

Hepatitis B (HB) Immunization Reference Guide for Health Care Providers



This guide summarizes the recommendations on HB immunization made by the National Advisory Committee on Immunization (NACI) and reproduced in the Canadian Immunization Guide (CIG). It is intended for all health care providers who administer HB-containing vaccines.

PEOPLE AT HIGHEST RISK OF HB INFECTION AND COMPLICATIONS

Pre-exposure immunization with an HB-containing vaccine is recommended for people at highest risk of transmission and of subsequent chronic HB carriage, including:

- Infants born to mothers who have HB or whose mothers are at high risk of HB;
- Household and sexual contacts of persons with disease due to or carriage of HB;
- People who use injection drugs;
- People with chronic renal disease, including those undergoing chronic dialysis;
- People with congenital immunodeficiencies;
- Unimmunized household contacts of HB carriers;
- People who are 25 years of age and older who engage in unprotected sexual activity, and procedures with percutaneous exposure, including injection drug use; and
- Children and adults from HB-endemic areas.

Immunization is also recommended for:

- Workers in child care settings in which there is a worker who has acute HB or is an HB carrier;
- Populations or communities in which HB is highly endemic;
- All prepubertal children;
- Children adopted from HB-endemic countries;
- Residents and staff of institutions for the developmentally challenged;
- Staff and inmates at correctional facilities;
- Health care workers, emergency service workers, and others with potential occupational exposure to blood or blood products and bodily fluids that may contain HB virus;
- Hemophiliacs and other people receiving repeated infusions of blood or blood products;
- People with HIV and Hepatitis C;
- People who have undergone hematopoietic stem cell transplantation (HSCT) or who are awaiting solid organ transplant;
- Individuals with lifestyle risks for infection, including:
 - People who have unprotected sex with new partners
 - People who have had more than one sexual partner in the previous 6 months
 - People with a history of sexually transmitted infections
 - People seeking evaluation or treatment for a sexually transmitted infection
 - People who engage in high-risk sexual practices
 - Men who have sex with men (MSM)
- Travellers to HB-endemic areas.

HB IMMUNIZATION RECOMMENDATIONS

Infants and Children (less than 18 years of age)

- The age at which routine HB-containing vaccine is offered varies from jurisdiction to jurisdiction. HB-containing vaccine should be provided according to provincial and territorial immunization schedules, using the recommended product-specific dose.
- In jurisdictions where HB vaccine is not provided at birth or in infancy, children at increased risk should be given HB-containing vaccine as soon as the risk is identified.

Adults (over 18 years of age)

- Adults who are at increased risk of exposure or complications from HB infection should receive either monovalent or HAHB vaccine.
- All susceptible adults who wish to decrease their risk of acquiring HB should be encouraged to be vaccinated.

Pregnant Women

- All pregnant women should be routinely screened for HBsAg.
- An unimmunized pregnant woman who has no markers for acute or chronic HB infection but who is at high risk of acquiring HB should be offered a complete HB vaccine series.

DOSAGE AND SCHEDULES FOR HB-CONTAINING VACCINES

Recipients	Vaccine														
	Monovalent hepatitis B						DTaP-HB-IPV-Hib			HAHB					
	RECOMBIVAX HB®			ENGERIX®-B			INFANRIX hexa™			TWINRIX®			TWINRIX® Junior		
	µg HBsAg	mL	Schedule	µg HBsAg	mL	Schedule	µg HBsAg	mL	Schedule	µg HBsAg	mL	Schedule	µg HBsAg	mL	Schedule
Infants and children															
Infants less than 6 months of age born to HB-negative mothers	5	0.5 4	0, 1, 6 5	10	0.5	0, 1, 6 or 0, 1, 2, 12	10	0.5	Months of age: 2, 4, 6, 12-23 or 2, 4, 6 or 2, 4, 12-23	Not indicated			Not indicated		
Infants of HB-positive mothers 6	5	0.5	0, 1, 6 5	10	0.5	0, 1, 6 or 0, 1, 2, 12	Not indicated before 6 weeks of age			Not indicated			Not indicated		
6 months to less than 24 months of age 7	5	0.5 4	0, 1, 6 5	10	0.5	0, 1, 6 or 0, 1, 2, 12	10	0.5	Months: (1 st dose = month 0) 0, 2, 4, 10-21 or 0, 2, 4 or 0, 2, 10-21	20	1.0	0, 6-12	10	0.5	0, 1, 6
24 months to less than 11 years of age	5	0.5 4	0, 1, 6 5	10	0.5	0, 1, 6 or 0, 1, 2, 12	May be given to children aged 24 months to less than 7 years, if necessary			20	1.0	0, 6-12	10	0.5	0, 1, 6
11 to less than 16 years of age	10	1.0	0, 4-6	20	1.0	0, 6	Not indicated			20	1.0	0, 6-12	10	0.5	0, 1, 6
	5	0.5	0, 1, 6 5	10 8	0.5	0, 1, 6 or 0, 1, 2, 12									
16 to less than 19 years of age	5	0.5	0, 1, 6 5	10	0.5	0, 1, 6 or 0, 1, 2, 12	Not indicated			Not indicated			10	0.5	0, 1, 6
Dialysis, chronic renal failure, and some immunocompromised 9 children, less than 16 years of age	double the µg dose for healthy child of same age		0, 1, 6 or 0, 1, 2, 12	double the µg dose for healthy child of same age		0, 1, 6 or 0, 1, 2, 12	Not indicated			Not indicated			Not indicated		
Dialysis, chronic renal failure, and some immunocompromised 9 people, 16 to less than 20 years of age	double the µg dose for healthy individual of same age		0, 1, 6 or 0, 1, 2, 12	40	2.0	0, 1, 2, 6	Not indicated			Not indicated			Not indicated		
Adults															
19 years of age	5	0.5	0, 1, 6 5	10	0.5	0, 1, 6 or 0, 1, 2, 12	Not indicated			20	1.0	0, 1, 6 or 0, day 7, day 21, month 12	Not indicated		
20 years of age and older	10	1.0	0, 1, 6 5	20	1.0	0, 1, 6 or 0, 1, 2, 12 or 0, day 7, day 21, month 12	Not indicated			20	1.0	0, 1, 6 or 0, day 7, day 21, month 12	Not indicated		
Dialysis, chronic renal failure, and some immunocompromised 9 people, 20 years of age and older	40 10	1.0	0, 1, 6	40	2.0	0, 1, 2, 6	Not indicated			Not indicated			Not indicated		

1 micrograms (µg) of HBsAg per dose

2 millilitres (mL) per dose

3 months: 1st dose = month 0

4 Following the review of Recombivax HB® vaccine immunogenicity and safety data, the National Advisory Committee on Immunization (NACI) is now recommending the provision of a full dose (0.5 ml / 5 microgram) to all children of HB-negative mothers who are less than 11 years of age. This change will harmonize dosing schedules and reduce vaccine wastage. Infants and children less than 11 years of age who were immunized with a complete series using this previously recommended 0.25mL dosage do not require revaccination.

5 Although a schedule of months 0, 1 and at least 2 is authorized, the preferred schedule is months 0, 1 and 6.

6 For post-exposure immunization of infants born to HB-infected mothers, refer to Post-exposure immunization. Premature infants (less than 37 weeks and weighing less than 2,000 grams) of HB-infected mothers require 4 doses of HB vaccine.

7 For pre-exposure immunization, persons 6 months of age and older may be immunized with HAHB vaccine, if indicated.

8 The manufacturer recommends the standard adult dosage (20 µg/1.0mL) using a 2-dose schedule if it is unlikely that there will be compliance with the 3- or 4-dose schedule.

9 Immunocompromised defined as: congenital immunodeficiency, hematopoietic stem cell transplant, solid organ transplant recipients, HIV-infected.

10 Adult dialysis formulation

Immunocompromised or Immunosuppressed People

- All individuals who are immunocompromised/immunosuppressed, are co-infected with HIV or HCV, or have chronic liver or kidney disease should be routinely screened for HB infection and immunity (HBsAg and anti-HBs).
- Individuals who will be undergoing immunosuppressive therapy including anti-tumour necrosis factor drugs and rituximab should have HBsAg and antibody testing.
- HB vaccine may be administered to immunocompromised persons and booster doses should be provided if anti-HBs titres fall below 10 IU/L. When considering immunization of an immunocompromised person, consultation with the individual's attending physician may be of assistance. For complex cases, referral to a physician with expertise in immunization or immunodeficiency is advised.
- For individuals with chronic renal disease and some people with immunocompromising conditions, a higher dose of monovalent HB vaccine is recommended. See table below for recommended dosages.

QUESTIONS & ANSWERS

1. **Q: How effective is the HB vaccine?**

A: HB vaccine is 95% to 100% effective pre-exposure. For post-exposure prophylaxis (PEP), HB vaccine is the most important intervention, providing 90% of the protection from hepatitis B.

2. **Q: Is post-immunization serological testing required?**

A: Testing for both HBsAg and anti-HBs is required to assess outcomes in people who are at risk of repeated exposure or at increased risk of adverse outcomes if they were to acquire HB infection. Otherwise, assessment of immune response is not generally recommended. Testing of infants born to HBsAg-positive mothers should be done after the last dose of the vaccine series is completed.

3. **Q: If the vaccination series is interrupted, does the series need to be restarted?**

A: If a recommended HB immunization schedule has been interrupted, it is not necessary to restart the series. The missed dose should be given at the earliest opportunity and the schedule completed as per the recommendations.

4. **Q: Is re-immunization with HB vaccine necessary?**

A: Routine booster doses of HB vaccine are not recommended for immunocompetent persons. Individuals at high risk of HB infection or complications who do not develop anti-HBs titre of at least 10 IU/L after the initial HB vaccine series should receive a second HB vaccine series.

5. **Q: Can HB vaccines be used interchangeably?**

A: Monovalent HB vaccines may be used interchangeably, according to the recommended dosage and schedule.

6. **Q: Is co-administration with other vaccines possible?**

A: HB-containing vaccines may be administered concomitantly with other vaccines or with HBIG. Different injection sites and separate needles and syringes must be used for concurrent parenteral injections.

7. **Q: What are possible contraindications and precautions?**

A: HB vaccines are contraindicated in persons with a history of anaphylaxis after previous administration. Routine administration of HB-containing vaccine should be postponed in persons with moderate or severe acute illness.

8. **Q: Is it safe to give the HB vaccine to pregnant women?**

A: The HB vaccine is not contraindicated in pregnancy. Unimmunized pregnant women who have no markers of HB infections but are at high risk of HB should be offered a complete HB vaccine series at the first opportunity during pregnancy. Post-immunization serologic testing should be conducted following the completion of the vaccine series.

REFERENCES

- Canadian Immunization Guide (CIG). Part 4 - Active Vaccines. <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-7-hepatitis-b-vaccine.html#a1>
- Castillo E, Murphy K, van Schalkwyk J et al. No. 342-Hepatitis B and Pregnancy. *Journal of Obstetrics and Gynaecology Canada*. March 2017 39(3); pp. 181-190.
- National Advisory Committee on Immunization (NACI). An Advisory Committee Statement (ACS): Update on the recommended use of Hepatitis B vaccine. 2017. <https://www.canada.ca/en/public-health/services/publications/healthy-living/update-recommended-use-hepatitis-b-vaccine.html>