HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted][1-4]

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 ≥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 ≥18 years old, previously unvaccinated or incompletely vaccinated, may receive HEPLISAV-B.

BRAND NAME	AGE INDICATION	DOSE	SERIES
HEPLISAV-B	≥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%).

Scan QR code on back for Full Prescribing Information.

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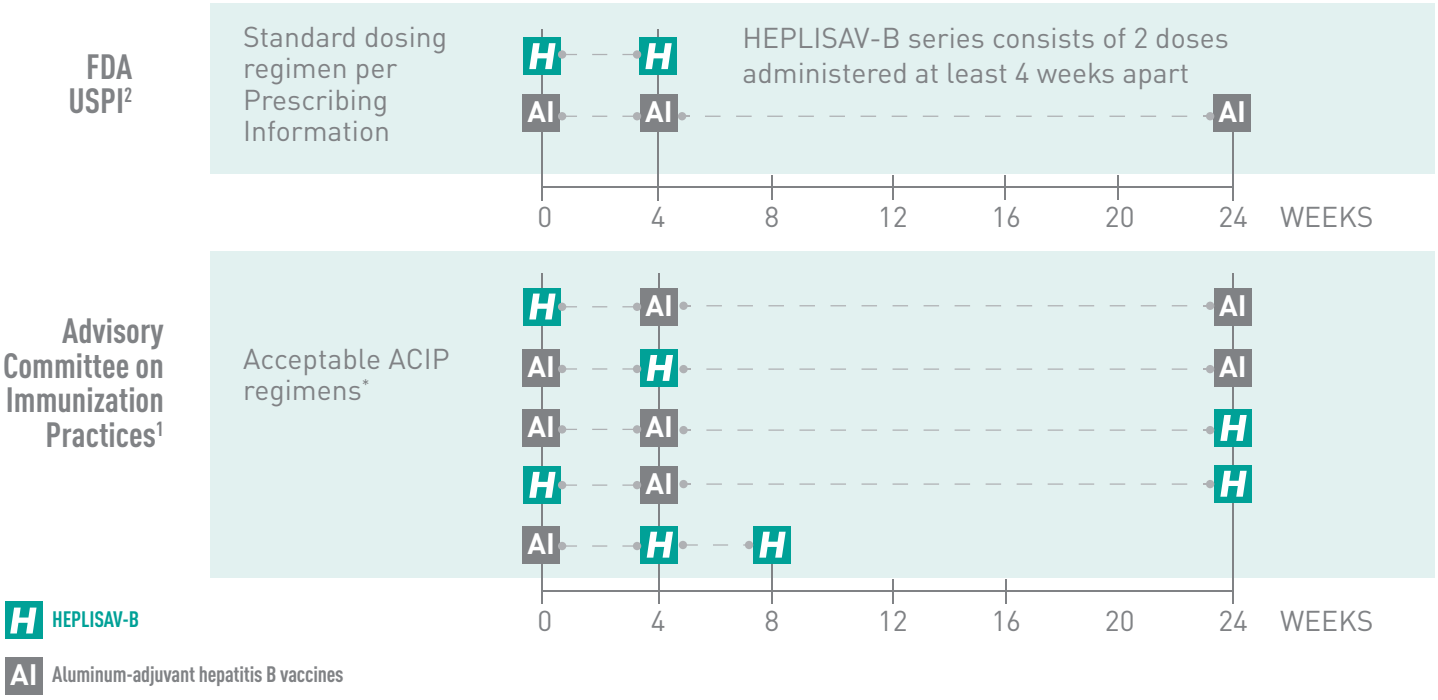
DOSING AND ADMINISTRATION

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



*Data are limited on the safety and immunogenicity effects when HEPLISAV-B is interchanged with hepatitis B vaccines from other manufacturers. The CDC's 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 above. 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.

USPI = United States prescribing information.

UNANIMOUSLY RECOMMENDED BY THE ACIP[1]

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.

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Please see Important Safety Information on front and scan QR code or ask your representative for Full Prescribing Information.

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DYNAVAX

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