains inactivated, protein virus particles.	
Lactation	May use for individuals who are lactating/feeding their milk to infants or children.	
Composition	Havrix 720 contains: 720 ELISA units per 0.5 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain). Havrix 1440 contains: 1440 ELISA units per 1 mL of formaldehyde-inactivated hepatitis A virus (HM175 hepatitis A virus strain). Both of the above also contain: - Aluminum hydroxide - Amino acids for injection - Disodium phosphate - Monopotassium phosphate - Polysorbate 20 - Potassium chloride - Sodium chloride - Water for injection. - Neomycin sulphate (residue from the manufacturing process).	Vaqta Pediatric/Adolescent Presentation contains: 25 units of hepatitis A virus protein/0.5 mL dose. Vaqta Adult Presentation Contains: 50 units of hepatitis A virus protein/1 mL dose. Both of the above also contain: - Aluminum hydroxyphosphate sulfate - Sodium borate - Sodium chloride - Water for injection - Neomycin (trace amounts) - Formaldehyde (trace amounts).
Blood/Blood Products	Grown on MRC-5 human diploid cell culture.	
Bovine/Porcine Products	Bovine Products: - Bovine-derived materials are components in the manufacturing process and are removed during purification. Porcine Products: - Does not contain porcine products.	
Latex	Does not contain latex.	May contain latex in vaccine or vaccine packaging.
Interchangeability	Hepatitis A vaccines produced by different manufacturers can be used interchangeably.	
Administration with Other Products	May be given at the same time as other non-live and live vaccines. - Use a separate needle and syringe for each vaccine. - See Standard for the Administration of Immunizations for more information.	
Additional Preparation Instructions	Shake well prior to administration.	None. Follow the Standard for the Administration of Immunizations
Appearance	Slightly opaque white suspension.	
Storage	- Store between +2°C and +8°C - Do not freeze	

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	- Do not use past the expiry date - Store in the original packaging when possible, to protect from light.	
Vaccine Code	HAV	
Antigen Code	HAV	
Licensed for	Havrix 720 Junior -12 months of age up to and including 18 years of age Havrix 1440 -19 years of age and older	Vaqta Pediatric/Adolescent Presentation -12 months of age up to and including 17 years of age Vaqta Adult Presentation -18 years of age and older
Off-license Use	Havrix 720 Junior -Recommended for off-license use in Alberta for infants 6 months to 11 months of age and older who meet eligibility criteria.	Vaqta Pediatric/Adolescent Presentation -Recommended for off-license use in Alberta for infants 6 months to 11 months of age and older who meet eligibility criteria.
Program Notes	1994 January 1: Hepatitis A vaccine became available in Alberta for at risk adults. 1997 June 1: Hepatitis A vaccine became available in Alberta for at risk children. 2016 November 1: Hepatitis A vaccine became available for infants 6 months and older. 2025 August 1: Clarified the 'Indications' section that individuals who are eligible for hepatitis A vaccine includes individuals with chronic liver disease from any cause.	
Related Resources	Hepatitis A Vaccine Information Sheet.	
References		
Committee on Infectious Diseases, American Academy of Pediatrics. (2024). <i>Red Book: 2014-2027 Report of the Committee on Infectious Disease (33rd ed.)</i>. American Academy of Pediatrics. Centers for Disease Control and Prevention. (2021). <i>Epidemiology and Prevention of Vaccine-Preventable Diseases (14th ed.)</i>. Public Health Foundation. GlaxoSmithKline Inc. (2023, November 9). HAVRIX: hepatitis A vaccine, inactivated. Health Canada Drug Product Database. https://pdf.hres.ca/dpd_pm/00073325.PDF Grabenstein, J. D. (2013). <i>Immunofacts: Vaccines and Immunological Drugs</i> (1st ed.). Wolters Kluwer. Immunize.org. (2024, August 27). <i>Ask the Experts: Hepatitis A</i>. http://www.immunize.org/askexperts/experts_hepa.asp Merck Canada Inc. (2013, March 12). VAQTA: hepatitis A vaccine, purified inactivated. Health Canada Drug Product Database. https://pdf.hres.ca/dpd_pm/00019913.PDF National Advisory Committee on Immunization. (2016, September 1). <i>Update on the Recommended Use of Hepatitis A Vaccine</i>. Public Agency of Canada. Primary and Preventative Health Services. (2025, August 1). Hepatitis A Vaccine (HAV). In <i>Alberta Immunization Policy: Biological products</i>. Government of Alberta. Primary and Preventative Health Services. (2024, April). Adverse Events Following Immunization (AEFI) policy for Alberta immunization providers. In <i>Alberta Immunization Policy: Adverse events – Immunization</i>. Government of Alberta. Primary and Preventative Health Services. (2021, October) Alberta Public Health Disease Management Guidelines –Hepatitis A. In <i>Public Health Disease Management Guidelines</i>. Government of Alberta. Public Health Agency of Canada. (2021, November). Hepatitis A. In <i>Canadian Immunization Guide</i>. Government of Canada.		

Appendix A: Hepatitis A Serology Interpretation	
Serology Result	Interpretation
HAV IgG: positive	Indicates immunity. No immunization required. Exception: If client has started a vaccine series, complete series as per schedule.
HAV IgM: positive ¹	Indicates current/recent viral hepatitis A infection or recent Hepatitis A immunization. ¹
HAV Total: positive ²	Indicates acute, recent, past/resolved exposure to Hepatitis A or immunity from immunization. ²
Pre-immunization HAV IgG: negative	Indicates susceptibility. Immunization is recommended.
Post-immunization HAV IgG: negative ³	Result is not a reliable indicator of immune status. ³

¹ HAV IgM can indicate evidence of disease; however, it can also be present as positive result following recent immunization. Assessment of a positive HAV IgM result should also include checking for recent immunization with hepatitis A containing vaccine. Follow up with the Provincial Notifiable Disease program immediately for further direction.

² HAV Total is a combination of IgG and IgM results. This result alone cannot differentiate between immunity as a result of history of disease or immunity due to immunization. Testing for HAV IgM is necessary to confirm the presence of acute or recent disease. Follow up with the Provincial Notifiable Disease program for further direction.

³ The sensitivity of post-immunization serology test is poor. A negative serology result does not necessarily indicate susceptibility. HAV IgG concentrations after immunization may be protective but low and may not be detected.