

Heplisav-B vs Engerix-B in Adults with Chronic Kidney Disease (CKD) HBV-17 Trial

Heplisav-B Vaccine versus Engerix-B Vaccine in Adults with CKD HBV-17 Trial: Design

- **Design**

- Phase 3 randomized, observer-blinded, active controlled, trial to compare the safety and efficacy of 3 doses of Heplisav-B versus 4 double-doses of Engerix B in adults with chronic kidney disease (CKD)

- **Participants** (n = 521 randomized, 507 analyzed)

- Ages: 18-75 years
- Chronic kidney disease: GFR ≤ 45 mL/min/1.73 m² +/- hemodialysis
- HBV vaccine naïve
- Exclusions: HBV*, HIV, HCV, pregnancy or lactation, autoimmune or other clinically significant illness, immunosuppressed

- **Setting**

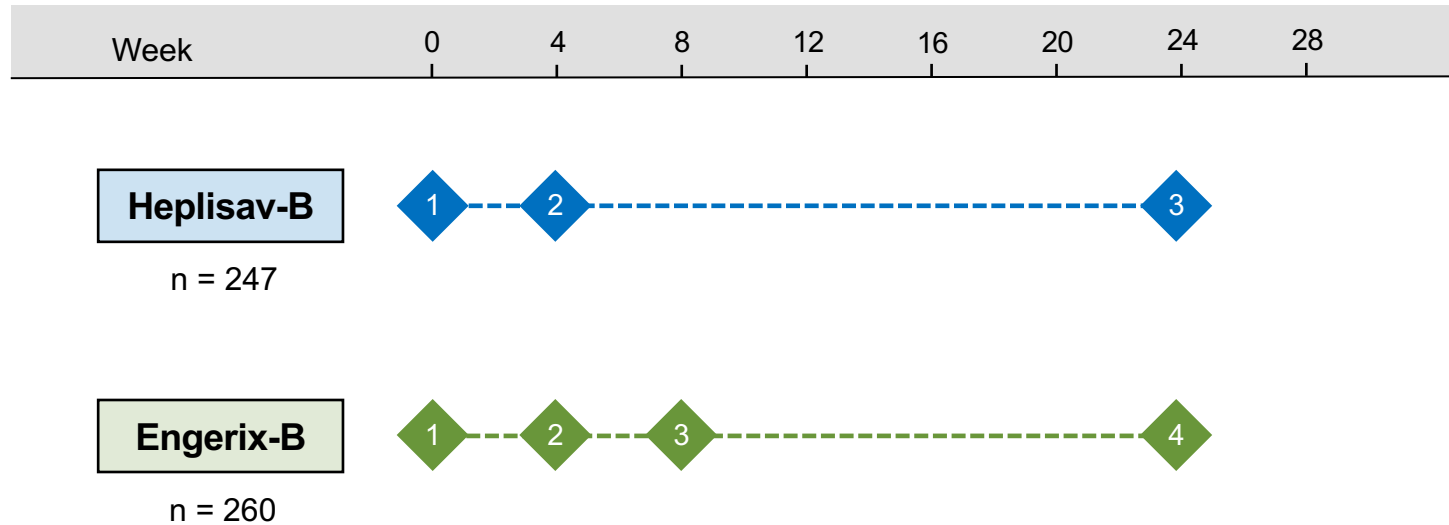
- Multiple centers in United States & Canada

- **Study End-Point**

- Seroprotection = anti-HBs level ≥ 10 mIU/mL

*Any positive for HBsAg, anti-HBs, or anti-HB core

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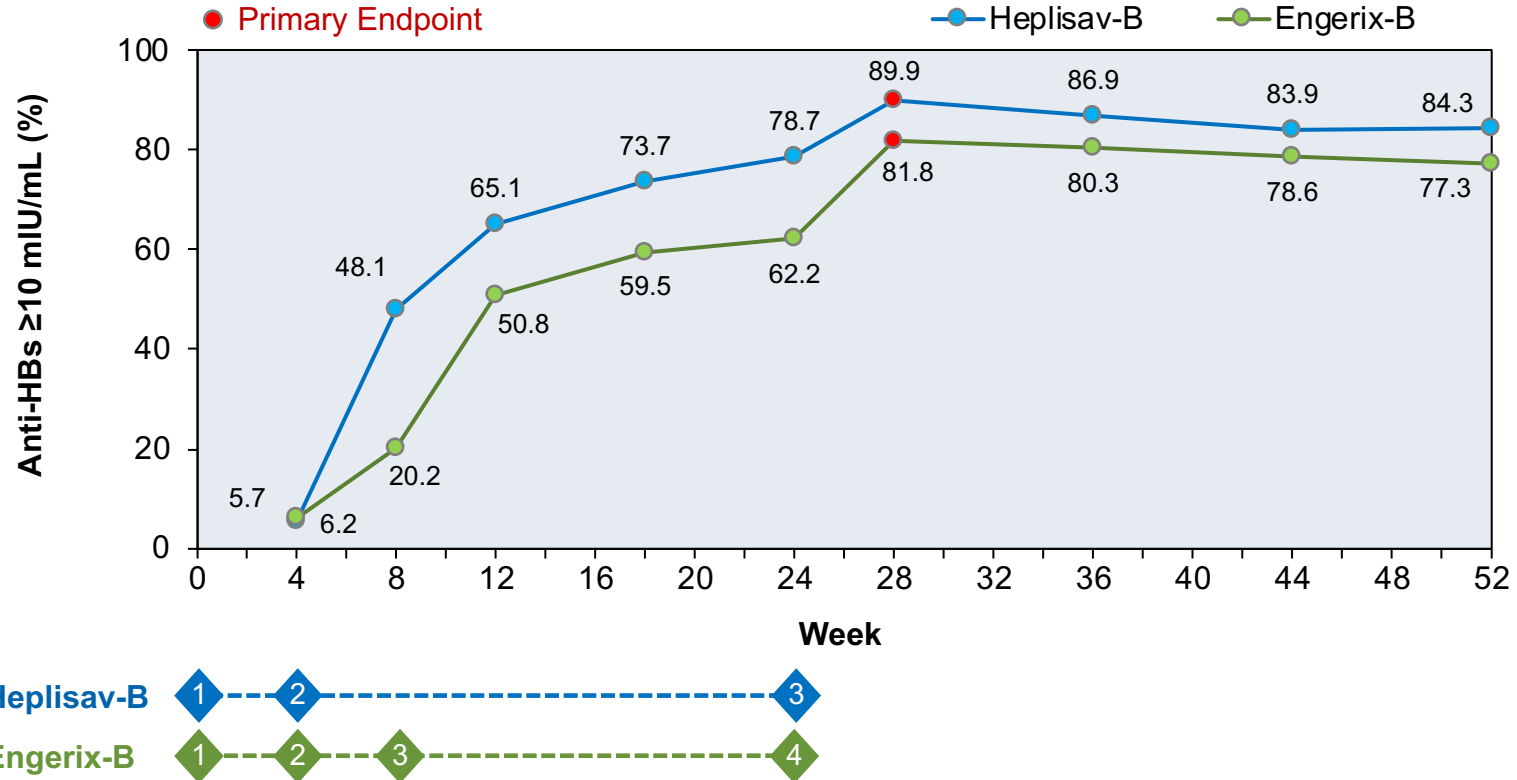


Vaccine Dosing

Heplisav-B: 0.5 mL dose (standard dose = 20 mcg) recombinant HBsAg at weeks 0, 4, and 24

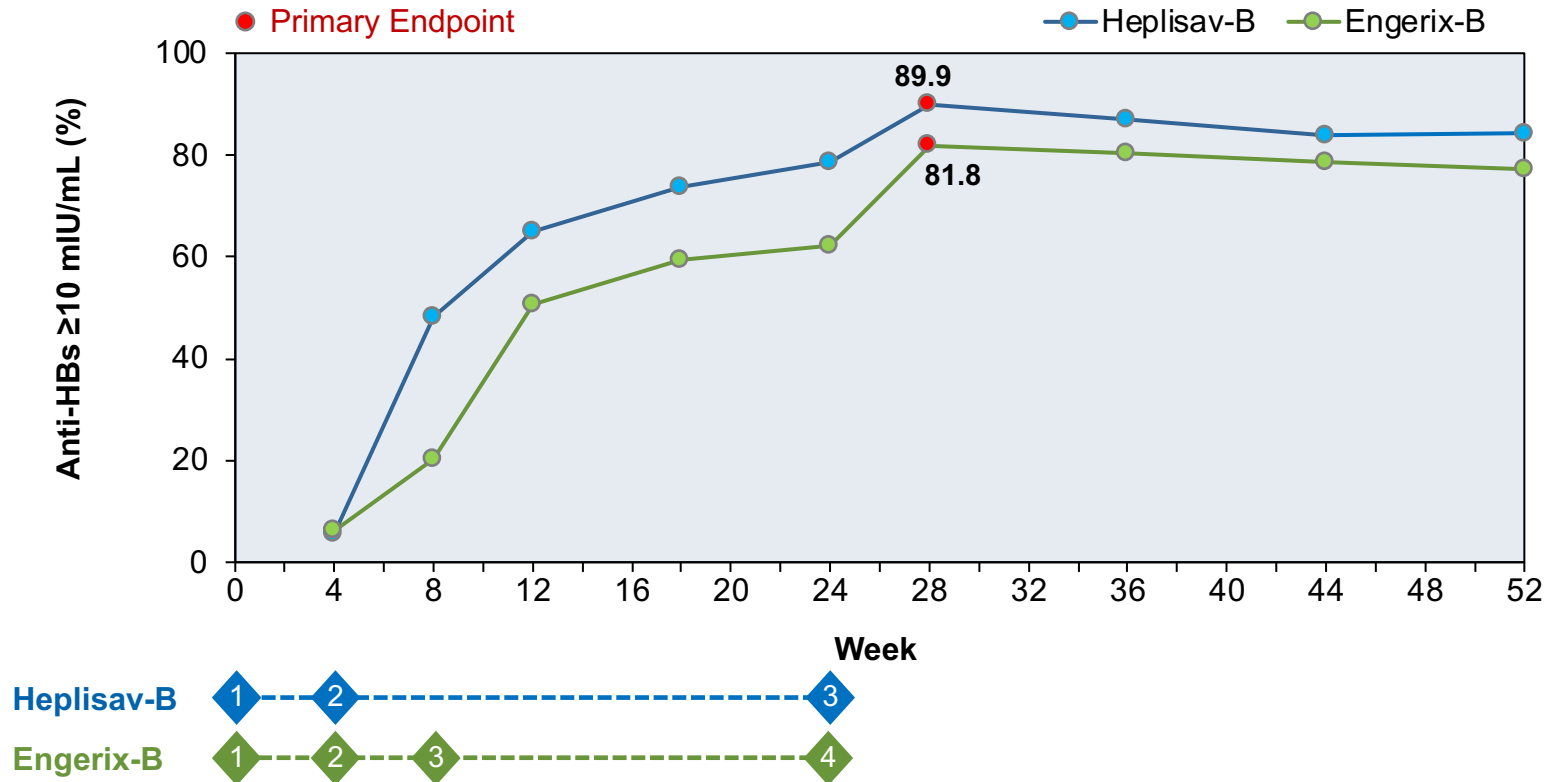
Engerix-B: 1 mL dose (double dose = 40 mcg) recombinant HBsAg at weeks 0, 4, 8, and 24

Heplisav-B Vaccine versus Engerix-B Vaccine in Adults with CKD HBV-17 Trial: Results (anti-HBs ≥ 10 mIU/mL)



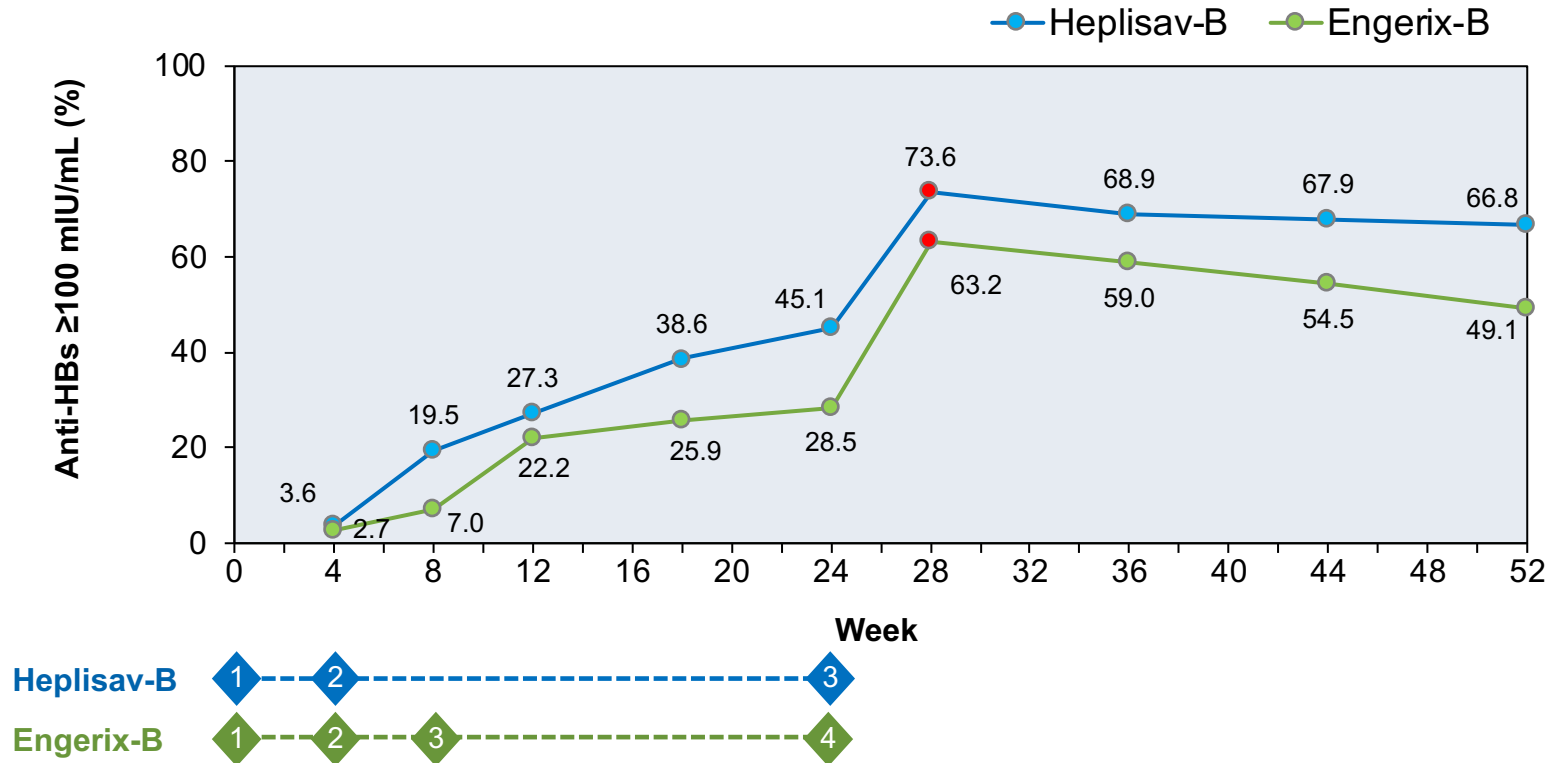
Source: Janssen RS, et al. Vaccine. 2013;31:5306-13.

Hepelisav-B Vaccine versus Engerix-B Vaccine in Adults with CKD HBV-17 Trial: Results (anti-HBs ≥ 10 mIU/mL)



Source: Janssen RS, et al. Vaccine. 2013;31:5306-13.

Heplisav-B Vaccine versus Engerix-B Vaccine in Adults with CKD HBV-17 Trial: Results (anti-HBs ≥ 100 mIU/mL)



Source: Janssen RS, et al. Vaccine. 2013;31:5306-13.

Hepelisav-B Vaccine versus Engerix-B Vaccine in Adults with CKD HBV-17 Trial: Conclusions

Conclusions: “In chronic kidney disease patients, 3 doses of HBsAg-1018 induced significantly higher seroprotection, earlier seroprotection, and more durable seroprotection than 4 double doses of HBsAg-Eng.”

This slide deck is from the University of Washington's
Hepatitis B Online and *Hepatitis C Online* projects.

Hepatitis B Online

www.hepatitisB.uw.edu

Hepatitis C Online

www.hepatitisC.uw.edu

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