

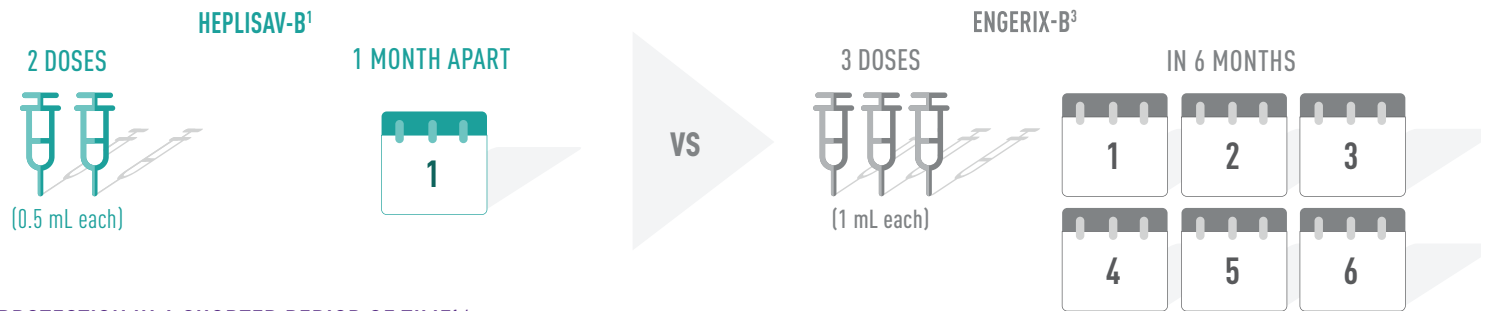
HEPLISAV-B[®]

Hepatitis B Vaccine (Recombinant), Adjuvanted

2 doses —in— **1 month**

THE FIRST AND ONLY 2-DOSE HEPATITIS B VACCINE FOR ADULTS ≥18 YEARS^{1,2}

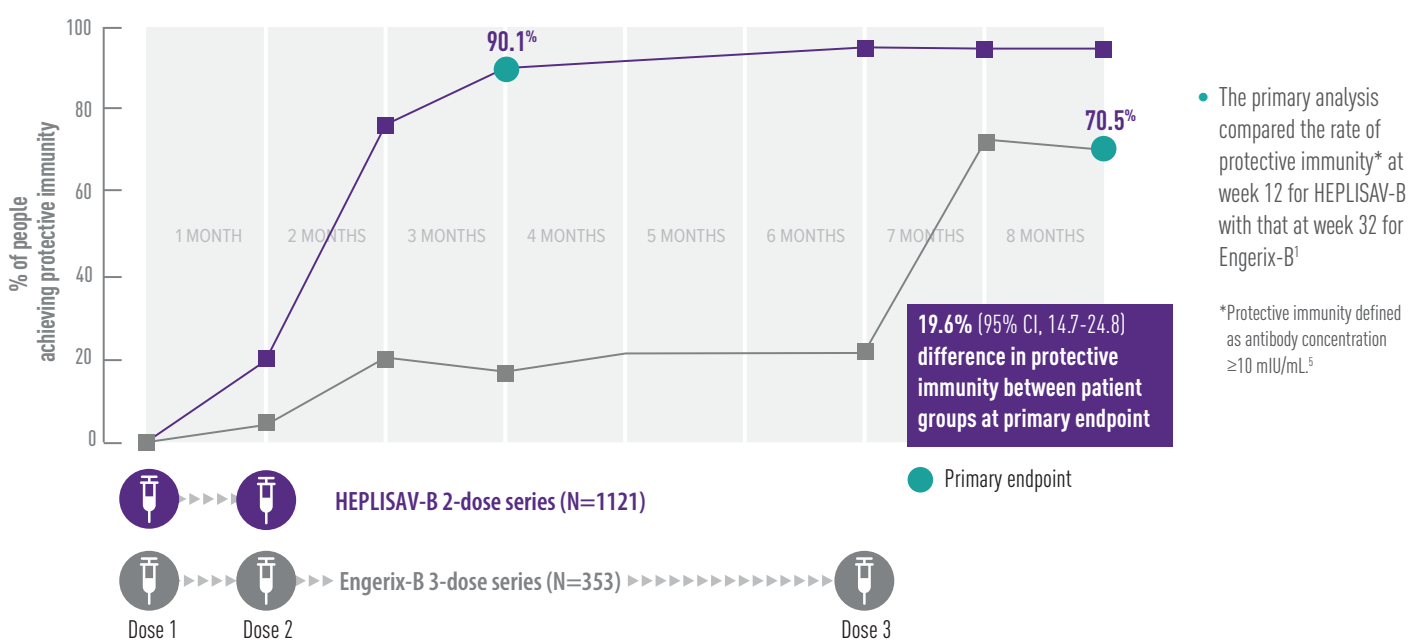
FEWER DOSES IN LESS TIME



PROTECTION IN A SHORTER PERIOD OF TIME^{1,4}

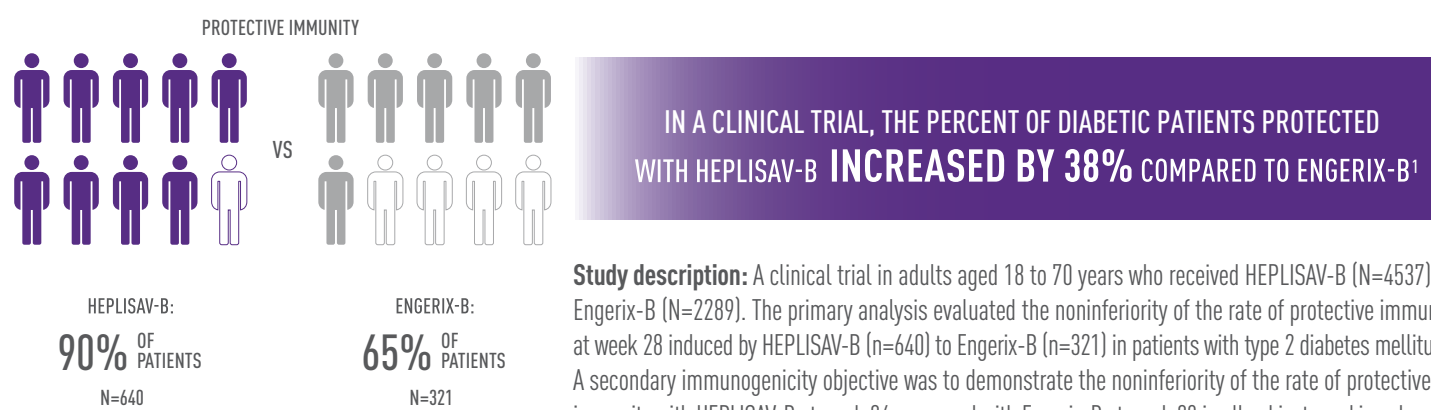
- In a clinical study, 2 doses of HEPLISAV-B provided earlier and higher levels of protective immunity than 3 doses of Engerix-B in patients aged 40-70^{1,4}

STATISTICALLY SIGNIFICANTLY HIGHER RATES OF PROTECTION VS ENGERIX-B AT EVERY TIMEPOINT^{1,4}



WITH JUST 2 DOSES IN 1 MONTH

HEPLISAV-B DELIVERED SIGNIFICANTLY HIGHER RATES OF PROTECTIVE IMMUNITY IN PATIENTS WITH DIABETES VS 3 DOSES OF ENGERIX-B IN 6 MONTHS¹



Study description: A clinical trial in adults aged 18 to 70 years who received HEPLISAV-B (N=4537) or Engerix-B (N=2289). The primary analysis evaluated the noninferiority of the rate of protective immunity at week 28 induced by HEPLISAV-B (n=640) to Engerix-B (n=321) in patients with type 2 diabetes mellitus. A secondary immunogenicity objective was to demonstrate the noninferiority of the rate of protective immunity with HEPLISAV-B at week 24 compared with Engerix-B at week 28 in all subjects and in subgroups defined by age, sex, body mass index (BMI), and smoking status among adults aged 18 to 70 years.^{1,6}

- With fewer doses and a shorter time to series completion, HEPLISAV-B may offer more adults with diabetes the opportunity to achieve protection¹

NO RESULTS UNDER 90%

- Consistently higher rates of protection in adults with diabetes and other populations with common factors that traditionally limit immune response—smoking, obesity, age >40 years, male gender^{1,6}
- HEPLISAV-B protected 90.0% to 99.1% of patients in the groups studied, whereas protection rates with Engerix-B were 65.1% to 92.4%, depending on patient factors¹

Engerix-B is a registered trademark of the GSK group of companies.

INDICATION

HEPLISAV-B is indicated for prevention against infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.

IMPORTANT SAFETY INFORMATION

Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

Please see additional Important Safety Information on page 2 and [click here](#) for full Prescribing Information.

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THE ACIP HEPATITIS VACCINES WORK GROUP* CONDUCTED A SYSTEMATIC REVIEW OF THE IMMUNOGENICITY AND SAFETY OF HEPLISAV-B AND CONCLUDED THE BELOW⁷

IMMUNOGENICITY^{1,6}

In 3 prospective, randomized, controlled clinical trials assessing protective immunity induced by HEPLISAV-B vs Engerix-B:

	With 2 doses in 1 month HEPLISAV-B	With 3 doses in 6 months Engerix-B
Rate of protective immunity across total population ^{1,6}	90.1% - 95.4% (N=7008)	70.5% - 81.3% (N=3163)
Rate of protective immunity across subpopulations of known hyporesponders in trial 3 ⁶	90.0% - 95.9% Patients with diabetes (n=640), aged 40-70 (n=3570), male (n=2203), obesity (n=2165), smokers (n=1371)	65.1% - 78.8% Patients with diabetes (n=321), aged 40-70 (n=1864), male (n=1150), obesity (n=1076), smokers (n=711)

- The trials compared the rates of protective immunity (antibody concentration ≥10 mIU/mL) induced by HEPLISAV-B and Engerix-B^{1,6}
Trial 1: month 3 for HEPLISAV-B and month 7 for Engerix-B; trial 2: month 3 for HEPLISAV-B and month 8 for Engerix-B;
trial 3: month 6 for HEPLISAV-B and month 7 for Engerix-B, except for patients with diabetes in whom protective immunity was measured at month 7 for both HEPLISAV-B and Engerix-B

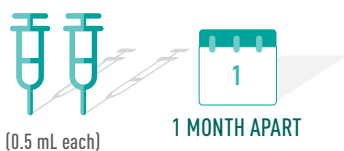
SAFETY^{1,7}

- HEPLISAV-B has an overall safety profile similar to that of Engerix-B

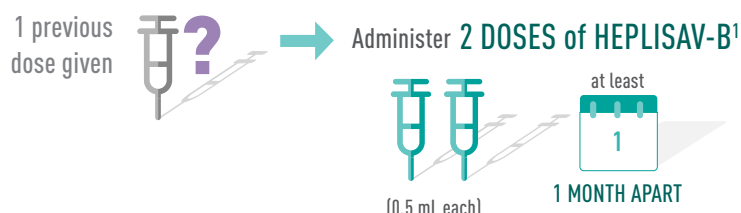
DOSING AND ADMINISTRATION¹

Hepatitis B vaccine-naïve adults⁷

Administer **2 DOSES** of HEPLISAV-B¹



ACIP recommendation: Adults who have initiated a hepatitis B vaccine series that is unknown or unavailable⁷



- Administer HEPLISAV-B by intramuscular injection in the deltoid region
- Store in a refrigerator at 2°C to 8°C (35°F to 46°F)
- Do not freeze

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www.cdc.gov/mmwr/volumes/67/wr/mm6715a5.htm

IMPORTANT SAFETY INFORMATION

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

The most common patient-reported adverse reactions reported within 7 days of vaccination were injection site pain (23%-39%), fatigue (11%-17%), and headache (8%-17%).

References: **1.** HEPLISAV-B [package insert]. Berkeley, CA: Dynavax Technologies Corporation; 2017. **2.** Centers for Disease Control and Prevention. Recommended immunization schedule for adults aged 19 years or older, United States, 2017. <https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>. Accessed October 5, 2017. **3.** Engerix-B [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2015. **4.** Dynavax Technologies Corporation. FDA Advisory Committee Briefing Document: HEPLISAV-B[®] [Hepatitis B Vaccine (Recombinant), Adjuvanted]. Presented at: Meeting of the Vaccines and Related Biological Products Advisory Committee; Silver Spring, MD; July 28, 2017. **5.** Centers for Disease Control and Prevention. Hepatitis B. In: Hamborsky J, Kroger A, Wolfe S, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 13th ed. Washington, DC: Public Health Foundation; 2015:149-174. <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepb.pdf>. Accessed October 16, 2017. **6.** Jackson S, Lentino J, Kopp J, et al; HBV-23 Study Group. Immunogenicity of a two-dose investigational hepatitis B vaccine, HBsAg-1018, using a toll-like receptor 9 agonist adjuvant compared with a licensed hepatitis B vaccine in adults. *Vaccine*. 2018;36:668-674. **7.** Schillie S, Harris A, Link-Gelles R, Romero J, Ward J, Nelson N. Recommendations of the Advisory Committee on Immunization Practices for use of a hepatitis B vaccine with a novel adjuvant. *MMWR Morb Mortal Wkly Rep*. 2018;67(15):455-458.

Please see additional Important Safety Information on front and [click here](#) for full Prescribing Information.

*The ACIP Hepatitis Vaccines Work Group comprises professionals from academic medicine (family medicine, internal medicine, pediatrics, obstetrics, infectious disease, occupational health, and preventive medicine specialists), federal and state public health entities, and medical societies.

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DYNAVAX

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