Hepatitis A and Hepatitis B Combined Vaccine

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.232**	
Created and approved by	Provincial Immunization Program		
Approval date	March 1, 2013	**Published**	March 2, 2026

	TWINRIX Junior & TWINRIX
Manufacturer	GlaxoSmithKline Inc.
Classification	Non-live: inactivated (hepatitis A) and recombinant (hepatitis B)

Indications for Provincially Funded Vaccine	**Pre-exposure only:**
	Individuals 1 year of age and older who are eligible for both hepatitis A and hepatitis B vaccines including those with:
	• Hemophilia A or B receiving plasma-derived replacement clotting factors
	  ○ 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.
	• Chronic liver disease from any cause (with the exception of HBsAg positive individuals)
	• Lifestyle risks of infections such as illicit drug use (injectable and non-injectable) and men having sex with men. See Hepatitis A Vaccine Biological Page and Hepatitis B Vaccine Biological Page for detailed indications.
	Note:
	• Do not use Hepatitis A and Hepatitis B Combined Vaccine for:
	  ○ Individuals who require double-strength hepatitis B vaccine. See Hepatitis B Vaccine Biological Page.
	  ○ Hepatitis A or hepatitis B post-exposure prophylaxis.

Serology	**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 Hepatitis A Vaccine Biological Page and Hepatitis B Vaccine Biological Page for guidance. **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 Hepatitis A Vaccine Biological Page and Hepatitis B Vaccine Biological Page for guidance. **Serology Interpretation:** Refer to Hepatitis A Vaccine Biological Page and Hepatitis B Vaccine Biological Page for guidance.
Schedule	• Dose 1: day 0 • Dose 2: 1 month after dose 1 • Dose 3: 6 months after dose 1, **and** 5 months after dose 2 **Note:** • Appropriate spacing of TWINRIX doses must be maintained to assure long term protection. • For those who may have an alternate immunization history refer to Standard for Recommended Immunization Schedules.
Preferred Use	N/A

	TWINRIX Junior & TWINRIX
Dose	**1 year of age up to and including 18 years of age** TWINRIX Junior • 0.5 mL **19 years of age and older** TWINRIX • 1 mL
Route	Intramuscular injection (IM)
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of TWINRIX Junior or TWINRIX vaccine. • Anaphylactic or other allergic reactions to a previous dose of vaccine containing hepatitis A or hepatitis B antigens. **Precautions:** • It is possible that individuals may be in the incubation period of a hepatitis A or hepatitis B infection at the time of immunization. It is not known whether TWINRIX Junior/TWINRIX will prevent hepatitis A and hepatitis B in such cases.
Possible Reactions	**Common:** • Pain, redness and swelling at the injection site • Fever • Headache • Fatigue, malaise, irritability • Decreased appetite, nausea, diarrhea, vomiting. **Uncommon:** • Dizziness • Myalgia • Rash • Upper respiratory tract infection. **Rare:** • Anaphylaxis • Arthralgia • Hypoaesthesia, paraesthesia • Hypotension • Influenza like illness, chills • Lymphadenopathy • Pruritus, urticaria • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	• May use for pregnant individuals who meet the indications for use of provincially funded vaccine and when the possible advantages outweigh the possible risks. • The safety of TWINRIX during pregnancy has not been studied in clinical trials. The effect of TWINRIX in pregnancy has been assessed in animals, and these studies do not indicate harmful effects. There is no theoretical reason to suspect an increased risk of adverse events to the pregnant individual or infant.
Lactation	May use for individuals who are lactating/feeding their milk to infants or children.
Composition	Each 0.5 mL dose contains: • 360 ELISA units HAV and 10mcg HBV

	TWINRIX Junior & TWINRIX

	• Aluminum hydroxide
	• Aluminum phosphate
	• Sodium chloride
	• Water for injection
	• Residual trace amounts:
	  ○ 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 Products	• Does not contain bovine or 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	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 syringe by tipping it upside down and back again, repeating this action vigorously for at least 15 seconds.
Appearance	Uniform hazy white suspension.
Storage	• Store between +2°C and +8°C • Do not freeze, discard if frozen • Do not use beyond the labeled expiry date • Store in original packaging to protect from light.
Vaccine Code	HABV
Antigen Code	Hepatitis A – HAV Hepatitis B – HBV
Licensed for	TWINRIX Junior - Individuals one year up to and including 18 years of age TWINRIX - Individuals 19 years of age and older
Program Notes	• 1997 January 1: Hepatitis A and B Combined Vaccine became available in Alberta for eligible children. • 2014 July 10: 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. • 2025 August 1: Clarified in the Indications section that individuals who are eligible for hepatitis A and hepatitis B vaccine include those with chronic liver disease from any cause. Updated to use inclusive language when referring to pregnant individuals.
Related Resources	Hepatitis A and Hepatitis B Combined Vaccine Information Sheet
References	

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