

Hepatitis B Vaccine RECOMBIVAX HB®

Supplier: Merck Canada Inc.

(Adult presentation: 10 mcg/1 mL; Pediatric presentation: 5 mcg/0.5 mL)

INDICATIONS:

- See [Hepatitis B Vaccine Pre-Exposure Indications](#).
- See [Hepatitis B Vaccine Post-Exposure Indications](#).
- Infants and children who are not receiving hepatitis B vaccine as a combination product in INFANRIX hexa® as part of the routine schedule.

DOSES AND SCHEDULE: ^{A, B}

High risk infants: ^C 1 dose given as 0.5 mL (5 mcg) **IM** at birth, followed by INFANRIX hexa® at 2, 4 and 6 months of age. ^D

Infants and children who are not receiving INFANRIX hexa® as part of the routine schedule: 3 doses given as 0.5 mL (5 mcg) **IM** at 2, 4, and 6 months of age. ^D

Children and adolescents not immunized in infancy:

- Children less than 11 years of age and adolescents 16-19 years of age (inclusive): 3 doses given as 0.5 mL (5 mcg) **IM** at 0, 1 and 6 months.
- Adolescents 11-15 years of age (inclusive): ^E 2 doses given as 1.0 mL (10 mcg) **IM** at 0 and 6 months. ^F

Eligible adults 20 years of age and older: 3 doses given as 1.0 mL (10 mcg) **IM** at 0, 1 and 6 months.

ADMINISTRATION:

No additional requirements.

BOOSTER DOSES:

Booster doses and/or re-immunization may be recommended for certain special populations; see [Communicable Disease Control Manual, Chapter 1: Hepatitis B](#), 5.2 Post-vaccination serology follow-up: boosters and re-immunization recommendations.

^A Clients with chronic kidney disease require a specific hepatitis B vaccine dosage and series (see [Hepatitis B Vaccine Program for Chronic Kidney Disease Clients](#)).

^B Individuals with the following immunocompromising conditions require the [Hepatitis B Vaccine Higher Dose Schedule](#): congenital immunodeficiency, hematopoietic stem cell transplant recipients, solid organ transplant candidates/recipients and HIV infection.

^C High risk infants as outlined in [Hepatitis B Vaccine Post-Exposure Indications](#).

^D Infants who have received doses of hepatitis B vaccine at birth and 1 month of age should receive a 3rd dose at 6 months of age. Infants weighing less than 2000 grams at birth who received doses on a 0, 1 and 6 month schedule will require a 4th dose of hepatitis B vaccine at 8 months of age.

^E A minimum age of 10 years and 8 months may be used for catch-up of grade 6 students for operational purposes.

^F A 3-dose schedule given as 0.5 mL (5 mcg) **IM** at 0, 1 and 6 months can be used if appropriate.

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SEROLOGICAL TESTING:

Post-immunization serologic testing is not recommended after receiving hepatitis B-containing vaccine in routine programs. However, it is recommended for certain special populations: see [Communicable Disease Control Manual, Chapter 1: Hepatitis B](#), 4.5 Post-vaccination Serology.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of any hepatitis B vaccine or to any component of RECOMBIVAX HB® or to latex.
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PRODUCT COMPONENTS:

Potential allergens: latex, yeast protein.

Other components: amorphous aluminum hydroxyphosphate, sodium borate, formaldehyde.

PRECAUTIONS:

Not applicable.

SPECIAL CONSIDERATIONS:

- ENGERIX®-B and RECOMBIVAX HB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the respective product. There must be a minimum of 24 weeks between doses 1 and 2 whenever both products are used in a 2-dose series.
 - If the immunization series is interrupted after the 1st dose, the 2nd dose should be administered as soon as possible. If only the 3rd dose is delayed, administer as soon as possible. If years have lapsed between the 1st and 2nd dose, it may be prudent to assess antibody response post-series, especially if the client is at significant risk.
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ADVERSE EVENTS:

Local: pain, redness, swelling.

Systemic: fever, headache, nausea, diarrhea, fatigue, malaise.