

Section 7:	Biological Product Information	Standard #: 07.232
Created by:	Province-wide Immunization Program Standards and Quality	
Approved by:	Province-wide Immunization Program, Standards and Quality	
Approval Date:	March 1, 2013	Revised: January 1, 2020

Twinrix®	
Manufacturer	GlaxoSmithKline Inc.
Biological Classification	Inactivated
Indications for Provincially Funded Vaccine	<p>Individuals 1 year of age and older who are eligible for both hepatitis A and hepatitis B vaccines as follows:</p> <ul style="list-style-type: none"> • Those with hemophilia A or B receiving plasma derived replacement clotting factors; <p>Note: The solvent-detergent method used to prepare all the present plasma-derived factor VIII and some factor IX concentrates does not reliably inactivate HAV, since virus does not have an envelope</p> • Those with chronic liver disease, including but not limited to: <ul style="list-style-type: none"> ○ Individuals infected with hepatitis C ○ Individuals with cirrhosis. • Those with lifestyle risks of infections (i.e. using illicit drugs [injectable and non-injectable] and males having sex with other males). See biological pages for #07.230 Hepatitis A Vaccine and #07.234 Hepatitis B Vaccine for detailed indications. <p>Note:</p> <ul style="list-style-type: none"> • Combined hepatitis A and hepatitis B vaccine is not recommended for post-exposure prophylaxis or for individuals who require double strength hepatitis B vaccine.
Serology	<p>Pre-Immunization serology: indicated for certain eligible individuals who may have previously had disease and have developed immunity to Hepatitis A and/or Hepatitis B. See biological pages for #07.230 for Hepatitis A vaccine and # 07.234 for Hepatitis B vaccine for detailed instructions.</p> <p>Post-Immunization serology: indicated for certain individuals to confirm immunity post-immunization to Hepatitis B. Post-immunization serology for Hepatitis A is not routinely recommended. Refer to biological pages for #07.230 for Hepatitis A vaccine and # 07.234 for Hepatitis B vaccine for detailed instructions.</p> <p>Interpretation: Refer to biological pages for #07.230 for Hepatitis A vaccine and # 07.234 for Hepatitis B vaccine for details.</p>
Schedule	<ul style="list-style-type: none"> • Dose 1 – day 0 • Dose 2 – 4 weeks after dose 1 • Dose 3 – 6 months after dose 1 <p>Note:</p> <ul style="list-style-type: none"> • Appropriate spacing of Twinrix® doses must be maintained to assure long term protection. The 1st and 2nd doses should be separated by at least 4 weeks and the 2nd and 3rd doses should be separated by at least 5 months. • For those who may have an alternate immunization history refer to #03.110 Standard for Recommended Immunization Schedules.
Preferred Use	N/A
Dose	Children 1 year of age up to and including 18 years of age: <ul style="list-style-type: none"> • 0.5 mL

	Twinrix®
	Individuals 19 years of age and older: <ul style="list-style-type: none"> • 1.0 mL
Route	IM
Contraindications/Precautions	<p>Contraindications:</p> <ul style="list-style-type: none"> • Known severe hypersensitivity to any component of hepatitis A or hepatitis B containing vaccine. • Anaphylactic or other allergic reactions to a previous dose of vaccine containing similar components. <p>Precautions:</p> <ul style="list-style-type: none"> • None identified.
Possible Reactions	<p>Common:</p> <ul style="list-style-type: none"> • Pain, redness and swelling at the injection site • Fever • Headache • Fatigue, malaise, irritability • Decreased appetite, nausea, diarrhea, vomiting <p>Uncommon:</p> <ul style="list-style-type: none"> • Dizziness • Myalgia • Rash • Upper respiratory tract infection <p>Rare:</p> <ul style="list-style-type: none"> • Anaphylaxis • Arthralgia • Hypoaesthesia, paraesthesia • Hypotension • Influenza like illness, chills • Lymphadenopathy • Pruritis, urticaria • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	Adequate data is not available for the use of combined hepatitis A and hepatitis B 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	Each 0.5 mL dose contains: <ul style="list-style-type: none"> • 360 ELISA units HAV and 10mcg HBV • Aluminum hydroxide • Aluminum phosphate • Sodium chloride • Water for injection • Residual trace amounts: <ul style="list-style-type: none"> ○ amino acids for injection, ○ formaldehyde, ○ neomycin sulphate, ○ polysorbate 20
Blood/Blood Products	The hepatitis A virus component is grown on MRC-5 human diploid cell culture.
Bovine/Porcine	<ul style="list-style-type: none"> • Bovine-derived materials are components in the manufacturing process and are removed during purification.

	Twinrix®
Products	<ul style="list-style-type: none"> Does not contain porcine products.
Latex	Does not contain latex.
Interchangeability	Twinrix® is the only combined hepatitis A and hepatitis B vaccine available for use in Canada. It can be used interchangeably with other hepatitis A and hepatitis B vaccines licensed for use in Canada as long as the age appropriate dose and spacing has been followed.
Administration with Other Products	<ul style="list-style-type: none"> May be given at the same time as other inactivated 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.
Storage	<ul style="list-style-type: none"> Store between +2° and +8°C Do not freeze, discard if frozen Do not use beyond the labeled expiry date Store in original packaging when possible to protect from light
Vaccine Code	HABV
Antigen Code	Hepatitis A - HAV Hepatitis B - HBV
Licensed for	All persons 1 year of age and older.
Notes:	
<ul style="list-style-type: none"> In July 2014, the eligibility for Twinrix® vaccine expanded to include adults who were eligible for both Hepatitis A and Hepatitis B vaccines and did not require double strength Hepatitis B vaccine. Hepatitis A and B Combined vaccine became available in Alberta for eligible children January 1, 1997. 	
Related Resources:	
<ul style="list-style-type: none"> AHS – Imm-07.232-R01 (July 18, 2014) HABV Vaccine Information Sheet 	
References:	
<ol style="list-style-type: none"> Alberta Health, Family and Population Health Division, Alberta Immunization Policy (2014, January 10). <i>Hepatitis A and B Combined Vaccine: Twinrix® Junior & Twinrix®</i>. Alberta Health and Wellness, Disease and Prevention. (2003). <i>Surveillance of adverse reactions to immunizing agents: Program guide for public health professionals</i>. American Academy of Pediatrics. Summaries of Infectious Diseases. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. <i>Red Book: 2012 Report of the Committee on Infectious Diseases</i>. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics: pp. 361-390 Centers for Disease Control and Prevention. (2011, January). General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). <i>Morbidity and Mortality Weekly Report, 60(2)</i>. Centers for Disease Control and Prevention. (2011, April). <i>Epidemiology and Prevention of Vaccine-Preventable Diseases 12th Edition (Pink Book)</i>. GlaxoSmithKline Inc. (2012, November 1). <i>TWINRIX®: Combined hepatitis A and hepatitis B vaccine. Product monograph</i>. National Advisory Committee on Immunization, (1999, June 1). Statement on Combination Vaccines against Hepatitis A and Hepatitis B. <i>Canada Communicable Disease Report, 25</i>. National Advisory Committee on Immunization. (2012). <i>Canadian immunization guide (Evergreen Edition)</i>. Ottawa, ON: Public Health Agency of Canada. http://www.phac-aspc.gc.ca/publicat/cig-gci/ 	