

## Hepatitis B Vaccine (HBV)

**Revision Date: September 1, 2018**

**Rationale for update:**

- Updating dosing and scheduling for hyporesponsive individuals under 16 years of age. (March 2018)
- Incorporated change in school immunization schedule from grade 5 to grade 6.

Please consult the Product Monograph <sup>1,2</sup> for further information about the vaccine.		
	<b>ENGERIX®-B</b>	<b>RECOMBIVAX HB®</b>
<b>Manufacturer</b>	GlaxoSmithKline Inc.	Merck Canada Inc.
<b>Licensed use</b>	Hepatitis B vaccine can be administered at any age from birth onward.	
<b>Off-license use</b>	None	Vaccine dose for all children from birth up to and including 10 years of age in Alberta is 0.5 mL (5 µg). <sup>3</sup>
<b>Indications for use of provincially funded vaccine</b>	<p><b>Note: Eligible individuals with anaphylactic reactions to latex should receive Engerix®-B vaccine.</b></p> <p><b>Pre-exposure:</b></p> <ul style="list-style-type: none"> <li>• Students in Grade 6 Universal program in Alberta.</li> <li>• Students in Grades 7 through 12 who have not received a series of hepatitis B vaccine.</li> <li>• 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.</li> <li>• Children younger than seven years of age whose families have immigrated to Canada from areas where there is a high prevalence (8% or higher) of hepatitis B (endemic for hepatitis B). See <a href="#">Hepatitis B Virus Infection – High Endemic Geographic Areas</a>.</li> <li>• 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 <a href="#">Provision of Occupational Vaccines</a>.</li> <li>• Hemophiliacs and others receiving repeated infusions of blood or blood products (hepatitis B vaccine is not provided for parents providing home infusion for their children).</li> <li>• Individuals with chronic liver disease from any cause, including hepatitis C infection.<sup>4</sup> <ul style="list-style-type: none"> <li>▪ Individuals with chronic liver disease with lab confirmation of positive anti-HBs but <b>without</b> documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</li> <li>▪ Individuals with chronic liver disease with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</li> </ul> </li> <li>• Individuals with Inflammatory Bowel disease (IBD) who will be on long term immunosuppressive medications including but not limited to Imuran or TNF antagonists like Remicade or Humira.<sup>4,5</sup></li> </ul>	

	<ul style="list-style-type: none"><li>• Non-immune individuals with chronic health conditions <b>that may be HYPORESPONSIVE to hepatitis B</b> vaccine should receive a higher dose of hepatitis B (see dose section for hyporesponsive individuals). These include:<ul style="list-style-type: none"><li>➢ Individuals with chronic renal disease or who are undergoing chronic hemodialysis/peritoneal dialysis, including those who are pre-dialysis (progressive renal insufficiency).</li><li>➢ Individuals with congenital immunodeficiencies.<sup>4</sup></li><li>➢ Individuals infected with HIV.<sup>4</sup></li><li>➢ Candidates for and recipients of solid organ transplant. See:<ul style="list-style-type: none"><li>▪ <a href="#">Immunization for Children Expecting Solid Organ Transplant before 18 Months of Age (Accelerated)</a>,</li><li>▪ <a href="#">Immunization for Children Expecting Solid Organ Transplant at 18 months of Age or Older (Catch-up Schedule)</a> and</li><li>▪ <a href="#">Immunization for Adult Solid Organ Candidates and Recipients</a>.</li></ul></li><li>➢ Recipients of hematopoietic stem cell transplant (HSCT). See:<ul style="list-style-type: none"><li>▪ <a href="#">Immunization for Child Hematopoietic Stem Cell Transplant Recipients and</a></li><li>▪ <a href="#">Immunization for Adult Hematopoietic Stem Cell Transplant Recipients</a>.</li></ul></li></ul></li><li>Note:<ul style="list-style-type: none"><li>▪ These individuals with lab confirmation of positive anti-HBs but <b>without</b> documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</li><li>▪ These individuals with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</li></ul></li><li>• Non-immune individuals with lifestyle risks for infection including:<ul style="list-style-type: none"><li>➢ Men who have sex with men (MSM).<sup>4</sup></li><li>➢ Individuals with more than one sexual partner in the previous six months.<sup>4</sup></li><li>➢ Individuals with a history of a sexually transmitted infection.<sup>4</sup></li><li>➢ Individuals seeking evaluation or treatment for a sexually transmitted infection.<sup>4</sup></li><li>➢ Individuals who engage in high risk sexual practices.<sup>4</sup></li><li>➢ Individuals who have unprotected sex with new partners.<sup>4</sup></li><li>➢ Individuals who use illicit drugs<sup>3</sup> and associated drug-using paraphernalia (e.g., tubes used for snorting), resulting in blood exposure.</li></ul></li><li>• Children and workers in child care settings in which there is a hepatitis B infected (acute or chronic) child or worker.<sup>4</sup></li><li>• Non-immune adults who have immigrated to Canada from areas where there is a high prevalence of hepatitis B.<sup>4</sup> See <a href="#">Hepatitis B Virus Infection – High Endemic Geographic Areas</a>.</li><li>• Residents and staff of institutions or group homes for the developmentally challenged.</li><li>• Populations or communities in which hepatitis B is highly endemic, following consultation with the Office of the Chief Medical Officer (OCMOH).</li><li>• Inmates in provincial correctional facilities who will be incarcerated for a sufficient length of time to complete a hepatitis B vaccine series.</li></ul>
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	<ul style="list-style-type: none"><li>• Inmates in long-term correctional facilities: Immunization 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 the correctional facility.</li></ul> <p><b>Post-exposure:</b></p> <ul style="list-style-type: none"><li>• <b>Newborns</b> born to hepatitis B infected mothers (acute cases or carriers) should receive hepatitis immune globulin (HBIG) and the first dose of hepatitis B vaccine as soon as possible after birth (within 12 hours) but within seven days after birth if HBIG/hepatitis B vaccine is delayed for any reason.<sup>6</sup></li></ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"><li>➢ 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.</li><li>➢ If results can be obtained within 12 hours, the first dose of hepatitis B vaccine should be administered. HBIG administration should be delayed pending results.<sup>4</sup></li><li>➢ 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.<sup>4</sup></li></ul> <ul style="list-style-type: none"><li>• <b>Infants (other than newborns) younger than 12 months of age:</b><ul style="list-style-type: none"><li>➢ Hepatitis B vaccine and HBIG if the mother or primary caregiver is an acute case.</li><li>➢ Hepatitis B vaccine only if the caregiver or significant household contact is a chronic carrier.</li></ul></li></ul> <p>Refer to: <i>Public Health Notifiable Disease Management Guidelines – Hepatitis<sup>7,8</sup></i> and <i>Alberta Prenatal Screening Program for Selected Communicable Diseases Public Health Guidelines – Hepatitis B<sup>6</sup></i></p> <ul style="list-style-type: none"><li>• <b>Susceptible household contacts, sexual partners and needle-sharing partners of individuals with acute or chronic hepatitis B infection.</b><ul style="list-style-type: none"><li>➢ Hepatitis B vaccine. HBIG may be recommended for some individuals depending upon the time from exposure and the specifics surrounding the exposure.</li></ul></li></ul> <p><b>Note:</b></p> <ul style="list-style-type: none"><li>▪ Susceptible household contacts, sexual partners and needle-sharing partners with lab confirmation of positive anti-HBs but <b>without</b> documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</li><li>▪ Susceptible household contacts, sexual partners and needle-sharing partners with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</li></ul> <p>Refer to: <i>Public Health Notifiable Disease Management Guidelines – Hepatitis B<sup>7,8</sup></i></p> <ul style="list-style-type: none"><li>• <b>Percutaneous (needle stick) or mucosal exposure:</b><ul style="list-style-type: none"><li>➢ Post-exposure follow-up and prophylaxis should be based on the immunization history and antibody status of the exposed person and, if known, the infectious nature of the source.</li></ul></li></ul>
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	<p>Note:</p> <ul style="list-style-type: none"> <li>▪ Individuals sustaining percutaneous (needle stick) or mucosal exposure with lab confirmation of positive anti-HBs but <b>without</b> documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</li> <li>▪ Individuals sustaining percutaneous (needle stick) or mucosal exposure with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</li> </ul> <p>Refer to: <i>Canadian Immunization Guide: Hepatitis B Vaccine (Figures 1 &amp; 2)</i>.<sup>4</sup>  <a href="https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-7-hepatitis-b-vaccine.html">https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-7-hepatitis-b-vaccine.html</a>.</p> <ul style="list-style-type: none"> <li>➢ 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, HBIG should be administered (as soon as possible but within seven days of exposure) with the first dose of the hepatitis B vaccine series.</li> </ul> <p>Refer to: <i>Alberta Guidelines for Non-Occupational, Occupational and Mandatory Testing and Disclosure Act Post-exposure Management and Prophylaxis: HIV, Hepatitis B, Hepatitis C and Sexually Transmitted Infections</i>.<sup>9</sup></p> <ul style="list-style-type: none"> <li>• <b>Susceptible individuals of sexual assault:</b> <ul style="list-style-type: none"> <li>➢ HBIG and hepatitis B vaccine should be offered.</li> </ul> </li> </ul> <p>Refer to: <i>Alberta Guidelines for Non-occupational, Occupational and Mandatory Testing and Disclosure Act Post-Exposure Management and Prophylaxis</i>.<sup>9</sup></p> <p><b>Hepatitis A and B Combined Vaccine:</b>          Hepatitis A and B Combined Vaccine may be considered for individuals eligible for both pre-exposure hepatitis A and hepatitis B vaccines. See Biological Products – <a href="#">Hepatitis A and B Combined Vaccine: TWINRIX®</a>.</p>
<p><b>Pre-immunization Serology</b></p>	<p><b>Pre-immunization Serology (HBsAg and anti-HBs) is recommended for the following individuals:</b></p> <ul style="list-style-type: none"> <li>• Individuals with high probability of past infection, including individuals with potential percutaneous or mucosal exposure to HB<sup>4</sup> and individuals with HCV.</li> <li>• Spouse or sexual partners and needle sharing partners of a hepatitis B case or chronic carrier. Refer to: <i>Public Health Notifiable Disease Management Guidelines – Hepatitis B</i>.<sup>7,8</sup> for serology recommendations and interpretation.</li> <li>• Household contacts (12 months of age and older) of a hepatitis B case or chronic carrier including those previously immunized through a universal or endemic hepatitis B immunization program.<sup>7,8</sup></li> <li>• Individuals who have emigrated from a country where hepatitis B is endemic. See <a href="#">Hepatitis B Virus Infection – High Endemic Geographic Areas</a>.</li> <li>• Health care workers (HCWs) and Post-secondary HCW students who meet any of the above recommendations for pre-immunization serology – refer to <a href="#">Provision of Occupational Vaccines</a> for specific serology recommendations.</li> </ul> <p><b>Pre-immunization Serology is NOT recommended for:</b></p> <ul style="list-style-type: none"> <li>• Individuals receiving hepatitis B immunization through universal immunization programs.</li> <li>• Newborns born to hepatitis B positive mothers and infants younger than 12 months of age.</li> <li>• Children younger than 7 years eligible through the hepatitis B endemic program.</li> </ul>

Dose and Schedule	ENGERIX®-B	RECOMBIVAX HB®
<p><i>See below for hyporesponsive individuals Dose and Schedule</i></p>	ENGERIX®-B (20 µg/1.0 mL)	RECOMBIVAX HB® (10 µg/1.0 mL)
	<p><b>Infant born to hepatitis B infected mother (3 doses):</b></p>	
	<p><b>Given as 0.5 mL</b></p>	
	<ul style="list-style-type: none"> <li>❖ Dose 1: at birth</li> <li>❖ Dose 2: two months of age</li> <li>❖ Dose 3: six months of age</li> </ul>	
	<p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>➤ The response to hepatitis B vaccine may be diminished in infants with a birth weight below 2,000 grams.<sup>4</sup></li> <li>➤ Neonates weighing less than 2,000 grams born to infected mothers require four doses of vaccine administered at birth, 1, 2, and 6 months of age, followed by serologic testing one month after completion of the series.<sup>4,6</sup></li> <li>➤ The final (third/fourth) dose in the series should not be administered to infants before 24 weeks (168 days) of age.<sup>4</sup></li> </ul> <p>INFANRIX hexa® may be considered for infants eligible for both DTaP-IPV-Hib and Hepatitis B vaccines. See Biological Products – <a href="#">DTaP-IPV-Hib-HB: INFANRIX hexa®</a> for indications.</p>	
<p><b>Other infants younger than 12 months of age (3 doses):</b></p>		
<p><b>Given as 0.5 mL</b></p>		
<ul style="list-style-type: none"> <li>❖ Dose 1: two months of age</li> <li>❖ Dose 2: four months of age</li> <li>❖ Dose 3: twelve months of age</li> </ul>		
<p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>➤ Neonates weighing less than 2,000 grams who received their first dose of hepatitis B vaccine at birth should receive three additional doses of vaccine administered at 1, 2, and 6 months of age.</li> </ul> <p>INFANRIX hexa® may be considered for infants eligible for both DTaP-IPV-Hib and Hepatitis B vaccines. See Biological Products – <a href="#">DTaP-IPV-Hib-HB: INFANRIX hexa®</a> for indications.</p>		
<p><b>Children 12 months of age up to and including 19 years of age (3 doses):</b></p>		
<p><b>Given as 0.5 mL</b></p>		
<ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: one month after dose one</li> <li>❖ Dose 3: six months after dose one</li> </ul>		
<p><b>Note:</b> Minimal acceptable schedule/condensed school schedule (for students up to and including 17 years of age in the school setting) is 0, 1, and 4 months, with one month (28 days) between the first and second dose, at least two months (56 days) between the second and third dose and at least four months (112 days) between the first and third dose.<sup>4</sup></p>		
<p><b>Adults 20 years of age and older (3 doses):</b></p>		
<p><b>Given as 1.0 mL</b></p>		
<ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: one month after dose one</li> <li>❖ Dose 3: six months after dose one</li> </ul>		

<p><b>Dose and Schedule for Hyporesponsive Individuals</b>  <i>(see Indications section above)</i></p>	<p><b>0 to 15 years</b></p>	<p><b>Individuals 0-15 years of age inclusive (3 doses):<sup>4</sup></b>  <b>Give as 1.0 mL dose (20 µg)</b></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: one month after dose 1</li> <li>❖ Dose 3: six months after dose 1</li> </ul>	<p><b>Individuals 0–15 years of age inclusive (3 doses):</b>  <b>Give as 1.0 ml (10 µg)</b></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: one month after dose 1</li> <li>❖ Dose 3: six months after dose 1</li> </ul>
	<p><b>16 to 19 years</b></p>	<p><b>Individuals 16 years of age up to and including 19 years of age (4 doses):<sup>1,4</sup></b>  <b>Give as 2.0 mL dose (40 µg)</b></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: one month after dose 1</li> <li>❖ Dose 3: two months after dose 1</li> <li>❖ Dose 4: six months after dose 1</li> </ul> <p><b>Note:</b> Those initiating a four dose schedule with Engerix®-B should complete the series using the same vaccine whenever possible.</p>	<p><b>Individuals 16 years of age up to and including 19 years of age (3 doses):</b>  <b>Give as 1.0 mL dose (10 µg)</b></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: one month after dose 1</li> <li>❖ Dose 3: six months after dose 1</li> </ul>
	<p><b>20 years and older</b></p>	<p><b>Individuals 20 years of age and older (4 doses):<sup>1,4</sup></b>  <b>Give as 2.0 mL dose (40 µg)</b></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: one month after dose 1</li> <li>❖ Dose 3: two months after dose 1</li> <li>❖ Dose 4: six months after dose 1</li> </ul> <p><b>Note:</b> Those initiating a four dose schedule with Engerix®-B should complete the series using the same vaccine whenever possible.</p>	<p><b>Individuals 20 years of age and older (3 doses)</b>  <b>Give as 1.0 mL (40 µg)</b></p> <ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: one month after dose 1</li> <li>❖ Dose 3: six months after dose 1</li> </ul> <p><b>Note:</b> Do not use this formulation for individuals younger than 20 years of age.<sup>1</sup></p>
	<p><b>Note:</b>                  Interruption of the hepatitis B vaccines series does not require that any dose be repeated if the minimum intervals between doses are respected. If years have elapsed between the first and second dose, it may be prudent to assess antibody response when the series is complete, especially if the individual is at significant risk of infection.</p>		
<p><b>Route</b></p>	<p>Intramuscular injection</p>		

<b>Post-immunization Serology and Follow-up</b>	<b>Post-immunization testing (anti-HBs) and follow-up is recommended for the following groups only as outlined below:</b>		
	<b>Groups</b>	<b>Serology</b>	<b>Follow-up</b>
	<u>Infants born to infected mothers</u>	Serology is recommended 1 – 6 months following the primary series of hepatitis B vaccine and the infant should be at least 9 months of age. <sup>4</sup>  Both anti-HBs and HBsAg to be done.	If the individual is negative for antibody after the first series, a second hepatitis B vaccine series. <sup>4</sup> should be administered, with repeat serology testing one month later.
	<u>Repeated Exposures:</u> Individuals who are sexual contacts, household contacts or needle sharing partners of cases or chronic carriers.	Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine and at least 6 months after HBIG. <sup>4</sup>	If the individual is negative for antibody after the first series, a second hepatitis B vaccine series <sup>4</sup> should be administered, with repeat serology testing one month later.
	<u>Hyporesponsive</u> Individuals who are hyporesponsive due to immunocompromising conditions (includes those with congenital immunodeficiencies, HSCT, SOT, HIV infected) often respond suboptimally 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. <sup>4</sup>	Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine.	Individuals who are immunocompromised and are negative for antibody after the first series, <b>should receive a second series</b> , followed by serology one month later. <sup>4</sup>  Periodic monitoring (by attending physician) for the presence of anti-HBs should be considered for immunocompromised individuals, taking into account the severity of the compromised state and whether or not the risk for hepatitis B infection is still present. Should antibody testing show suboptimal protection, a booster dose of vaccine and retesting should be undertaken. <sup>4</sup>
	<u>Renal disease:</u> Individuals who are hyporesponsive due to renal disease (hemodialysis, peritoneal dialysis and pre-dialysis) often respond suboptimally 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. <sup>3</sup>	Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine.	Individuals who have renal disease (hemodialysis, peritoneal dialysis and pre-dialysis) and are negative for antibody after the first series, <b>should receive a second series</b> , followed by serology one month later. <sup>4,10</sup>  Persons with chronic renal disease or on dialysis should be evaluated yearly for anti-HBs. <sup>4,10</sup> Should antibody testing show suboptimal protection, a booster dose of vaccine should be give. <sup>4,12</sup>
<u>Liver disease:</u> Individuals with chronic liver disease including hepatitis C conversion.	Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine.	If they have not responded to the first hepatitis B vaccine series, offer a second series but consider using higher dose vaccine schedule for hyporesponsive individuals. <sup>4</sup>	

	<p><b>Occupational:</b> All health care workers/students in health-related disciplines who qualify for hepatitis B immunization.</p>	<p>Serology done 1 – 6 months following the primary series of hepatitis B vaccine.</p>	<p>If the individual is negative for antibody after the first series, a second hepatitis B vaccine series<sup>4</sup> should be administered, with repeat serology testing one month later.</p>
		<p>If immunization was completed more than six months previously and post-immunization screening was not done, testing should be done as part of a routine assessment.</p>	<p>If the individual is negative the worker/individual should be given 1 booster dose of hepatitis B vaccine followed by serology one month later. If the individual is still negative after the 4<sup>th</sup> dose, the second series of hepatitis B vaccine should be completed followed by serology 1 month later.<sup>4</sup></p>
		<ul style="list-style-type: none"> <li>➤ Once a positive result is recorded following a complete, documented series; no further serology is recommended.</li> <li>➤ HCWs upon hire or during their WHS 'communicable disease assessment' who have lab confirmation of positive anti-HBs but <b>without</b> documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.<sup>4</sup></li> <li>➤ HCWs who have been previously assessed do not require reassessment or updating at this time.</li> <li>➤ Post-secondary HCW students who have lab confirmation of positive anti-HBs but <b>without</b> documentation of any doses of hepatitis B vaccine should be offered a series of hepatitis B vaccine to ensure long term immunity.</li> <li>➤ HCWs and Post-secondary HCW students who have lab confirmation of positive anti-HBs with any incomplete series should have their series completed.</li> </ul>	
<p><b>Any individual who fails to respond to the second series of vaccine are unlikely to benefit from further doses.<sup>4</sup> Therefore, if protective levels are not achieved, the individual should be considered a non- responder and susceptible.</b></p> <p><b>Revaccination (i.e. booster dose or revaccination with a complete series) is not generally recommended for individuals outside of these identified groups.<sup>11,12</sup> If serology was inadvertently done and are found to be antiHBs negative these individuals do not qualify for additional doses of provincially funded vaccine.</b></p>			
<p><b>Contraindications</b></p>	<ul style="list-style-type: none"> <li>• Known severe hypersensitivity to any component of the vaccine.</li> <li>• Anaphylactic reactions to a previous dose of vaccine containing hepatitis B antigen.</li> </ul> <p><u>For Recombivax HB® only:</u></p> <ul style="list-style-type: none"> <li>• Anaphylactic reactions to latex.</li> </ul>		
<p><b>Precautions</b></p>	<p>Should not be administered in the gluteal area or intradermally, as this may result in lower immune response.<sup>1,2,4</sup></p>		
<p><b>Possible reactions</b></p>	<p><b>Common:</b></p> <ul style="list-style-type: none"> <li>• Injection site pain, soreness, tenderness, pruritus, erythema, swelling, warmth and nodule formation.<sup>1,2</sup></li> <li>• Irritability, headache, fatigue, drowsiness, malaise, dizziness, myalgia, pharyngitis and fever.<sup>1,2</sup></li> <li>• Loss of appetite, nausea and diarrhea.<sup>1,2</sup></li> </ul> <p><b>Uncommon:</b></p> <ul style="list-style-type: none"> <li>• Dizziness, myalgia.<sup>2</sup></li> </ul>		

	<p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>• Lymphadenopathy, paresthesia, rash, urticaria, and arthralgia.<sup>1,2</sup></li> <li>• Anaphylaxis, allergic reactions.<sup>1,2</sup></li> </ul> <p><b>Note:</b> 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.<sup>4</sup></p> <p>Refer to: <i>Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.</i><sup>13</sup></p>
<b>Pregnancy</b>	Hepatitis B vaccine should be administered to pregnant women when indicated. <sup>4</sup> Data is not available on the effect of hepatitis B vaccine on fetal development; <sup>1,2</sup> however, the risk is expected to be negligible as the vaccine consists of non-infectious subunits.
<b>Lactation</b>	Hepatitis B vaccine should be administered to breastfeeding women when indicated. It is not known whether hepatitis B vaccine is excreted in human milk. <sup>1,2</sup>

**References**

<sup>1</sup> GlaxoSmithKline Inc. (2018 June 15). Engerix®-B: Hepatitis B vaccine (recombinant). *Product Monograph*.

<sup>2</sup> Merck Canada Inc. (2012, May 15) Recombivax HB®: Hepatitis B vaccine (recombinant). *Product Monograph*. [https://pdf.hres.ca/dpd\\_pm/00016542.PDF](https://pdf.hres.ca/dpd_pm/00016542.PDF)

<sup>3</sup> Alberta Advisory Committee on Immunization (AACI). (2011, May 31). Record of Decisions.

<sup>4</sup> National Advisory Committee on Immunization. (2017) *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. [www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php](http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php)

<sup>5</sup> Wasan, S. (2010, January 26). A Practical Guide to Vaccinating the Inflammatory Bowel Disease Patient. *The American College of Gastroenterology. The American Journal of Gastroenterology*, 105:1231-1238.

<sup>6</sup> Alberta Health and Wellness, Disease Control and Prevention. (2007, July). *Prenatal Screening Program for Selected Communicable Diseases: Public Health Guidelines*. [www.health.alberta.ca/professionals/notifiable-diseases-guide.html](http://www.health.alberta.ca/professionals/notifiable-diseases-guide.html)

<sup>7</sup> Alberta Health and Wellness. *Public Health Notifiable Disease Management Guidelines – Hepatitis B (Acute Case)*. [www.health.alberta.ca/professionals/notifiable-diseases-guide.html](http://www.health.alberta.ca/professionals/notifiable-diseases-guide.html)

<sup>8</sup> Alberta Health and Wellness. *Public Health Notifiable Disease Management Guidelines - Hepatitis B (Chronic Carrier)*. [www.health.alberta.ca/professionals/notifiable-diseases-guide.html](http://www.health.alberta.ca/professionals/notifiable-diseases-guide.html)

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<sup>10</sup> *Advisory Committee on Immunization Practices (ACIP)*. (2012). *Guideline for Vaccinating Kidney Dialysis Patients and Patients with Chronic Kidney Disease*. Retrieved on March 15, 2016 from [www.cdc.gov/vaccines/pubs/downloads/dialysis-guide-2012.pdf](http://www.cdc.gov/vaccines/pubs/downloads/dialysis-guide-2012.pdf)

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<sup>12</sup> Centers for Disease Control and Prevention. (2018) Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) *Morbidity and Mortality Weekly Report (MMWR)*, 67(No.RR-1):1-31. <http://dx.doi.org/10.15585/mmwr.rr6701a1>

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