## Reombivax HB®

**Manufacturer**
Merck Canada Inc.

**Biological Classification**
Inactivated: Recombinant

## Engerix®-B

**Manufacturer**
GlaxoSmithKline Inc.

**Biological Classification**
Inactivated: Recombinant

### Indications for Provincially Funded Vaccine

**Pre-exposure:**
- Students in Grade 6 as part of the provincial school based immunization program.
- Students in Grades 7 through 12 who have not received a series of hepatitis B vaccine.
  - For students in ungraded classes, vaccine can be provided on a case by case basis, generally at 9 years up to and including 18 years of age. The guiding principle should be to offer protection to students prior to them leaving the school system.
- 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.
- Children from birth up to and including 6 years of age, whose families have immigrated to Canada from areas where there is a high prevalence (8% or higher) of 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 (8% or higher) of hepatitis B. See Hepatitis B Virus Infection – High Endemic Geographic Areas.
- 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. Refer to Hepatitis B Risk Assessment.
- Residents and staff of institutions or group homes for the developmentally challenged.
- Non-immune individuals with lifestyle risks of infection including:
  - Men having sex with men (MSM).
  - Those with multiple sexual partners (e.g., have had more than one sexual partner in the previous six months).
  - Those with a history of sexually transmitted infections (STI) or those seeking evaluation or treatment for an STI.
  - Those who engage in high risk sexual practices.
  - Those who have unprotected sex with new partners.
  - Those who use illicit drugs and associated drug-using paraphernalia (e.g., needles, tubes used for snorting), resulting in blood exposure.
- 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).
- 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®.
- Individuals with chronic liver disease from any cause, including hepatitis C infection.

### Note:

For questions related to Travel and or For Sale vaccine refer to AHS Travel Health and Contracted Immunization Services resources.
<table>
<thead>
<tr>
<th><strong>Recombivax HB®</strong></th>
<th><strong>Engerix®-B</strong></th>
</tr>
</thead>
</table>

**Note:**
- Individuals with chronic liver disease 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.
- Individuals with chronic liver disease with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.
- Non-immune individuals with chronic health conditions that may be HYPORESPONSIVE to hepatitis B vaccine should receive a higher dose of hepatitis B (see dose section). These include:
  - Individuals with chronic renal disease or who are undergoing chronic hemodialysis/peritoneal dialysis, including those who are pre-dialysis (progressive renal insufficiency).
  - Individuals with congenital immunodeficiencies.
  - Individuals infected with HIV.
  - Candidates and recipients of Solid Organ Transplant (SOT) – See *Standard for Immunization of Transplant Candidates and Recipients*.
  - Recipients of Hematopoietic Stem Cell Transplant (HSCT) – See *Standard for Immunization of Transplant Candidates and Recipients*.

**Note:**
- 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.
- Individuals with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.
- Periodic serological testing may be done by the attending physician for hyporesponsive individuals. See serology section for more information.
- Inmates in provincial correctional facilities who will be incarcerated for a sufficient length of time to complete a hepatitis B vaccine series.

**Note:**
- 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.
- Staff and children in child care settings in which there is a hepatitis B infected staff or child.
  - If exceptional circumstances such as biting behavior or special medical conditions exist and Hepatitis B status is unknown, consult with MOH/designate.
- Populations or communities in which hepatitis B is highly endemic, following consultation with MOH/designate.

**Note:**
- Combined hepatitis A and B vaccine may be indicated for individuals 1 year of age and older who qualify for both hepatitis A and B vaccines for pre-exposure if they do not require the double strength hepatitis B vaccine (see Twinrix® Vaccine Biological Page).

**Post-exposure:**
- **Infants:**
  - 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.

  **Note:**
  - 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, the first dose of Hepatitis B vaccine should be administered with the decision to administer HBIg awaiting results.
Recombivax HB® | Engerix®-B

- If screening results are not 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.
  - Infants (other than newborns) younger than 12 months of age should receive:
    - 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.

- Susceptible household contacts, sexual partners and needle sharing partners of individuals with acute or chronic hepatitis B infection.
  - Hepatitis B vaccine. HBIG may be recommended for some individuals depending on the time from exposure and the specifics of the exposure. Refer to: Public Health Notifiable Disease Management Guidelines – Hepatitis B

  Note:
  - 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 should be offered a series of hepatitis B vaccine to ensure long term immunity.
  - 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.

- Percutaneous (needle stick) or mucosal exposure.
  - 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.

  Note:
  - 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 should be offered a series of hepatitis B vaccine to ensure long term immunity.
  - Individuals sustaining percutaneous (needle stick) or mucosal exposure with lab confirmation of positive anti-HBs with any incomplete series should have their series completed.
  - 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.

  - Susceptible individuals of sexual assault.
    - HBIG and hepatitis B vaccine should be offered.

For further guidelines related to post-exposure follow-up refer to the following (http://www.health.alberta.ca/professionals/notifiable-diseases-guide.html):
- Public Health Notifiable Disease Management Guidelines – Hepatitis B.
- Alberta Prenatal Screening Program for Selected Communicable Diseases Public Health Guidelines
Serology

Pre-immunization serology is recommended for the following individuals if they are eligible as per the Indications Section:

- Antigen (HBsAg) and antibody (Anti-HBs) testing is recommended for:
  - Spouse or sexual partners and needle sharing partners of a hepatitis B case or chronic carrier. Refer to AH Public Health Notifiable Disease Management Guidelines
  - 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. Refer to AH Public Health Notifiable Disease Management Guidelines
  - Those with high probability of past infection:
    - Those who have received repeated blood transfusions
    - Those with a history of dialysis
    - Those with lifestyle risks of infection
    - Those who have immigrated to Canada from a country where hepatitis B is endemic – see Hepatitis B Endemic Countries List

- Health care workers (HCWs) and Post-secondary HCW students who meet any of the above recommendations for pre-immunization serology. Health care workers and post-secondary health care students who have documented history of a complete HBV immunization series or report HBV immunization but have no or incomplete documentation should have serologic testing done as outlined in the Standard for Immunization of Health Care Workers and Standard for Immunization of Post Secondary Students. For HCWs/health care students with high probability of past infection an Anti-HBc should also be done.

Pre-immunization serology is NOT recommended for:

- Routine population-based hepatitis B immunization programs.
- Newborns born to hepatitis B positive mothers and infants younger than 12 months of age.
- Children from birth up to and including 6 years of age who are eligible for hepatitis B vaccine under the endemic program.

Post Immunization Serology:

Post-immunization testing (anti-HBs) and follow-up is recommended for the following groups only as outlined below:

<table>
<thead>
<tr>
<th>Groups</th>
<th>Serology</th>
<th>Follow-up</th>
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</thead>
<tbody>
<tr>
<td>Infants born to infected mothers</td>
<td>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. Both anti-HBs and HBsAg should be done.</td>
<td>If the individual is negative for antibody after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing one month later.</td>
</tr>
<tr>
<td>Repeated Exposures: Individuals who are sexual contacts, household contacts or needle sharing partners of cases or chronic carriers.</td>
<td>Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine.</td>
<td>If the individual is negative for antibody after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing one month later.</td>
</tr>
<tr>
<td><strong>Recombivax HB®</strong></td>
<td><strong>Engerix®-B</strong></td>
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<tr>
<td><strong>Immunocompromised:</strong> 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.</td>
<td>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, should receive a second series, followed by serology one month later. 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.</td>
<td></td>
</tr>
<tr>
<td><strong>Renal disease:</strong> Individuals who are hyporesponsive due to renal disease (hemodialysis, peritoneal dialysis, and predialysis) 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.</td>
<td>Serology should be done 1 – 6 months following the primary series of hepatitis B vaccine.</td>
<td></td>
</tr>
<tr>
<td><strong>Liver disease:</strong> Individuals with chronic liver disease including disease caused by hepatitis C conversion.</td>
<td>If they have not responded to the first hepatitis B vaccine series, offer a second series using higher dose vaccine schedule for hyporesponsive individuals.</td>
<td></td>
</tr>
<tr>
<td><strong>Occupational:</strong> All health care workers/students in health-related disciplines who qualify for hepatitis B immunization.</td>
<td>Serology done 1 – 6 months following the primary series of hepatitis B vaccine. If the individual is negative for antibody after the first series, a second hepatitis B vaccine series should be administered, with repeat serology testing one month later.</td>
<td></td>
</tr>
</tbody>
</table>
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.

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 4th dose, the second series of hepatitis B vaccine should be completed followed by serology 1 month later.

Once a positive result is recorded following a complete, documented series; no further serology is recommended.

- HCWs upon hire or during their WHS ‘communicable disease assessment’ who have 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.
- HCWs who have been previously assessed do not require reassessment or updating at this time.
- Post-secondary HCW students who have 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.
- HCWs and Post-secondary HCW students who have lab confirmation of positive anti-HBs with any incomplete series should have their series completed.

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.

Reimmunization (i.e., booster dose or reimmunization with a complete series) is not generally recommended for individuals outside of these identified groups. If serology was inadvertently done and are found to be anti-HBs negative, these individuals do not qualify for additional doses of provincially funded vaccine.

**Schedule**

**Healthy Individuals** (see below for hyporesponsive individuals):

**Infants born to hepatitis B surface antigen positive (HBsAg) mother:**
- Dose 1 – at birth, given with HBlg
- Dose 2 – 2 months of age
- Dose 3 – 6 months of age

**Note:**
- Third dose should not be given to infants before 6 months (24 weeks or 168 days) of age.

**Pre-term Infants with birth weight less than 2000 grams born to hepatitis B surface antigen positive (HBsAg) mother:**
- Dose 1 – at birth, given with HBlg
- Dose 2 – 1 months of age
- Dose 3 – 2 months of age
- Dose 4 – 6 months of age
### Population, Public and Indigenous Health

**Recombivax HB®**

- **Pre-term Infants with birth weight less than 2000 grams who receive hepatitis B vaccine at birth (e.g., father or other primary caregiver is HBsAg positive):**
  - Dose 1 – at birth
  - Dose 2 – 1 months of age
  - Dose 3 – 2 months of age
  - Dose 4 – 6 months of age

**Notes:**
- The response to hepatitis B vaccine may be diminished in pre-term infants with a birth weight below 2,000 grams. Neonates weighing less than 2,000 grams who receive hepatitis B vaccine at birth require four doses of vaccine; administered at birth, 1, 2 and 6 months of age, followed by serologic testing at minimum 9 months of age and at least one month after completion of series.
- Fourth dose should not be given to infants before 6 months (24 weeks or 168 days) of age.

**Other Infants from birth up to and including 11 months of age:**
  - Dose 1 – 2 months of age
  - Dose 2 – 4 months of age
  - Dose 3 – 12 months of age

**Notes:**
- May consider use of Infanrix hexa® in certain situations. See *Infanrix hexa® Vaccine Biological Page (#07.214)* for indications. The schedule and spacing considerations for Infanrix-hexa® vaccine varies slightly from those of the individual HBV and DTaP-IPV-Hib vaccines. Ensure the appropriate schedule is followed for the vaccine(s) that are being used.
- Infanrix-hexa® should not be used for **high risk infants weighing less than 2000g** who received Hepatitis B vaccine and/or HBIG at birth. These infants should continue to receive the separate Hepatitis B vaccine according to the schedule outlined above.
- Third dose should not be given to infants before 6 months (24 weeks or 168 days) of age.
- For children who begin immunization off schedule minimum intervals can be used. Refer to Spacing Considerations.

**Students being immunized in the school setting:**
  - Dose 1 – day 0
  - Dose 2 – 1 month after dose 1
  - Dose 3 – 4 to 6 months after dose 1

**Note:**
- The minimum acceptable schedule/condensed schedule for school programs 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 4 months (112 days) between the first and third dose.

**Individuals 12 months of age and older, and adults (excluding students receiving vaccine in a school setting):**
  - Dose 1 – day 0
  - Dose 2 – 1 month after dose 1
  - Dose 3 – 6 months after dose 1

**Note:**
- May consider use of Infanrix hexa® in certain situations for children up to and including 23 months. See *Infanrix hexa® Vaccine Biological Page (#07.214)* for indications. The schedule and spacing considerations for Infanrix-hexa® vaccine varies slightly from those of the individual HBV and DTaP-IPV-Hib vaccines. Ensure the appropriate schedule is followed for the vaccine(s) that are being used.

**Engerix®-B**

- **Pre-term Infants with birth weight less than 2000 grams who receive hepatitis B vaccine at birth (e.g., father or other primary caregiver is HBsAg positive):**
  - Dose 1 – at birth
  - Dose 2 – 1 months of age
  - Dose 3 – 2 months of age
  - Dose 4 – 6 months of age

**Notes:**
- The response to hepatitis B vaccine may be diminished in pre-term infants with a birth weight below 2,000 grams. Neonates weighing less than 2,000 grams who receive hepatitis B vaccine at birth require four doses of vaccine; administered at birth, 1, 2 and 6 months of age, followed by serologic testing at minimum 9 months of age and at least one month after completion of series.
- Fourth dose should not be given to infants before 6 months (24 weeks or 168 days) of age.

**Other Infants from birth up to and including 11 months of age:**
  - Dose 1 – 2 months of age
  - Dose 2 – 4 months of age
  - Dose 3 – 12 months of age

**Notes:**
- May consider use of Infanrix hexa® in certain situations. See *Infanrix hexa® Vaccine Biological Page (#07.214)* for indications. The schedule and spacing considerations for Infanrix-hexa® vaccine varies slightly from those of the individual HBV and DTaP-IPV-Hib vaccines. Ensure the appropriate schedule is followed for the vaccine(s) that are being used.
- Infanrix-hexa® should not be used for **high risk infants weighing less than 2000g** who received Hepatitis B vaccine and/or HBIG at birth. These infants should continue to receive the separate Hepatitis B vaccine according to the schedule outlined above.
- Third dose should not be given to infants before 6 months (24 weeks or 168 days) of age.
- For children who begin immunization off schedule minimum intervals can be used. Refer to Spacing Considerations.

**Students being immunized in the school setting:**
  - Dose 1 – day 0
  - Dose 2 – 1 month after dose 1
  - Dose 3 – 4 to 6 months after dose 1

**Note:**
- The minimum acceptable schedule/condensed schedule for school programs 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 4 months (112 days) between the first and third dose.

**Individuals 12 months of age and older, and adults (excluding students receiving vaccine in a school setting):**
  - Dose 1 – day 0
  - Dose 2 – 1 month after dose 1
  - Dose 3 – 6 months after dose 1

**Note:**
- May consider use of Infanrix hexa® in certain situations for children up to and including 23 months. See *Infanrix hexa® Vaccine Biological Page (#07.214)* for indications. The schedule and spacing considerations for Infanrix-hexa® vaccine varies slightly from those of the individual HBV and DTaP-IPV-Hib vaccines. Ensure the appropriate schedule is followed for the vaccine(s) that are being used.
### Hyporesponsive individuals being immunized with Recombivax HB® and Recombivax HB® Dialysis Strength (40 mcg/1.0mL) Vaccine:
- Dose 1 – day 0
- Dose 2 – 1 month after dose 1
- Dose 3 – 6 to 12 months after dose 1
  
  (see above schedules based on age)

### Hyporesponsive individuals being immunized with Engerix®-B Vaccine:
- Hyporesponsive individuals from birth up to and including 15 years of age should receive three doses according to the following schedule:
  - Dose 1 – day 0
  - Dose 2 – 1 month after dose 1
  - Dose 3 – 6 months after dose 1
- Hyporesponsive individuals 16 years of age and older should receive four doses according to the following schedule:
  - 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

### Spacing Considerations:
- Interruption of the immunization schedule does not require any dose(s) be repeated if the minimum intervals between doses are respected.
- Minimum acceptable schedule/condensed schedule 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.
- For those who may have an alternate immunization history refer to #03.110 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:
- There is no preference indicated for the use of Recombivax HB® or Engerix®-B for those eligible for regular strength vaccine.
  - Both vaccines are safe and immunogenic for all ages
  - Persons with medical contraindications to one product should be offered the alternate product if supply is available

### Dose

<table>
<thead>
<tr>
<th>Recombivax HB® (10mcg/1.0mL)</th>
<th>Engerix®-B (20 mcg/1.0 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy individuals:</td>
<td></td>
</tr>
<tr>
<td>birth up to and including 19 years of age:</td>
<td>birth up to and including 19 years of age:</td>
</tr>
<tr>
<td>0.5mL (5.0mcg)</td>
<td>0.5mL (10mcg)</td>
</tr>
<tr>
<td>20 years of age and older</td>
<td>20 years of age and older</td>
</tr>
<tr>
<td>1.0mL (10mcg)</td>
<td>1.0mL (20mcg)</td>
</tr>
<tr>
<td>Hyporesponsive persons:</td>
<td>Hyporesponsive persons:</td>
</tr>
<tr>
<td>birth up to and including 15 years of age:</td>
<td>birth up to and including 15 years of age:</td>
</tr>
<tr>
<td>1.0 mL Recombivax HB® (10mcg)</td>
<td>1.0 mL Engerix®-B (20 mcg)</td>
</tr>
<tr>
<td>16 years of age up to and including 19 years of age:</td>
<td>16 years of age and older</td>
</tr>
<tr>
<td>1.0 mL Recombivax HB® (10mcg)</td>
<td>2.0 mL Engerix®-B (40 mcg)</td>
</tr>
<tr>
<td>20 years of age and older</td>
<td></td>
</tr>
<tr>
<td>1.0 mL Recombivax HB® Dialysis Strength Vaccine (40mcg)</td>
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**Note:**
Those initiating a four-dose schedule with ENGERIX®-B should complete the series using the same vaccine whenever possible.
<table>
<thead>
<tr>
<th>Note:</th>
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<tbody>
<tr>
<td>Hyporesponsive persons 20 years of age and older should receive <strong>Recombivax HB® Dialysis Strength</strong> Vaccine. If Recombivax HB® Dialysis Strength Vaccine is unavailable; Engerix®-B may be used following the schedule outlined in the schedule section.</td>
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<tr>
<th>Route</th>
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<tbody>
<tr>
<td><strong>Note:</strong></td>
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<tr>
<td>Vaccine should not be administered in the gluteal areas as this may result in lower immune response. If vaccine is inadvertently given in the gluteal area the individual should be tested for immunity and re-immunized if antibody concentrations are inadequate.³</td>
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<table>
<thead>
<tr>
<th>Contraindications/Precautions</th>
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</thead>
<tbody>
<tr>
<td><strong>Contraindications:</strong></td>
</tr>
<tr>
<td>Known severe hypersensitivity to any component of a hepatitis B containing vaccine.</td>
</tr>
<tr>
<td>Anaphylactic reactions or other allergic reaction to a previous dose of vaccine containing similar components.</td>
</tr>
<tr>
<td><strong>Precautions:</strong></td>
</tr>
<tr>
<td>None identified.</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Possible Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Common:</strong></td>
</tr>
<tr>
<td>Injection site pain, soreness, tenderness, pruritus, erythema, swelling, warmth and nodule formation.</td>
</tr>
<tr>
<td>Irritability, headache, fatigue, drowsiness, malaise, pharyngitis and fever.</td>
</tr>
<tr>
<td>Loss of appetite, nausea and diarrhea.</td>
</tr>
<tr>
<td><strong>Uncommon:</strong></td>
</tr>
<tr>
<td>Dizziness, myalgia</td>
</tr>
<tr>
<td><strong>Rare:</strong></td>
</tr>
<tr>
<td>Lymphadenopathy, paresthesia, rash, urticaria and arthralgia.</td>
</tr>
<tr>
<td>Anaphylaxis, allergic reactions.</td>
</tr>
<tr>
<td>As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Pregnancy</th>
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</thead>
<tbody>
<tr>
<td>Hepatitis B vaccine should be administered to pregnant women when indicated.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Eligible pregnant woman should receive provincially funded vaccine.</td>
</tr>
<tr>
<td>Pregnant women at high risk of hepatitis B infection should be tested for antibody response following receipt of hepatitis B vaccine series. See serology section for more information.</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Lactation</th>
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</thead>
<tbody>
<tr>
<td>Can be administered to eligible breastfeeding women.</td>
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<thead>
<tr>
<th>Composition</th>
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</thead>
<tbody>
<tr>
<td>Each 0.5 mL dose contains:</td>
</tr>
<tr>
<td>5 mcg hepatitis B surface antigen</td>
</tr>
<tr>
<td>0.25 mg amorphous aluminum hydroxyphosphate</td>
</tr>
<tr>
<td>4.5 mg sodium chloride</td>
</tr>
<tr>
<td>35.0 mcg sodium borate</td>
</tr>
<tr>
<td>Water for injection</td>
</tr>
<tr>
<td>Each 1.0 mL dose contains:</td>
</tr>
<tr>
<td>10 mcg hepatitis B surface antigen</td>
</tr>
<tr>
<td>0.5 mg amorphous aluminum hydroxyphosphate</td>
</tr>
<tr>
<td>9.0 mg sodium chloride</td>
</tr>
<tr>
<td>70.0 mcg sodium borate</td>
</tr>
<tr>
<td>Water for injection</td>
</tr>
</tbody>
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</tr>
<tr>
<td>0.25 mg aluminum hydroxide</td>
</tr>
<tr>
<td>Each 1.0 mL dose contains:</td>
</tr>
<tr>
<td>20 mcg hepatitis B surface antigen</td>
</tr>
<tr>
<td>0.5 mg aluminum hydroxide</td>
</tr>
<tr>
<td>Single dose presentations are preservative free</td>
</tr>
</tbody>
</table>

Alberta Health Services  
Immunization Program Standards Manual  
Population, Public and Indigenous Health
<table>
<thead>
<tr>
<th><strong>Recombivax HB®</strong></th>
<th><strong>Engerix®-B</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Each 1.0 mL dose of Recombivax HB® Dialysis Strength contains:</td>
<td></td>
</tr>
<tr>
<td>• 40 mcg hepatitis B surface antigen</td>
<td></td>
</tr>
<tr>
<td>• 0.5 mg amorphous aluminum hydroxyphosphate</td>
<td></td>
</tr>
<tr>
<td>• 9.0 mg sodium chloride</td>
<td></td>
</tr>
<tr>
<td>• 70.0 mcg sodium borate</td>
<td></td>
</tr>
<tr>
<td>• Water for injection</td>
<td></td>
</tr>
<tr>
<td>The following manufacturing residuals may be found in the above preparations of Recombivax HB® vaccine:</td>
<td></td>
</tr>
<tr>
<td>• Less than 1% yeast protein</td>
<td></td>
</tr>
<tr>
<td>• Less than 15 mcg/mL formaldehyde</td>
<td></td>
</tr>
<tr>
<td>These presentations are preservative free</td>
<td></td>
</tr>
<tr>
<td>For a detailed list of ingredients see the link below to the Canadian Immunization Guide: <a href="http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-14-eng.php">http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-14-eng.php</a></td>
<td></td>
</tr>
<tr>
<td><strong>Blood/Blood Products</strong></td>
<td>Contains no human blood/blood products.</td>
</tr>
<tr>
<td><strong>Bovine/Porcine Products</strong></td>
<td>Contains no bovine or porcine products</td>
</tr>
<tr>
<td><strong>Latex</strong></td>
<td>Latex in vial stopper</td>
</tr>
<tr>
<td><strong>Interchangeability</strong></td>
<td>Hepatitis B vaccines produced by different manufacturers can be used interchangeably despite different doses and schedules.</td>
</tr>
<tr>
<td></td>
<td>The dose administered should be that recommended by the manufacturer for the specific product being used.</td>
</tr>
<tr>
<td></td>
<td>When possible, series should be completed with the same vaccine, especially with hyporesponsive individuals. If this is not possible, hyporesponsive individuals 16 years and older who have received any doses of Engerix®-B vaccine should be completed using the 4 dose schedule. Refer to schedule section for more details.</td>
</tr>
<tr>
<td><strong>Administration with Other Products</strong></td>
<td>MAY be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine.</td>
</tr>
<tr>
<td></td>
<td>The same limb may be used if necessary, but different sites must be chosen.</td>
</tr>
<tr>
<td><strong>Appearance</strong></td>
<td>Slightly opaque, white suspension</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>Store at +2° to +8°C</td>
</tr>
<tr>
<td></td>
<td>Do not freeze</td>
</tr>
<tr>
<td></td>
<td>Do not use past the expiry date</td>
</tr>
<tr>
<td></td>
<td>Store in original packaging when possible to protect from light</td>
</tr>
<tr>
<td><strong>Vaccine Code</strong></td>
<td>HBV – regular strength product</td>
</tr>
<tr>
<td></td>
<td>HBVD – dialysis strength vaccine</td>
</tr>
<tr>
<td><strong>Antigen Code</strong></td>
<td>HBV</td>
</tr>
<tr>
<td><strong>Licensed for</strong></td>
<td>Recombivax HB® regular strength:</td>
</tr>
<tr>
<td></td>
<td>• licensed for persons of all ages.</td>
</tr>
<tr>
<td></td>
<td>• A 0.5 mL dose has been approved by Alberta Health for off license use of Recombivax HB® for eligible healthy children from birth up to and including 10 years of age who are not contacts of HBsAg positive mothers.</td>
</tr>
<tr>
<td></td>
<td>Individuals of all ages.</td>
</tr>
</tbody>
</table>
### Notes:
- Hepatitis B vaccine became available in Alberta for the neonatal program in January 1, 1983.
- Infanrix hexa® became available in July 1, 2016.
- The routine school immunization program for grade 5 students started in September 1995.
- The catch-up school immunization program for grade 12 students was available from September 1999 to June 2002.
- 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 became eligible February 2018.
- Individuals with Inflammatory Bowel disease (IBD) who will be on long term immunosuppressive medications became eligible February 2018.
- In September 2018, the routine school immunization program for Hepatitis B vaccine changed from being offered in grade 5 to grade 6.

### Related Resources:
- Hepatitis B Vaccine Information Sheet (104505). (January 1, 2015)

### References:
6. Alberta Health Services. (2016 August 23). Joint Memo from Dr. Gerry Predy, Senior Medical Officer of Health; Dr. Stephen Tsokereskos, Medical Director Workplace Health and Safety: HCW hepatitis B Immunization following a BBFE incident.