Hepatitis B Vaccines

Table 1: Recommended doses of Hepatitis B (HB) vaccine by age group and vaccine type

Infants of Hepatitis B Surface Antigen (HBsAg) Positive (+) Mothers*	Infants, Children & Adolescents 0-19 yrs**	2 – Dose Regimen Adolescents 11-15 yrs†	Adults ≥ 18 yrs**	·	Predialysis/Dialysis/ Immunocompromised Adults ≥20 yrs‡
Heplisav-B (HepB-CpG) (Dynavax Technologies Corporation)					
N/A	N/A	N/A	0.5 mL IM 2 doses @ 0, 1 mo	0.5 mL IM 2 doses @ 0, 1 mo	Safety & effectiveness not established
Recombivax HB (Merck)					
5 mcg	5 mcg	10 mcg †	N/A	10 mcg	40 mcg
0.5 mL IM	0.5 mL IM	1 mL IM		1 mL IM	1 mL IM
3 doses @	3 doses @	2 doses @		3 doses @	3 doses @
0, 1-2, and 6-18 mo	0, 1-2, and 6-18	0, 4-6 mo		0, 1, and 6 mo	0, 1, and 6 mo
Engerix – B (GlaxoSmithKline)					
10 mcg§	10 mcg	N/A	N/A	20 mcg	40 mcg ¶
0.5 mL IM	0.5 mL IM			1 mL IM	1 mL IM
3 doses @	3 doses @			3 doses @	3 doses @
0, 1-2, and 6-18 mo	0, 1-2, and 6-18 mo			0, 1, and 4-6 mo	0, 1, and 6 mo

Indications:

• Hepatitis B (HB) vaccine is recommended to induce active immunity against hepatitis B virus (HBV) among patients of all ages who are currently or will become at increased risk of infection.

Hepatitis B (HB) Vaccine Recommendations for Infants of HBsAg (+) Mothers*

- Infants of HBsAg-positive mothers or unknown HBsAg status: Administer HB vaccine and Hepatitis B Immune Globulin (HBIG) within 12 hours of birth.
- Preterm infants (< 2,000 grams at birth) born to HBsAg-positive mothers: 4 doses: Administer HB vaccine and Hepatitis B Immune Globulin (HBIG) within 12 hours of birth. Do not count the birth dose in the 3-dose schedule. Administer next dose in the series when the infant reaches a chronologic age of 1 month, the third dose 1-2 months after the second, and the fourth dose at 6 months of age.
- Infants whose mother's HBsAg status is unknown at birth: Same as for infant of HBsAg+ mother except do not give HBIG unless mother is confirmed to be HBsAg+. If mother is HBsAg+, administer HBIG as soon as possible to infant, but no later than 7 days after birth.
- Preterm infants (< 2,000 grams at birth) whose mother's HBsAg status is unknown: 4 doses: Administer HB vaccine and HBIG within 12 hours of birth. The birth vaccine dose is not counted as part of the series, and the infant should receive three additional doses beginning at age 1 month.

Routine HB Vaccine Recommendations**

- Routine Infant Immunization: For medically stable infants weighing ≥2000 grams at birth born to <u>HBsAg-negative</u> mothers, administer the first vaccine dose within 24 hours of birth. Continue with the schedule as recommended. Do not administer the final dose before 6 months of age.
- Preterm infants (<2000 grams at birth) whose mothers are HBsAg-negative: Administer 3 doses of HB vaccine. Administer the first dose of HB vaccine at chronologic age 1 month or at hospital discharge.
 Continue with the vaccination schedule as recommended.
- Child, Adolescent and Adult: See Table 1.



Other HB Vaccine Recommendations

Alternate Schedule for Engerix-B§

 4 doses: 0 (initial), 1 month, 2 months, and 12 months after initial dose. Designed for certain populations, e.g., infants born to HBsAg+ mothers.

RECOMBIVAX HB†

 Must complete the adolescent schedule before the 16th birthday, otherwise complete a 3 dose schedule.

Dialysis/Immunocompromised patients <20 years‡

 Use standard vaccine dose and schedule given for infants, children, and adolescents. Higher doses might be more immunogenic, but no specific recommendations have been made.

Engerix-B Adult Formulation for dialysis patients¹¹

 Use two 1 mL doses (20 mcg/dose) administered at one site on each visit.

Adults at Increased Risk for HBV

 Administer the age-appropriate dose of HB vaccine for patients who have not been previously vaccinated. See "Populations at Increased Risk" box

Combination Vaccines

- Do not use combination vaccines for the birth dose.
- May use Pediarix (DTaP + IPV + HB) and Twinrix (HB + HA) vaccines when either antigen is indicated.
- For more information on HB combination vaccines go to the Vaccine Preventable Disease Control Program website at www.publichealth.lacounty.gov/ip/providers resources.htm

Post-vaccination Serology (PVS) Testing

PVS testing should include HBsAg and antibody to HBsAg (anti-HBs). PVS testing is recommended for the following:

- All infants born to HBsAg+ mothers at 9-12 months of age. If HepB series is delayed, test 1-2 months after final dose.
- Infants born to HBsAg-positive women who don't develop protective levels of anti-HBs after a 3-dose series should receive an additional dose of HB vaccine.
- Healthcare personnel who have contact with blood and are at increased risk for needle sticks or sharp instruments, test 1-2 months after completion of the 3-dose series.
- Chronic hemodialysis patients
- Other immunocompromised persons
- Persons with HIV
- Sex partners of HBsAg+ persons
- Persons who don't develop protective levels of anti-HBs after a 2 dose (HepB-CpG) or 3-dose series should receive 3 additional doses of HB vaccine.

Populations at Increased Risk Hepatitis B Virus (HBV)

- Alaska Natives & Pacific Islanders
- Chronic Liver Disease
- Clients and staff in institutions for the developmentally disabled
- Clotting factor recipients
- Diabetics
- Health care personnel (HCP)
- HIV infection
- Household contacts of HBsAg-positive persons
- <u>Immigrants, refugees, & orphans/adoptees</u> <u>from HBV-endemic area</u>
- Injection-drug users
- Inmates of long-term correctional facilities
- International Travelers traveling to <u>areas</u> with high rates of HBV
- Men who have sex with men (MSM)
- People undergoing hemodialysis
- People who receive care in settings where a high proportion of adults have risks for HBV
- Public Safety Workers
- Sexual exposure risk

Route & Site

- Administer IM into the deltoid muscle for young children (≥3 years), adolescents and adults. Use the anterolateral thigh for younger children and infants.
- Administer HB vaccine simultaneously with other age appropriate vaccines.

Contraindications

 Severe allergic reaction, e.g. anaphalaxis to a vaccine component, including yeast or following a prior dose.

Precautions

Moderate or severe acute illness until improved.

Adverse Reactions

- Injection site: pain
- Systemic: fatigue, headache, irritability, and fever

Storage and Handling

- Store vaccine in the refrigerator between 35 – 46° F (2 – 8°C).
- Exposure to freezing temperatures (≤32°F) destroys the potency of the vaccine.





