

Immunizing Pharmacist Protocol

Pediatric Hepatitis B Vaccines and Combos: Enderix B®; Recombivax HB®

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1. What's new

Combined previously separate “Infants with birth weight <2000 grams” (2019) and “Hepatitis B vaccine pediatric formulations” (2019) into one standing order.

2. Oregon immunization model standing order

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

Immunizing Pharmacist

Date

3. Vaccine schedule for Hepatitis B

Dose and Route: 0.5 mL IM			
Dose	Preferred age	Minimum acceptable age	Minimum acceptable spacing
1	Birth	Birth	
2	2 months	4 weeks	4 weeks
3	6 months	6 months	8 weeks

4. Licensed Hepatitis B vaccine

Product Name ^{1,2}	Vaccine Components	Acceptable Age Range	Preferred age	Thimerosal
Engerix B [®] , pediatric formulation	Hepatitis B	Birth – 19 years*	Birth	None
Recombivax HB [®] , pediatric formulation	Hepatitis B	Birth – 19 years*	Birth	None

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

5. Recommendations for use³

Routine Pediatric Hepatitis B Vaccine Schedule			
Dose	Preferred Age	Minimum Acceptable Age	Minimum Acceptable Spacing
1	Birth*	Birth	
2	2 months	4 weeks	4 weeks after dose 1
3	6 months	6 months	8 weeks after dose 2 <u>and</u> 16 weeks after dose 1

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

Alternative Hepatitis B Vaccine Schedules¹⁻²

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	7–10 years	1 month	1 month	2 months	12 months
		3	7–16 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. Contraindications¹⁻²

- A. Severe allergic reaction to a previous dose or to a vaccine component.
- B. Hypersensitivity to yeast.

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. Warnings and precautions¹⁻²

- A. Engerix B[®] and Recombivax HB[®]: Dry natural rubber latex is used in the vial stopper, the syringe plunger stopper and tip cap.

8. Other considerations³

- A. For retrospective checking, doses that violate the minimum acceptable spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum acceptable interval or age should be repeated as age-appropriate.
- B. 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.

9. Side effects and adverse reactions¹⁻²

Adverse Event	Children
Engerix B[®], Recombivax HB[®]	
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

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

11. Adverse events reporting

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at <https://vaers.hhs.gov/reportevent.html>.

- A. Save a copy of the report number for your records
- B. Send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278).

Private providers are to report events directly to VAERS and can read about options on how to do so at <https://vaers.hhs.gov/reportevent.html>.

VAERS Reporting Table:

https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290-(2)(3).⁴

Event and interval from vaccination
<ol style="list-style-type: none">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).

12. References

1. Engerix-B®. [Package insert]. 2019. Retrieved from www.fda.gov/vaccines-blood-biologics/vaccines/engerix-b. Accessed 24 July 2020.
2. Recombivax® HB. [Package insert]. 2018. Retrieved from www.fda.gov/vaccines-blood-biologics/vaccines/recombivax-hb. Accessed 24 July 2020.
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 24 July 2020.
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 24 July 2020.
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 10 July 2020

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](#)

13. Appendix

None.