

## HEPLISAV-B® (Hepatitis B Vaccine [Recombinant], Adjuvanted)<sup>1-4</sup>

On November 9, 2017, the Food and Drug Administration (FDA) approved a single-antigen hepatitis B vaccine with a novel immunostimulatory sequence adjuvant (HEPLISAV-B) for the prevention of hepatitis B virus (HBV) in persons aged  $\geq 18$  years. On April 20, 2018, the Centers for Disease Control and Prevention (CDC) published a report summarizing the recommendations of its Advisory Committee on Immunization Practices (ACIP) specific to HEPLISAV-B, which stated that patients aged  $\geq 18$  years old, previously unvaccinated or incompletely vaccinated, may receive HEPLISAV-B.

BRAND NAME	AGE INDICATION	DOSE	SERIES
HEPLISAV-B	$\geq 18$ years	0.5 mL IM	2 doses; 0 then 1 month after initial dose

### EFFICACY AND SAFETY

In clinical studies, HEPLISAV-B provided higher rates of protective immunity compared to Engerix-B: 95% of patients aged 18 to 55 and 90% of patients aged 40 to 70 achieved protective immunity with HEPLISAV-B, whereas 81.3% of patients aged 18 to 55 and 70.5% of patients aged 40 to 70 achieved protective immunity with Engerix-B. HEPLISAV-B is an inactivated vaccine, which, per CDC guidelines, may be administered simultaneously with or at any interval before or after receiving other vaccines without substantially impairing the development of a protective antibody response. Available human data on HEPLISAV-B administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. HEPLISAV-B does not contain gelatin, neomycin, or latex in any component of the vaccine.

### SCREEN FOR CONTRAINDICATIONS AND PRECAUTIONS

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. Consult the Prescribing Information for additional safety information and possible side effects. Please see Important Safety Information on this page.

### USE IN IMMUNOCOMPROMISED ADULTS

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B. Per the ACIP, if using HEPLISAV-B in immunocompromised adults, administer the usual 2-dose series (0.5 mL/dose given as a 2-dose series at least 1 month apart) followed by testing for antibodies against hepatitis B surface antigen (anti-HBs) 1 to 2 months after the final dose. Persons with anti-HBs  $< 10$  mIU/mL following 2 doses of vaccine should be revaccinated. Revaccination may be achieved through the administration of a second complete vaccine series followed by anti-HBs testing 1 to 2 months after the final dose. Alternatively, a single dose may be used for revaccination followed by anti-HBs testing 1 to 2 months later (and, if anti-HBs remains  $< 10$  mIU/mL, completion of the second hepatitis B vaccine series followed again by anti-HBs testing 1 to 2 months after the final dose).

### INTERCHANGEABILITY

Data are limited on the safety and immunogenicity effects when HEPLISAV-B is interchanged with hepatitis B vaccines from other manufacturers. The ACIP guidance for interchangeability indicates that when feasible, the same manufacturer's vaccines should be used to complete a hepatitis B series. A 2-dose HEPLISAV-B vaccine series only applies when both doses in the series consist of HEPLISAV-B. A dosing regimen consisting of 2 different vaccine products should consist of a total of 3 doses in the possible combinations shown on the following page. Adhere to minimum windows: 4 weeks between dose 1 and 2; 8 weeks between dose 2 and 3; 16 weeks between dose 1 and 3. Doses administered at less than the minimal interval should be repeated. However, a series containing 2 doses of HEPLISAV-B administered at least 4 weeks apart is valid, even if the patient received a single earlier dose from another manufacturer.





### STORAGE CONDITIONS

HEPLISAV-B is stored in a refrigerator at 2°C to 8°C (35°F to 46°F) as a pre-filled syringe. Do not freeze; discard if the vaccine has been frozen. Do not use the vaccine after the expiration date shown on the prefilled syringe label.

### ADMINISTRATION AND SIDE EFFECTS

HEPLISAV-B is administered intramuscularly and has similar rates of occurrence as Engerix-B for common adverse reactions, such as injection site pain, fatigue, headache, malaise, myalgia, injection site swelling, and fever.

### ADMINISTER THE VACCINE CORRECTLY

-  **Schedule:** Administer 2 doses at least one month apart
-  **Dose (volume):** 0.5 mL each dose
-  **Route:** Intramuscular (IM) injection
-  **Site:** Deltoid muscle



### INDICATION

HEPLISAV-B is indicated for prevention of 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.

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%).

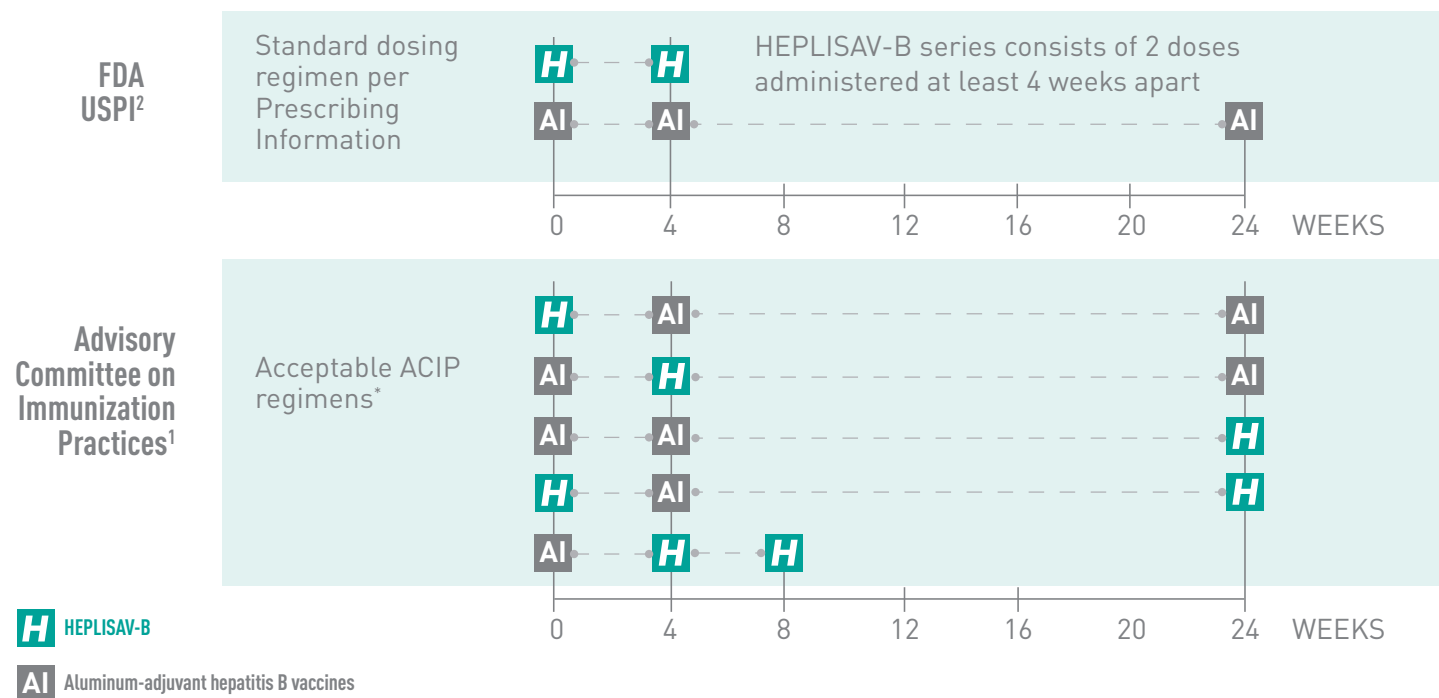
Please [click here](#) for full Prescribing Information.

**HEPLISAV-B®**  
Hepatitis B Vaccine (Recombinant), Adjuvanted

**HeplisavB.com**

## DOSING AND ADMINISTRATION

# Interchangeability and Dosing Schedule Scenarios for HEPLISAV-B with a manufacturer of aluminum adjuvant hepatitis B vaccine to complete a dosing regimen



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USPI = United States prescribing information.

UNANIMOUSLY RECOMMENDED BY THE ACIP<sup>1</sup>

**HEPLISAV-B<sup>®</sup>**  
Hepatitis B Vaccine (Recombinant), Adjuvanted  
**HeplisavB.com**

**References:** 1. 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. 2. HEPLISAV-B [package insert]. Emeryville, CA: Dynavax Technologies Corporation; 2020. 3. Centers for Disease Control and Prevention. Timing and spacing of immunobiologics. <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html#t-03>. Accessed June 11, 2019. 4. Centers for Disease Control and Prevention. Immunization schedules: Heplisav-B (HepB-CpG) vaccine. <https://www.cdc.gov/vaccines/schedules/vacc-updates/heplisav-b.html>. Accessed May 23, 2019.

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

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