

Hepatitis B Vaccine

BIOLOGICAL PAGE

Section [number]	Biological Product Information	Standard # 07.234
Created and approved by	Provincial Immunization Program Standards and Quality	
Approval date	March 1, 2013	Published August 1, 2025

	Engerix-B	Recombivax HB
Manufacturer	GlaxoSmithKline Inc.	Merck Canada Inc.
Classification	Non-live: Recombinant	
Indications for Provincially Funded Vaccine	<p>Pre-exposure:</p> <p>Refer to Appendix A: Serology Interpretation and Appendix B: Serology Recommendations and Follow-up for pre-immunization serology interpretation and recommendations.</p> <p>Universal:</p> <ul style="list-style-type: none"> Individuals born March 1, 2018 or later when immunization with DTaP-IPV-Hib-HB is not needed or contraindicated Students in Grade 6 Universal program in Alberta <ul style="list-style-type: none"> For students in ungraded classes, vaccine can be provided on a case by case basis, generally at 10 years up to and including 18 years of age. The guiding principle is to offer protection to students prior to them leaving the school system See Roles and Responsibilities of Immunization Providers for school catch-up programs. Individuals born in 1981 or later who would have been eligible for the school universal hepatitis B vaccine program and who have not received a series of hepatitis B vaccine. <p>Endemic:</p> <ul style="list-style-type: none"> Children whose families have immigrated to Canada from areas where there is a high prevalence of hepatitis B (endemic for hepatitis B). See Hepatitis B Virus Infection - High Endemic Geographic Areas. Non-immune adults who have immigrated to Canada from areas where there is a high prevalence of hepatitis B. See Hepatitis B Virus Infection - High Endemic Geographic Areas. Populations or communities in Alberta in which hepatitis B is highly endemic, following consultation with Medical Officer of Health (MOH). <p>Chronic Health Conditions:</p> <ul style="list-style-type: none"> Individuals with hemophilia and others receiving repeated infusions of blood or blood products (hepatitis B vaccine is not provided for parents providing home infusion for their children) Individuals with chronic liver disease from any cause (with the exception of HBsAg positive individuals) Individuals with Inflammatory Bowel Disease (IBD), or other chronic inflammatory conditions, who will be on long term immunosuppressive medications including, but not limited to, azathioprine (Imuran) or TNF antagonists like infliximab (Remicade) or adalimumab (Humira). <p>Note:</p> <ul style="list-style-type: none"> Offer individuals with chronic liver disease with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine a series of hepatitis B vaccine to ensure long term immunity. 	

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	<ul style="list-style-type: none"> Complete any incomplete series of hepatitis B vaccine for individuals with chronic liver disease with lab confirmation of positive anti-HBs to ensure long term immunity. <p>Individuals with chronic health conditions that may be HYPORESPONSIVE to hepatitis B vaccine should receive higher dose hepatitis B vaccine:</p> <p>These include:</p> <ul style="list-style-type: none"> Individuals with chronic renal disease or who are undergoing chronic hemodialysis/peritoneal dialysis, including those who are pre-dialysis (progressive renal insufficiency). See Hepatitis B (HBVD) Algorithm for Chronic Renal Disease for additional information Individuals with congenital immunodeficiencies Individuals infected with HIV Candidates for and recipients of Solid Organ Transplant (SOT): <ul style="list-style-type: none"> Standard for Immunization of Transplant Candidates and Recipients Immunization of Adult Solid Organ Transplant Candidates and Recipients Immunization of Children Expecting Solid Organ Transplant Before 18 Months of Age (Accelerated) Immunization for Children Expecting Solid Organ Transplant After 18 Months of Age Recipients of Hematopoietic Stem Cell Transplant (HSCT): <ul style="list-style-type: none"> Standard for the Immunization of Transplant Candidates and Recipients Immunization for Adult HSCT Transplant Recipients Immunization for Child HSCT Transplant Recipients <p>Note:</p> <ul style="list-style-type: none"> Offer individuals with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine a series of hepatitis B vaccine to ensure long term immunity. Complete the vaccine series for individuals with lab confirmation of positive anti-HBs with any incomplete series. Periodic serological testing may be done by the attending physician for hyporesponsive individuals. See Appendix A: Serology Interpretation for more information. <p>Lifestyle Risks:</p> <p>Individuals with lifestyle risks of infection including:</p> <ul style="list-style-type: none"> Men who have sex with men (MSM) Individuals with more than one sexual partner in the previous 6 months Individuals with a history of a sexually transmitted infection Individuals seeking evaluation or treatment for a sexually transmitted infection Individuals who engage in high-risk sexual practices Individuals who have unprotected sex with new partners Individuals who use illicit drugs and associated drug-using paraphernalia (for example, needles, tubes used for snorting), resulting in blood exposure. <p>Occupational/Other Settings:</p> <ul style="list-style-type: none"> Individuals who are workers, volunteers or students (accepted into post-secondary educational programs) and who have a reasonable anticipated risk of exposure to blood/bloody body fluids and/or sharps injuries during the course of their work. See Occupational Considerations for Immunization and Hepatitis B Risk Assessment. Children and workers in childcare settings in which there is a hepatitis B infected (acute or chronic) child or worker. <ul style="list-style-type: none"> If exceptional circumstances such as biting behavior or special medical conditions exist and Hepatitis B status is unknown, consult with zone MOH/MOH designate. Residents and staff of institutions or group homes for the developmentally challenged. 	

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	<ul style="list-style-type: none"> Inmates in provincial correctional facilities who will be incarcerated for a sufficient length of time to complete a hepatitis B vaccine series. <ul style="list-style-type: none"> Immunization of inmates in long-term correctional facilities is the responsibility of the Federal Correctional Service. However, vaccine will be provided provincially for completion of immunization of discharged inmates who began their hepatitis B series in federal prisons. <p>Note:</p> <p>Use Hepatitis A and Hepatitis B Combined Vaccine for individuals 1 year of age and older who are eligible for both pre-exposure hepatitis A and B vaccines if they do not require the double strength hepatitis B vaccine. See HABV Vaccine Biological Page.</p> <p>Post-exposure:</p> <p>Refer to Appendix A: Serology Interpretation and Appendix B: Serology Recommendations and Follow-up for post-immunization serology interpretation and recommendations.</p> <p>Infants:</p> <ul style="list-style-type: none"> Newborns born to hepatitis B surface antigen positive (HBsAg) mothers (acute cases or carriers) should receive hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine as soon as possible after birth (within 12 hours) but within 7 days after birth if HBIG/hepatitis B vaccine is delayed for any reason. <p>Note:</p> <ul style="list-style-type: none"> If prenatal screening has not been done prior to delivery, it should be done as soon as possible after admission for delivery. In addition, repeat testing should be considered in uninfected, susceptible women with continuing high-risk factors. If results can be obtained within 12 hours, give the first dose of Hepatitis B vaccine. Delay HBIG administration pending results. If results will not be available within 12 hours, administer hepatitis B vaccine and consider administration of HBIG, taking into account maternal risk factors and erring on the side of providing HBIG if there is any question of possible maternal hepatitis B infection. <ul style="list-style-type: none"> Infants (other than newborns) younger than 12 months of age: <ul style="list-style-type: none"> Hepatitis B vaccine and HBIG if the mother or primary caregiver is an acute case Hepatitis B vaccine only if the caregiver or significant household contact is a chronic carrier. <p>Refer to: Alberta public health disease management guidelines: hepatitis B -acute and chronic and Alberta prenatal screening program for select communicable diseases – Hepatitis B.</p> <ul style="list-style-type: none"> Susceptible household contacts, sexual partners and needle sharing partners of individuals with acute or chronic hepatitis B infection: <ul style="list-style-type: none"> Hepatitis B vaccine HBIG may be recommended for some individuals depending upon the time from exposure and the specific details of the exposure. <p>Refer to Alberta public health disease management guidelines: hepatitis B -acute and chronic</p> <p>Note:</p> <ul style="list-style-type: none"> Offer susceptible household contacts, sexual partners and needle-sharing partners with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine a series of hepatitis B vaccine to ensure long term immunity. Complete the hepatitis B series for susceptible household contacts, sexual partners and needle-sharing partners with lab confirmation of positive anti-HBs with any incomplete series. 	

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	<ul style="list-style-type: none"> • Percutaneous (needle stick) or mucosal exposure: <ul style="list-style-type: none"> ○ Post-exposure follow-up and prophylaxis is based on the immunization history and antibody status of the exposed individual and, if known, the infectious nature of the source. ○ When a susceptible individual sustains a “community needle stick” injury (needle stick in a non-health care setting), the risk of exposure to hepatitis B is increased. If the individual has no history of a hepatitis B vaccine series and the source is HBsAg positive, high risk, unknown or not available for testing, administer HBIG (as soon as possible but within 7 days of exposure) with the first dose of the hepatitis B vaccine series. • Note: <ul style="list-style-type: none"> ▪ Offer individuals sustaining percutaneous (needle stick) or mucosal exposure with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine a series of hepatitis B vaccine to ensure long term immunity. ▪ Complete the hepatitis B series for individuals sustaining percutaneous (needle stick) or mucosal exposure with lab confirmation of positive anti-HBs with any incomplete series. • Susceptible individuals of sexual assault. <ul style="list-style-type: none"> ○ Offer HBIG and hepatitis B vaccine. • Note: For further guidelines related to post-exposure follow-up refer to the following: <ul style="list-style-type: none"> • Alberta public health disease management guidelines: hepatitis B -acute and chronic • Alberta guidelines for post-exposure management and prophylaxis: HIV, hepatitis B, hepatitis C and sexually transmitted infections • Canadian Immunization Guide: Hepatitis B Vaccine (Figures 1 & 2) 	
Serology	See Appendix A: Serology Interpretation and Appendix B: Serology Recommendations and Follow-up .	
Schedule and Dose For Healthy Individuals	Individuals immunized with Engerix-B Vaccine (20 mcg/1 mL):	Individuals immunized with Recombivax HB Vaccine (10 mcg/1 mL):
	<p>Newborns born to hepatitis B surface antigen positive (HBsAg) mother (3 doses): Give as 0.5 mL</p> <ul style="list-style-type: none"> • Dose 1: at birth, given with HBIG • Dose 2: 2 months of age • Dose 3: 6 months of age <p>Note:</p> <ul style="list-style-type: none"> ○ The final (third) dose should not be given to infants before 6 months (24 weeks or 168 days) of age. <p>Newborns with birth weight less than 2,000 grams born to hepatitis B surface antigen positive (HBsAg) mother (4 doses): Give as 0.5 mL</p> <ul style="list-style-type: none"> • Dose 1: at birth, given with HBIG • Dose 2: 1 month of age • Dose 3: 2 months of age • Dose 4: 6 months of age <p>Note:</p> <ul style="list-style-type: none"> ○ DTaP-IPV-Hib-HB may be used for children 2 months up to and including 23 months of age. See DTaP-IPV-Hib-HB Combined Vaccine Biological Page for indications. The schedule and spacing considerations for DTaP-IPV-Hib-HB vaccine varies from HBV and 	

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	<p>DTaP-IPV-Hib vaccines. Ensure the appropriate schedule is followed for the vaccine(s) that are being used.</p> <ul style="list-style-type: none"> ○ The response to hepatitis B vaccine may be diminished in infants with a birth weight below 2,000 grams. ○ The final (fourth) dose should not be given to infants before 6 months (24 weeks or 168 days) of age. ○ Offer serological testing at a minimum of 9 months of age and at least 1 month after completion of 4-dose series. <p>Other infants from birth up to and including 11 months of age (3 doses):</p> <p>Give as 0.5 mL</p> <ul style="list-style-type: none"> • Dose 1: 2 months of age • Dose 2: 4 months of age • Dose 3: 12 months of age <p>Note:</p> <ul style="list-style-type: none"> ○ The final (third) dose should not be given to infants before 6 months (24 weeks or 168 days) of age. ○ If the infant is identified as a significant household contact of a hepatitis B carrier, offer hepatitis B vaccine as soon as possible. ○ Minimum intervals can be used for children who begin immunization off schedule – refer to Spacing Considerations. <p>Infants with birth weight less than 2,000 grams who receive hepatitis B vaccine at birth (for example, any of the primary caregivers is HBsAg positive) (4 doses):</p> <p>Give as 0.5 mL</p> <ul style="list-style-type: none"> • Dose 1: at birth • Dose 2: 1 month of age • Dose 3: 2 months of age • Dose 4: 6 months of age <p>Note:</p> <ul style="list-style-type: none"> ○ DTaP-IPV-Hib-HB may be used for children 2 months up to and including 23 months of age. See DTaP-IPV-Hib-HB Combined Vaccine Biological Page for indications. The schedule and spacing considerations for DTaP-IPV-Hib-HB vaccine varies from HBV and DTaP-IPV-Hib vaccines. Ensure the appropriate schedule is followed for the vaccine(s) that are being used. ○ The response to hepatitis B vaccine may be diminished in infants with a birth weight below 2,000 grams. ○ The final (fourth) dose should not be given to infants before 6 months (24 weeks or 168 days) of age. ○ Offer serological testing at a minimum of 9 months of age and at least 1 month after completion of 4-dose series. 	
	<p>Children 12 months of age up to and including 10 years of age (3 doses):</p> <p>Give as 0.5 mL</p> <ul style="list-style-type: none"> • Dose 1: day 0 • Dose 2: 1 month after dose 1 • Dose 3: 6 months after dose 1, and 5 months after dose 2 <p>Note:</p> <ul style="list-style-type: none"> ○ If the child is identified as a significant household contact of a hepatitis B carrier, offer hepatitis B vaccine as soon as possible. 	

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	<p>Students 11 years of age up to and including 15 years of age (2 doses):</p> <p>Give as 1 mL</p> <ul style="list-style-type: none"> This includes grade 6 students younger than 11 years of age as eligibility for a two-dose series is determined by grade level. <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 6 months after dose 1 <p>Minimal acceptable spacing between the first and second dose is 24 weeks.</p> <p>Note:</p> <ul style="list-style-type: none"> If 0.5 mL dose is given within the series, a 3-dose schedule must be followed: <p>Give as 0.5 mL</p> <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 1 month after dose 1 Dose 3: 6 months after dose 1, and 5 months after dose 2 <ul style="list-style-type: none"> The minimum acceptable interval is 0, 1 and 4 months, with 1 month (28 days) between the first and second dose, at least 2 months (56 days) between the second and third dose and at least 4 months (112 days) between the first and third dose. Initiate a 3-dose schedule if a student will turn 16 years of age before a 2-dose series can be completed (see below). 	
	<p>Individuals 16 years of age up to and including 19 years of age (3 doses):</p> <p>Give as 0.5 mL</p> <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 1 month after dose 1 Dose 3: 6 months after dose 1, and 5 months after dose 2 <p>Note:</p> <ul style="list-style-type: none"> Revert to a 3-dose schedule for individuals who received a 1 mL dose of hepatitis B vaccine as their first dose at 11 to 15 years of age and present at 16 years of age or older for subsequent doses 	
	<p>Individuals 20 years of age and older (3 doses):</p> <p>Give as 1 mL</p> <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 1 month after dose 1 Dose 3: 6 months after dose 1, and 5 months after dose 2 	
	<p>Spacing Considerations:</p> <ul style="list-style-type: none"> If the recommended schedule cannot be followed, refer to Standard for Recommended Immunization Schedules Section 5: Minimum Age and Minimum Intervals Between Vaccine Doses. Do not repeat any dose(s) if there is an interruption of the immunization schedule, if the minimum intervals between doses are respected. For those who may have an alternate immunization history refer to Standard for Recommended Immunization Schedules. If a second hepatitis B immunization series is required, this can be started once the need is identified. Complete Immunization started in another province or territory prior to grade 6, as they present to public health using the current schedule. 	

	Engerix-B	Recombivax HB
Schedule and Dose for Hyporesponsive Individuals	Hyporesponsive individuals immunized with Engerix-B Vaccine (20 mcg/1 mL):	Hyporesponsive individuals immunized with Recombivax HB Vaccine (10 mcg/1 mL):
	Birth to 15 years of age	
	Individuals from birth up to and including 15 years of age (3 doses): Give as 1 mL <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 1 month after dose 1 Dose 3: 6 months after dose 1, and 5 months after dose 2 	Individuals from birth up to and including 15 years of age (3 doses): Give as 1 mL <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 1 month after dose 1 Dose 3: 6 months after dose 1, and 5 months after dose 2
	16 years to 19 years of age	
	Individuals 16 years of age up to and including 19 years of age (4 doses): Give as 2 mL <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 1 month after dose 1 Dose 3: 2 months after dose 1 Dose 4: 6 months after dose 1 Note: <ul style="list-style-type: none"> Those initiating a 4-dose schedule with Engerix-B should complete the series using the same vaccine whenever possible. Minimum interval between the third and fourth dose is 4 months and at least 6 months between the first and fourth dose. 	Individuals 16 years of age up to and including 19 years of age (3 doses): Give as 1 mL <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 1 month after dose 1 Dose 3: 6 months after dose 1, and 5 months after dose 2
	If any dose in the series was Engerix-B, administer a total of 4 doses of vaccine for those 16 years of age and older.	
	Hyporesponsive individuals immunized with Engerix-B Vaccine (20 mcg/1 mL):	Hyporesponsive individuals immunized with Recombivax HB Adult Dialysis Strength Vaccine (40 mcg/1 mL):
	20 years and older	
	Individuals 20 years of age and older (4 doses): Give as 2 mL <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 1 month after dose 1 Dose 3: 2 months after dose 1 Dose 4: 6 months after dose 1 Note: <ul style="list-style-type: none"> Those initiating a 4-dose schedule with Engerix-B should complete the series using the same vaccine whenever possible. Minimum interval between the third and fourth dose is 4 months and at least 6 months between the first and fourth dose. 	Individuals 20 years of age and older (3 doses): Give as 1 mL <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Do not use this formulation for individuals younger than 20 years of age.

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	<ul style="list-style-type: none"> Use Recombivax HB Dialysis Strength Vaccine for hyporesponsive individuals 20 years of age and older. If Recombivax HB Dialysis Strength Vaccine is unavailable or the individual has a medical contraindication to this product, Engerix-B may be used following the schedule outlined. If any dose in the series was Engerix-B, administer a total of 4 doses of vaccine for those 16 years of age and older. 	
	<p>Spacing Considerations:</p> <ul style="list-style-type: none"> Interruption of the immunization schedule does not require any dose(s) be repeated if the minimum intervals between doses are respected. For those who may have an alternate immunization history refer to Standard for Recommended Immunization Schedules. If a second hepatitis B immunization series is required, this can be started once the need is identified. Immunization started in another province or territory prior to grade 6 can be completed as they present to public health using the current schedule and dose recommended in Alberta. 	
Preferred Use	<ul style="list-style-type: none"> There is no preference indicated for the use of Recombivax HB or Engerix-B for those eligible for regular strength vaccine. <ul style="list-style-type: none"> Both vaccines are safe and immunogenic for all ages. Individuals with medical contraindications to one product should be offered the alternate product if supply is available. 	
Route	Intramuscular injection (IM)	
Contraindications/Precautions	<p>Contraindications:</p> <ul style="list-style-type: none"> Known severe hypersensitivity to any component of a hepatitis B containing vaccine. Anaphylactic reactions or other allergic reactions to a previous dose of vaccine containing similar components. For Recombivax HB only: anaphylactic reactions to latex. <p>Precautions:</p> <ul style="list-style-type: none"> None identified. 	
Possible Reactions	<p>Common:</p> <ul style="list-style-type: none"> Injection site pain, soreness, tenderness, pruritus, erythema, ecchymoses, swelling, induration, warmth and nodule formation Irritability, headache, fatigue/asthenia, malaise, pharyngitis and fever Loss of appetite, nausea, vomiting, diarrhea and abdominal pain <p>Uncommon:</p> <ul style="list-style-type: none"> Dizziness, myalgia <p>Rare:</p> <ul style="list-style-type: none"> Lymphadenopathy, paresthesia, rash, urticaria and arthralgia Anaphylaxis, angioedema, allergic reactions As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information. <p>Note:</p> <p>A number of studies have been unable to demonstrate any evidence of a causal association following hepatitis B vaccine and the following chronic illnesses: chronic fatigue syndrome, multiple sclerosis, Guillain-Barré syndrome (GBS) or rheumatoid arthritis.</p>	
Pregnancy	<p>May use during pregnancy.</p> <ul style="list-style-type: none"> Data is not available on the effect of hepatitis B vaccine on fetal development; however, the risk is expected to be negligible as the vaccine consists of non-infectious subunits. 	

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	<ul style="list-style-type: none"> Eligible individuals who are pregnant should receive provincially funded vaccine. Test individuals who are pregnant at high risk of hepatitis B infection for antibody response following receipt of hepatitis B vaccine series. See Appendix A: Serology Interpretation for more information. 	
Lactation	May use for individuals who are lactating/feeding their milk to infants or children. It is not known whether hepatitis B vaccine is excreted in human milk.	
Composition	<p>Each 0.5 mL dose contains:</p> <ul style="list-style-type: none"> 10 mcg hepatitis B surface antigen 0.25 mg aluminum hydroxide. <p>Each 1 mL dose contains:</p> <ul style="list-style-type: none"> 20 mcg hepatitis B surface antigen 0.5 mg aluminum hydroxide. <p>Non-medicinal Ingredients:</p> <ul style="list-style-type: none"> disodium phosphate hydrate sodium chloride sodium dihydrogen phosphate dihydrate water for injection. <p>Single dose presentations are preservative free.</p>	<p>Each 0.5 mL dose contains:</p> <ul style="list-style-type: none"> 5 mcg hepatitis B surface antigen 0.25 mg amorphous aluminum hydroxyphosphate 4.5 mg sodium chloride 35 mcg sodium borate Water for injection. <p>Each 1 mL dose contains:</p> <ul style="list-style-type: none"> 10 mcg hepatitis B surface antigen 0.5 mg amorphous aluminum hydroxyphosphate 9 mg sodium chloride 70 mcg sodium borate Water for injection. <p>Each 1 mL dose of Recombivax HB Dialysis Strength contains:</p> <ul style="list-style-type: none"> 40 mcg hepatitis B surface antigen 0.5 mg amorphous aluminum hydroxyphosphate 9 mg sodium chloride 70 mcg sodium borate Water for injection. <p>The following manufacturing residuals may be found in the above preparations of Recombivax HB vaccine:</p> <ul style="list-style-type: none"> Less than 1% yeast protein Less than 15 mcg/mL formaldehyde. <p>These presentations are preservative free (thimerosal-free).</p>
	For a detailed list of ingredients see the Product Monograph for each vaccine.	
Blood/Blood Products	Contains no human blood/blood products.	
Bovine/Porcine Products	Contains no bovine or porcine products.	
Latex	Does not contain latex.	Latex in vial stopper.
Interchangeability	<ul style="list-style-type: none"> Hepatitis B vaccines produced by different manufacturers can be used interchangeably despite different doses and schedules. Administer the dose recommended by the manufacturer for the specific product being used. When possible, complete the series with the same vaccine, especially with hyporesponsive individuals. If this is not possible, complete hyporesponsive individuals 16 years and older who have received any doses of Engerix-B vaccine using the 4-dose schedule. Refer to schedule and dose section for more details. 	

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Administration with Other Products	May be given at the same time as other non-live and live vaccines. <ul style="list-style-type: none"> • Use a separate needle and syringe for each vaccine. • See Standard for the Administration of Immunizations for more information. 	
Appearance	Slightly opaque, white suspension.	
Storage	<ul style="list-style-type: none"> • Store at +2°C to +8°C. • Do not freeze. • Do not use past the expiry date. • Store in original packaging when possible to protect from light. 	
Vaccine Code	HBV	HBV – regular strength product HBVD – dialysis strength vaccine
Antigen Code	HBV	
Licensed for	Individuals of all ages.	Recombivax HB regular strength: <ul style="list-style-type: none"> • Licensed for individuals of all ages. • Vaccine dose for all children from birth up to and including 10 years of age in Alberta is 0.5 mL (5 µg). Recombivax HB Dialysis Strength: Licensed for individuals 20 years of age and older.
Program Notes	<ul style="list-style-type: none"> • 1983 January 1: Hepatitis B vaccine introduced in Alberta for the neonatal program for infants at high risk; Hepatitis B Dialysis Strength (Recombivax) introduced. • 1995 September: Hepatitis B introduced into routine school immunization program for students in grade 5. • 1999 September: Hepatitis B catch-up school immunization program for grade 12 students was available from September 1999 to June 2002. • 2011 August: Hepatitis B vaccine change in dosage for all individuals 0-10 years of age including students in Grade 5 from 0.25 mL to 0.5 mL. • 2016 July 1: Infanrix hexa® introduced for children under 2 years of age eligible for DTaP-IPV-Hib and hepatitis B. • 2017 November: Individuals at high risk: recommended documented series for those with only verbal history or who are anti-HBs positive and recommend a complete second series if anti-HBs negative after first series. • 2018 February: Individuals born in 1981 or later who would have been eligible for the school universal hepatitis B vaccine program and who have not received a series of hepatitis B vaccine are eligible for hepatitis B vaccine. • 2018 February: Individuals with Inflammatory Bowel disease (IBD) who will be on long term immunosuppressive medications became eligible for hepatitis B vaccine. • 2018 September: Routine school immunization schedule for hepatitis B vaccine changed from being offered in grade 5 to grade 6. • 2019 August: Routine school immunization schedule for hepatitis B changed from 3 dose to 2 dose for grade 6 students. • 2023 December 4: Post-immunization serology recommendations updated. • 2024 April 2: Post-immunization serology recommendations updated. • 2025 January 31: Indications for provincially funded vaccine updated. Post-immunization serology recommendations updated. • 2025 August 1: Reference to school age catch-up (grades 7-12) removed. Roles and Responsibilities policy hyperlink added to reference this information. 	

	Engerix-B	Recombivax HB
Related Resources	Hepatitis B Vaccine Information Sheet	
References		
<p>Advisory Committee on Immunization Practices. (2024, July 22). General Best Practice Guidelines for Immunization. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html</p> <p>Advisory Committee on Immunization Practices (2015, July). Guidelines for Vaccinating Kidney Dialysis Patients and Patients with Chronic Kidney Disease. In Recommendations of the Advisory Committee on Immunization Practices (2012, December). Centres for Disease Control and Prevention. https://stacks.cdc.gov/view/cdc/143156/cdc_143156_DS1.pdf</p> <p>Alberta Health. (2024, April). Adverse Events Following Immunization (AEFI) policy for Alberta immunization providers. In Alberta Immunization Policy: Adverse events – immunization (2019). Government of Alberta.</p> <p>Alberta Health (2019, March). Alberta guidelines for post-exposure management and prophylaxis: HIV, hepatitis B, hepatitis C and sexually Transmitted Infections. In <i>Alberta Public Health Disease Management Guidelines</i>. Government of Alberta.</p> <p>Alberta Health (2018, October). Alberta prenatal screening guidelines for select communicable diseases. In <i>Alberta Public Health Disease Management Guidelines</i>. Government of Alberta.</p> <p>Alberta Health (2024, June). Alberta public health notifiable disease management guidelines -hepatitis B (acute and chronic). In <i>Alberta Public Health Disease Management Guidelines</i>. Government of Alberta.</p> <p>Alberta Health. (2025, August 1). Hepatitis A and B combined vaccine (HABV). In <i>Alberta Immunization Policy: Biological Products</i>. Government of Alberta.</p> <p>Alberta Health. (2025, August 1). Hepatitis B Vaccine. In <i>Alberta Immunization Policy: Biological Products</i>. Government of Alberta.</p> <p>Alberta Health. (2024, April 2). Hepatitis B Virus Infection –High Endemic Geographic Areas. In <i>Alberta Immunization Policy: Biological Products</i>. Government of Alberta.</p> <p>Alberta Health. (2023, July). Hepatitis B (HBVD) Algorithm for Chronic Renal Disease. In <i>Alberta Immunization Policy: Biological Products</i>. Government of Alberta.</p> <p>Centers for Disease Control and Prevention. (2023, August). General Best Practice Guidelines for Immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP). https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html</p> <p>Centers for Disease Control and Prevention. (2021). Epidemiology and Prevention of Vaccine-Preventable Diseases 14th Edition (Pink Book).</p> <p>Centers for Disease Control and Prevention. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) [Internet]. Morbidity and Mortality Weekly Report (MMWR), 67(No. RR-1). 2018. p. 1–31. Available from: http://dx.doi.org/10.15585/mmwr.rr6701a1.</p> <p>GlaxoSmithKline Inc. (2023, November 09). ENERGIX-B®: Hepatitis B vaccine (recombinant). Health Canada Drug Product Database. https://pdf.hres.ca/dpd_pm/00073321.PDF.</p> <p>Immunization Action Coalition. Ask the Experts: Hepatitis B. 2019 [cited 2019, Jan 25]. Available from: https://www.immunize.org/ask-experts/topic/hepb/#recommendations.</p> <p>Merck Canada Inc. (2012, May 15). RECOMBIVAX HB®: Hepatitis B vaccine (recombinant). Health Canada Drug Product Database. https://pdf.hres.ca/dpd_pm/00016542.PDF.</p> <p>National Advisory Committee on Immunization. (1999, June 1). Statement on Combination Vaccines against Hepatitis A and Hepatitis B. Canada Communicable Disease Report, 25.</p>		

APPENDIX A: SEROLOGY INTERPRETATION

Serology Result	Interpretation
<ul style="list-style-type: none"> • anti-HBs positive** • HBsAg negative • anti-HBc negative 	<p>Considered immune.</p> <p>Refer to Appendix B: Serology Recommendations and Follow-up for those requiring documented doses of hepatitis B vaccine regardless of positive anti-HBs serology.</p>
<ul style="list-style-type: none"> • anti-HBs positive** • HBsAg negative • anti-HBc positive 	<p>Considered immune. No vaccine indicated.</p>
<ul style="list-style-type: none"> • anti-HBs negative • HBsAg negative • anti-HBc negative 	<p>Susceptible. Proceed with immunization as per eligibility criteria.</p>
<ul style="list-style-type: none"> • anti-HBs negative • HBsAg positive • anti-HBc negative or positive 	<p>No vaccine indicated.</p> <p>Refer to Alberta public health disease management guidelines: hepatitis B -acute and chronic for interpretation and follow-up.</p>
<ul style="list-style-type: none"> • anti-HBs negative • HBsAg negative • anti-HBc positive 	<p>Refer to Alberta public health disease management guidelines: hepatitis B -acute and chronic for interpretation and follow-up.</p>
<p>**Anti-HBs positive is equal to or greater than 10 IU/L. Anti-HBs negative is less than 10 IU/L.</p>	

APPENDIX B: SEROLOGY RECOMMENDATIONS AND FOLLOW-UP

For individuals who are eligible for more than one reason – follow the most comprehensive serology recommendations for the respective eligibility groups.

Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
<ul style="list-style-type: none"> Individuals with chronic renal disease including hemodialysis, peritoneal dialysis, and pre-dialysis 	Pre-immunization serology is not routinely recommended	Serology (anti-HBs) should be done 1–6 months following the primary series of hepatitis B vaccine	<p>Individuals who are hyporesponsive due to renal disease (hemodialysis, peritoneal dialysis and pre-dialysis) often respond sub-optimally to hepatitis B vaccine and should receive a higher vaccine dose according to the schedule for hyporesponsive individuals. If protection is achieved and then wanes, subsequent exposure may result in acute disease or carrier state.</p> <p>Individuals who are anti-HBs negative after the first series should receive a second series, followed by serology one month later.</p> <p>Individuals with chronic renal disease or on dialysis should be evaluated annually for anti-HBs. If anti-HBs testing shows suboptimal protection, give a booster dose of vaccine.</p> <p>See Hepatitis B (HBVD) Algorithm for Chronic Renal Disease (alberta.ca) for additional information.</p> <p>Individuals with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine OR those with incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity.</p>
<ul style="list-style-type: none"> Individuals with congenital immunodeficiencies Candidates for and recipients of solid organ transplant (SOT) Recipients of hematopoietic stem cell transplant (HSCT) 	Pre-immunization serology is not routinely recommended	Serology (anti-HBs) should be done 1–6 months following the primary series of hepatitis B vaccine	<p>Individuals who are hyporesponsive due to congenital immunodeficiencies, HSCT, SOT and HIV infection often respond sub-optimally to hepatitis B vaccine and may need additional antigen to mount a response. If protection is achieved and then wanes, subsequent exposure may result in acute disease or carrier state.</p> <p>Individuals who are anti-HBs negative after the first series should receive a second series, followed by serology one month later.</p> <p>Consider periodic monitoring (by attending physician) for the presence of anti-HBs, taking into account the severity of the compromised state and whether or not the risk for hepatitis B infection is still present. Should anti-HBs testing show suboptimal protection, a booster dose of vaccine and retesting should be undertaken.</p> <p>Individuals with lab confirmation of positive anti-HBs (and anti-HBc negative) but without documentation of any doses of hepatitis B vaccine OR those with incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity.</p>

APPENDIX B: SEROLOGY RECOMMENDATIONS AND FOLLOW-UP

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Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
<ul style="list-style-type: none"> Individuals infected with HIV 	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended	Serology (anti-HBs) should be done 1–6 months following the primary series of hepatitis B vaccine	<p>Individuals who are hyporesponsive due to congenital immunodeficiencies, HSCT, SOT and HIV infection often respond sub-optimally to hepatitis B vaccine and may need additional antigen to mount a response. If protection is achieved and then wanes, subsequent exposure may result in acute disease or carrier state.</p> <p>Individuals who are anti-HBs negative after the first series should receive a second series, followed by serology one month later.</p> <p>Consider periodic monitoring (by attending physician) for the presence of anti-HBs, taking into account the severity of the compromised state and whether or not the risk for hepatitis B infection is still present. Should anti-HBs testing show suboptimal protection, a booster dose of vaccine and retesting should be undertaken.</p> <p>Individuals with lab confirmation of positive anti-HBs (and anti-HBc negative) but without documentation of any doses of hepatitis B vaccine OR those with incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity.</p>
<ul style="list-style-type: none"> Individuals with chronic liver disease 	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended	Serology (anti-HBs) should be done 1–6 months following the primary series of hepatitis B vaccine	<p>Individuals who are anti-HBs negative after the first series should receive a second series using a higher dose vaccine schedule for hyporesponsive individuals followed by serology one month later.</p> <p>Individuals with lab confirmation of positive anti-HBs (and anti-HBc negative) but without documentation of any doses of hepatitis B vaccine OR those with incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity.</p>
<ul style="list-style-type: none"> Newborns born to hepatitis B infected mothers Infants (other than newborns) younger than 12 months of age with hepatitis B infected caregiver or household contact 	Pre-immunization serology is not recommended	Serology (anti-HBs and HBsAg) is recommended 1–6 months following the primary series of hepatitis B vaccine and the infant should be at least 9 months of age	<p>If the individual is anti-HBs negative after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing one month later.</p> <p>Once a positive antibody result is documented no further serology is recommended.</p> <p>Refer to Alberta public health disease management guidelines: hepatitis B -acute and chronic and Alberta prenatal screening program for select communicable diseases – Hepatitis B.</p>

APPENDIX B: SEROLOGY RECOMMENDATIONS AND FOLLOW-UP

For individuals who are eligible for more than one reason – follow the most comprehensive serology recommendations for the respective eligibility groups.

Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
<ul style="list-style-type: none"> Susceptible household contacts, sexual partners and needle-sharing partners of individuals with acute or chronic hepatitis B infection 	<p>Refer to Alberta public health disease management guidelines: hepatitis B -acute and chronic (Management of Contacts [Low Risk or High Risk] of Previous Hepatitis B Infection) for specific serology recommendations and interpretation.</p>		<p>Once a positive anti-HBs result is documented no further serology is recommended.</p> <p>Individuals with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine OR those with incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity.</p>
<ul style="list-style-type: none"> HCWs and Post-Secondary Health Care Students 	<p>Pre-immunization serology (including anti-HBs, HBsAg and anti-HBc total) is recommended for the following:</p> <ul style="list-style-type: none"> Individuals who have emigrated from a country where hepatitis B is endemic. (see Hepatitis B Virus Infection – High Endemic Geographic Areas) Spouse or sexual partners and needle sharing partners of a hepatitis B case or chronic carrier. Household contacts of a hepatitis B case or chronic carrier. 	<p>Serology (anti-HBs) should be done 1–6 months following the primary series of hepatitis B vaccine</p>	<p>For HCWs:</p> <p>If the individual is anti-HBs negative after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing 1 month later.</p> <p>If the vaccine series was completed more than 6 months previously and post-immunization serology was not done, testing should be done as part of a routine assessment.</p> <ul style="list-style-type: none"> If the individual is anti-HBs negative, the individual should be given one booster dose of hepatitis B vaccine followed by serology 1 month later. If the individual is still negative after the booster dose, the second series of hepatitis B vaccine should be completed followed by serology 1 month later. <p>HCWs upon hire or during their WHS Communicable Disease Assessment and Post-secondary HCW students who have lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine or incomplete series should be offered a complete series of hepatitis B vaccine to ensure long term immunity.</p> <p>HCWs who have been previously assessed do not require reassessment or updating at this time.</p> <p>Once a positive anti-HBs result is documented no further serology is recommended.</p>

APPENDIX B: SEROLOGY RECOMMENDATIONS AND FOLLOW-UP

For individuals who are eligible for more than one reason – follow the most comprehensive serology recommendations for the respective eligibility groups.

Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
<ul style="list-style-type: none"> Individuals who are workers or volunteers and who have a reasonable anticipated risk of exposure to blood/bloody body fluids 	Pre-immunization serology is not routinely recommended	Serology (anti-HBs) should be done 1–6 months following the primary series of hepatitis B vaccine	<p>If the individual is anti-HBs negative within 6 months of completion of the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing 1 month later.</p> <p>If the vaccine series was completed more than 6 months previously and post-immunization serology was not done, testing should be done as part of a routine assessment.</p> <ul style="list-style-type: none"> If the individual is anti-HBs negative, one booster dose of hepatitis B vaccine should be administered followed by serology 1 month later. If the individual is still negative after the booster dose, the second series of hepatitis B vaccine should be completed followed by serology 1 month later. <p>Once a positive anti-HBs result is documented no further serology is recommended.</p>
<ul style="list-style-type: none"> Individuals who use illicit drugs and associated drug-using paraphernalia resulting in blood exposure 	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended	Serology (anti-HBs) should be done 1–6 months following the primary series of hepatitis B vaccine	<p>If the individual is anti-HBs negative after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing 1 month later.</p> <p>If vaccine series was completed more than 6 months previously and post-immunization serology was not done, testing should be done as part of a routine assessment.</p> <ul style="list-style-type: none"> If the individual is anti-HBs negative, the individual should be given one booster dose of hepatitis B vaccine followed by serology 1 month later. If the individual is still negative after the booster dose the second series of hepatitis B vaccine should be completed followed by serology 1 month later. <p>Individuals with lab confirmation of positive anti-HBs but without documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</p> <p>Individuals with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</p> <p>Once a positive anti-HBs result is documented no further serology is recommended.</p>

APPENDIX B: SEROLOGY RECOMMENDATIONS AND FOLLOW-UP

For individuals who are eligible for more than one reason – follow the most comprehensive serology recommendations for the respective eligibility groups.

Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
Lifestyle risks <ul style="list-style-type: none"> Men who have sex with men (MSM) Individuals with more than one sexual partner in the previous 6 months Individuals with a history of a sexually transmitted infection (STI) Individuals seeking evaluation or treatment for an STI Individuals who engage in high-risk sexual practices Individuals who have unprotected sex with new partners 	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended	Post-immunization serology is not routinely recommended	<p>Reimmunization (that is, booster dose or reimmunization with a complete series) is not generally recommended.</p> <p>For individuals who were immunized as infants, children or adults, testing for anti-HBs years after immunization might not distinguish vaccine non-responders from responders. Anti-HBs wanes and titres may become non-detectable over time; however immune memory persists.</p> <p>If post-immunization serology was inadvertently done and found to be anti-HBs negative, one booster dose of hepatitis B vaccine should be administered. Additional serology is not required.</p>

APPENDIX B: SEROLOGY RECOMMENDATIONS AND FOLLOW-UP

For individuals who are eligible for more than one reason – follow the most comprehensive serology recommendations for the respective eligibility groups.

Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
<ul style="list-style-type: none"> Adults who have immigrated to Canada from endemic areas 	Pre-immunization serology (anti-HBs, HBsAg and anti-HBc) is recommended	Post-immunization serology is not recommended	<p>Reimmunization (that is, booster dose or reimmunization with a complete series) is not generally recommended.</p> <p>For individuals who were immunized as infants, children or adults, testing for anti-HBs years after immunization might not distinguish vaccine non-responders from responders. Anti-HBs wanes and titres may become non-detectable over time; however immune memory persists.</p> <p>If post-immunization serology was inadvertently done and found to be anti-HBs negative, these individuals do not qualify for additional doses of provincially funded vaccine.</p>
<ul style="list-style-type: none"> Individuals with hemophilia and others receiving repeated infusions of blood or blood products 	Pre-immunization serology is not routinely recommended	Post-immunization serology is not routinely recommended	<p>Reimmunization (that is, booster dose or reimmunization with a complete series) is not generally recommended.</p> <p>For individuals who were immunized as infants, children or adults, testing for anti-HBs years after immunization might not distinguish vaccine non-responders from responders. Anti-HBs wanes and titres may become non-detectable over time; however immune memory persists.</p>
<ul style="list-style-type: none"> Individuals with Inflammatory Bowel disease (IBD), or other chronic inflammatory conditions, who will be on long term immunosuppressive medications 	Pre-immunization serology is not recommended	Post-immunization serology is not recommended	<p>If post-immunization serology was inadvertently done and found to be anti-HBs negative these individuals do not qualify for additional doses of provincially funded vaccine.</p>

APPENDIX B: SEROLOGY RECOMMENDATIONS AND FOLLOW-UP

For individuals who are eligible for more than one reason – follow the most comprehensive serology recommendations for the respective eligibility groups.

Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
<ul style="list-style-type: none">• Children whose families have immigrated to Canada from an endemic area	Pre-immunization serology is not recommended	Post-immunization serology is not recommended	
<ul style="list-style-type: none">• Populations or communities in Alberta in which hepatitis B is highly endemic	Pre-immunization serology is not routinely recommended	Post-immunization serology is not recommended	
<ul style="list-style-type: none">• Children and workers in childcare settings in which there is a hepatitis B infected child or worker• Residents and staff of institutions or group homes for the developmentally challenged• Inmates in provincial correctional facilities	Pre-immunization serology is not recommended	Post-immunization serology is not recommended	Reimmunization (that is, booster dose or reimmunization with a complete series) is not generally recommended. For individuals who were immunized as infants, children or adults, testing for anti-HBs years after immunization might not distinguish vaccine non-responders from responders. Anti-HBs wanes and titres may become non-detectable over time; however immune memory persists. If post-immunization serology was inadvertently done and round to be anti-HBs negative, these individuals do not qualify for additional doses of provincially funded vaccine. See statements above.
<ul style="list-style-type: none">• Students in Grade 6• Students in Grades 7 through 12• Individuals born in 1981 or later	Pre-immunization serology is not recommended	Post-immunization serology is not recommended	
<ul style="list-style-type: none">• Percutaneous (needle stick) or mucosal exposure (blood and body fluid exposures)	Refer to Alberta guidelines for post-exposure management and prophylaxis: HIV, hepatitis B, hepatitis C and sexually transmitted infections for specific serology recommendations and interpretation.		

APPENDIX B: SEROLOGY RECOMMENDATIONS AND FOLLOW-UP			
For individuals who are eligible for more than one reason – follow the most comprehensive serology recommendations for the respective eligibility groups.			
Groups	Pre-immunization Serology recommendation	Post-immunization Serology recommendation	Follow-up Special Considerations
<ul style="list-style-type: none">Susceptible individuals of sexual assault	Refer to Alberta guidelines for post-exposure management and prophylaxis: HIV, hepatitis B, hepatitis C and sexually transmitted infections for specific serology recommendations and interpretation.		
Any individual who fails to respond to the second series of vaccine is unlikely to benefit from further doses. Therefore, if protective levels are not achieved, the individual should be considered a non-responder and susceptible.			