Alberta Health Services	Hepatitis A Vaccine Biological Page		
Section 7:	**Biological Product Information**		**Standard #: 07.230**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program, Standards and Quality		
Approval Date:	March 1, 2013	**Revised:**	April 15, 2019

	Havrix®	**Vaqta®**
Manufacturer	GlaxoSmithKline Inc.	Merck Canada Inc.
Biological Classification	Inactivated	

Indications for Provincially Funded Vaccine	**Pre-exposure for individuals 6 months of age and older:**
	• Individuals with chronic liver disease, including but not limited to:
	  ○ hepatitis B carriers
	  ○ hepatitis C positive individuals
	• Candidates for or recipients of liver transplantation
	  ○ See #08.304 Standard for Immunization of Transplant Candidates and Recipients
	• Individuals who have developed chronic liver graft versus host disease following hematopoietic stem cell transplant (HSCT)
	  ○ See #08.304 Standard for Immunization of Transplant Candidates and Recipients
	• 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
	• Household or close contacts of children adopted from hepatitis A endemic countries
	
	Note:
	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

• Individuals who live in communities with high rates of hepatitis A infection (includes 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
• Specific occupational groups who handle non-human primates (includes zookeepers, veterinarians and researchers).

Note:
Combined hepatitis A and B vaccine TWINRIX® eligibility:
TWINRIX® should be considered 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 Biologicals TWINRIX®

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	Post-exposure prophylaxis is provided to the following: Post-exposure prophylaxis should be administered 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) and may include hepatitis A vaccine, immune globulin or both. See specific recommendations below. • Contacts at risk of developing severe complications (i.e. 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) should receive both hepatitis A vaccine (two-dose series) and immune globulin. See Immune Globulin Biological Page #07.250. **Both doses of hepatitis A vaccine will be provincially funded.** • Contacts younger than 6 months of age and individuals in whom hepatitis A vaccine is contraindicated should receive immune globulin only. See Immune Globulin Biological Page #07.250. • All other contacts should receive hepatitis A vaccine. One dose of hepatitis A vaccine will be provincially funded but individuals should be encouraged to receive the 2nd dose for long term protection. Both doses of vaccine will be provincially funded for individuals eligible to receive hepatitis A vaccine as outlined in pre-exposure indications. **Note:** Hepatitis A vaccine 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. This would be at the discretion of the Medical Officer of Health, on a case-by-case basis. • For further information related to post-exposure follow-up, refer to Public Health Notifiable Disease Management Guidelines – Hepatitis A. (https://open.alberta.ca/publications/hepatitis-a).	
Serology	**Serology for anti-HAV** (IgG) is recommended prior to immunization for the following individuals who are eligible for pre-exposure immunization: • 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 • individuals diagnosed with hepatitis B and/or hepatitis C infection **Post-immunization serology:** • Serological testing is not routinely recommended after receiving hepatitis A containing vaccine **Interpretation:** • HAV IgG – *positive*: indicates immunity. No vaccine required. **Exception:** If client has started a vaccine series, complete series as per schedule. • HAV IgG (pre-immunization) *negative*: indicates susceptibility. Vaccine is required. • HAV IgG (post-immunization) *negative*: result is not a reliable indicator of immune status. See Notes. • HAV IgM – *positive*: indicates current/recent viral hepatitis A infection or recent Hepatitis A immunization. See Notes. • Total HAV – *positive*: indicates acute, recent, past/resolved exposure to Hepatitis A or immunity from vaccination. See Notes. **Notes:** • The sensitivity of the post-immunization serology test is poor and may not detect low, but protective, HAV IgG concentrations after vaccination. A negative result does not necessarily indicate susceptibility.	

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	• Occasionally HAV IgM serology is inadvertently drawn when an individual presents to their health care provider with an expected reaction following immunization with hepatitis A containing vaccine. Although HAV IgM can indicate evidence of disease, it can also be present 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 Zone Notifiable Disease program immediately for further direction should this situation present. • Total HAV 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 vaccination. Testing for HAV IgM is necessary to confirm the presence of acute or recent disease. Follow up with the Zone Notifiable Disease program for further direction should this situation present.	
Schedule	• Dose 1 – day 0 • Dose 2 – minimum 6 months following dose 1 **Notes:** • 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 Standard for Children expecting SOT before 18 months of age #08.304 • See #03.110 Standard for Recommended Immunization Schedules for further information regarding alternate, rapid or combined schedules. **Combined hepatitis A and B vaccine TWINRIX® eligibility:** **TWINRIX®** should be considered 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 Biologicals TWINRIX®	
Preferred Use	There is no preference indicated for the use of Havrix® or Vaqta® in specific age or risk groups. • Both vaccines are safe and immunogenic in individuals for which the vaccines are recommended. • Individuals with medical contraindications to one product should be offered the alternate product if supply is available.	
Dose	**Children/adolescents 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 • 1.0 mL	**Children/adolescents 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 • 1.0 mL
Route	IM	
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of hepatitis A containing vaccine. • Anaphylactic or other allergic reactions to a previous dose of vaccine containing similar components. **Precautions:** • 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 or not hepatitis A vaccine will prevent hepatitis A infection in such cases.	

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Possible Reactions	**Common:** • Pain, redness, swelling, tenderness, warmth and induration at the injection site. • Headache, fever, irritability, loss of appetite, drowsiness, malaise, fatigue, dizziness, rhinitis, rash, myalgia, abdominal pain, pharyngitis, stiffness and gastrointestinal symptoms. **Rare:** • Anaphylaxis, allergic reactions, • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	
Pregnancy	Hepatitis A vaccine may be administered to pregnant women when indicated. However, adequate data is not available for the use of hepatitis A vaccine during pregnancy and therefore will not routinely be recommended in Alberta for pregnant women. However, use of this vaccine during pregnancy may be considered in consultation with your MOH based on the individual's risk of disease versus benefit of the vaccine.	
Lactation	Can be administered to eligible breastfeeding women.	
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 1.0 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 • Neomycin sulphate • Polysorbate 20 • Potassium chloride • Sodium chloride • Water for injection	Vaqta® Pediatric/Adolescent Presentation contains: • 25 U of hepatitis A virus protein/0.5 mL dose Vaqta® Adult Presentation Contains: • 50 U of hepatitis A virus protein/1.0 mL dose Both of the above also contain: • Aluminum hydroxyphosphate sulfate • Neomycin (trace amounts) • Formaldehyde (trace amounts) • Sodium borate • Sodium chloride • Water for injection
Blood/Blood Products	Grown on MRC-5 human diploid cell culture.	
Bovine/Porcine Products	• Bovine-derived materials are components in the manufacturing process and are removed during purification. • 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 inactivated and live vaccines using a separate needle and syringe for each vaccine. • The same limb may be used if necessary, but different sites on the limb must be chosen.	
Appearance	Slightly opaque white suspension	

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Storage	• Store between +2° and +8°C • Do not freeze • 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 **Havrix® 720** Junior- Recommended for off-license use in Alberta for infants 6 months of age and older, as well as individuals up to and including 18 years of age who meet eligibility criteria.	**Vaqta®** pediatric presentation - 12 months of age up to and including **17** years of age **Vaqta®** adult presentation – 18 years of age and older **Vaqta®** pediatric presentation - Recommended for off-license use in Alberta for infants 6 months of age and older, as well as individuals up to and including 17 years of age who meet eligibility criteria.

Notes:

- Hepatitis A vaccine became available in Alberta for at risk adults January 1, 1994.
- Hepatitis A vaccine became available in Alberta for at risk children June 1, 1997.
  Hepatitis A vaccine became available for infants 6 months and older November 1, 2016.

Related Resources:

1. **AHS-Imm-07.230-R01 (July 18, 2014)**: Immunization Information – Hepatitis A Vaccine.

References:

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16. Centers for Disease Control and Prevention. (2016, July 13). *Hepatitis A Questions and Answers for Health Professionals.* Division of Viral Hepatitis. Retrieved June 30, 2017 from https://www.cdc.gov/hepatitis/hav/havfaq.htm
17. Immunization Action Coalition. (2017, February 19). *Ask the Experts: Diseases and Vaccine - Hepatitis A*. Retrieved June 30, 2017 from http://www.immunize.org/askexperts/experts_hepa.asp