

Pharmacy Protocol

Pediatric Hepatitis B and Combination Vaccines: Engerix B®; Recombivax HB®;

Last Reviewed	14 April 2021
Last Revised	14 April 2021
This order expires	30 April 2023

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1. What's new

No clinically significant changes.

2. Oregon immunization protocol

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen client for contraindications and precautions.
- C. Provide a current Vaccine Information Statement (VIS), answering any questions.
- D. Record all required data elements in the client's permanent health record.
- E. Verify needle length for intramuscular (IM) injection.
- F. To avoid shoulder injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the vastus lateralis and deltoid muscles and use proper IM administration technique.
- G. Give hepatitis B vaccine to persons according to risk group, age, type of vaccine and vaccine status. See section 3 for schedule.
- H. May be given with all ACIP-recommended child and adult vaccinations.
- I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

I have read, understand, and agree to participate by the terms of this protocol.

Pharmacist Signature

Date

3. Vaccine schedule for Hepatitis B³

Dose	Minimum acceptable age	Minimum spacing after previous dose
1	7 years	
2	7 years, 1 month	4 weeks
3	7 years, 6 months	8 weeks <u>and</u> 16 weeks after dose 1

4. Licensed Hepatitis B vaccines

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
Engerix B ¹ , pediatric formulation	Hep. B	0.5-mL single-dose vials and prefilled syringes	Birth – 19 years*	None
Recombivax HB ² , pediatric formulation	Hep. B	0.5-mL single-dose vials and prefilled syringes	Birth – 19 years*	

*Use adult formulation for persons ≥ 20 years of age^{1,2}.

5. Recommendations for use

Pediatric Hep. B, Single-antigen (Engerix-B, Recombivax-HB) Vaccine ³	
Dose	Minimum spacing after previous dose
1	
2	4 weeks
3	8 weeks <u>and</u> 16 weeks after dose 1

Catch-up Hepatitis B Vaccine Schedule ³		
Dose	Preferred Spacing	Minimum spacing after previous dose
1	Anytime	
2	2 months after dose 1	4 weeks
3	4 months after dose 2 <u>and</u> 6 months after dose 1	8 weeks <u>and</u> 16 weeks after dose 1

Alternative Hepatitis B Vaccine Schedules^{1, 2}

Vaccine and Formulation	Dose Volume	Number of Doses in Series	Age at First Dose	Interval from 1 to 2	Interval from 2 to 3	Interval from 1 to 3	Interval from 1 to 4
Engerix B (20 µg/mL)	0.5 mL	4	1–10 years	1 month	1 month	2 months	12 months
		3	5–16 years	12 months	12 months	24 months	
	1.0 mL*	4	11–18 years	1 month	1 month	2 months	12 months
		3		1 month	2 months	6 months	
Recombivax HB (10 µg/mL)	1.0 mL	2	11–15 years [◇]	4 to 6 months			

* 1.0-mL dose recommended for persons who travel to endemic areas, sexual contacts and children born to HBsAg+ mothers.

◇ Both doses must be 1.0 mL of Recombivax HB[®]. Series must be completed prior to 16th birthday or an additional dose is required.

6. Vaccine Excipients

Vaccine ⁵	Vaccine Excipient Summary
Engerix B	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Recombivax HB	formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein

7. Contraindications

- A. Severe allergic reaction to a previous dose or to a vaccine component.
- B. Hypersensitivity to yeast.^{1,2}

8. Warnings and precautions

- A. Moderate or severe acute illness with or without fever.
- B. Engerix B¹ and Recombivax HB²: Dry natural rubber latex is used in the vial

stopper, the syringe plunger stopper and tip cap.

9. Other considerations⁴

- A. Adoptees born in Asia, the Pacific Islands, Africa, and other regions of high or intermediate hepatitis B endemicity should undergo serologic testing for HBsAg regardless of vaccination status. Adoptees born in countries other than those mentioned above whose records indicate receipt of ≥ 3 doses of vaccine can be considered protected if ≥ 1 dose was administered at age ≥ 6 months.

10. Side effects and adverse reactions

Adverse Event	Infants and Children
Engerix B¹, Recombivax HB²,	
Pain at the injection site	Uncommon, up to 9%
Fatigue, headache, other mild systemic symptoms	Common, up to 20%
Temperature up to 37.7 C ($\leq 99.9^{\circ}\text{F}$)	Uncommon, up to 6%
Any severe reaction	Rare

11. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues
Engerix B ¹ , Recombivax HB ²	Store at 2°–8° C	Do not use if vaccine has been frozen.

12. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html>. VAERS Reporting Table: <https://vaers.hhs.gov/resources/infoproviders.html>

Event and interval from vaccination

- A. Anaphylaxis or anaphylactic shock (7 days)
- B. Brachial neuritis (28 days)
- C. Shoulder injury related to vaccine administration (7 days)

- D. Vasovagal syncope (7 days)
- E. Any acute complications or sequelae (including death) of the above event (interval not applicable)
- F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval: see package insert).

13. References

1. Engerix-B®. [Package insert]. 2019. Retrieved from www.fda.gov/media/119403/download. Accessed 1 April 2021.
2. Recombivax HB®. [Package insert]. 2018. Retrieved from www.fda.gov/media/74274/download. Accessed 1 April 2021.
3. Schillie S, Vellozzi C, Reingold A, et al. Prevention of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices. MMWR 2018; 67(RR-1):1–31. Available at www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm?s_cid=rr6701a1_w. Accessed 1 April 2021.
4. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practice Guidelines for Immunization. 2017. Available at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 1 April 2021.
5. Centers for Disease Control and Prevention. Vaccine Excipient Summary. Available at: <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf> Accessed 1 April 2021.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this standing order is available at: [standing orders](#)

Electronic copy of this pharmacy protocol is available at: [protocols](#)

14. Appendix

None.