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

Centers for Disease Control and Prevention (CDC)

Centers for Disease Control and Prevention
MMWR

Recommendations of the Advisory Committee on Immunization Practices for Use of a Hepatitis B Vaccine with a Novel Adjuvant

Schillie S, Harris A, Link-Gelles R, Romero J, Ward J, Nelson N.

MMWR Morb Mortal Wkly Rep. 2018;67(15):455-458.

"The benefits of protection with 2 doses administered over 1 month make [HEPLISAV-B] an important option for prevention of HBV."[1]

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 (eg, 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 throughout this brochure and click here for full Prescribing Information.

HBV=hepatitis B virus.

The Advisory Committee on Immunization Practices (ACIP) is chartered as a federal advisory committee that provides expert external advice and guidance to the Director of CDC on use of vaccines and related agents for the control of vaccine-preventable diseases in the US civilian population. ACIP recommendations adopted by the CDC Director become agency guidelines on the date published in *Morbidity and Mortality Weekly Report (MMWR)*.

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IN THE APRIL 2018 *MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR)*:

HEPLISAV-B® (HEPATITIS B VACCINE [RECOMBINANT], ADJUVANTED) UNANIMOUSLY RECOMMENDED BY THE CDC'S ACIP[1]

INTRODUCTION[1]

- Vaccination is the primary means for preventing HBV infection and its complications
- On November 9, 2017, HEPLISAV-B was approved by the Food and Drug Administration for the prevention of HBV in adults aged ≥18 years
- HEPLISAV-B is administered as 2 doses, 1 month apart
- HEPLISAV-B is a single-antigen vaccine with a novel immunostimulatory sequence adjuvant, 1018
- The 1018 adjuvant binds to Toll-like receptor 9 and is believed to stimulate a directed immune response to hepatitis B surface antigen (HBsAg)

THE ACIP HEPATITIS VACCINES WORK GROUP* CONDUCTED A SYSTEMATIC REVIEW OF THE IMMUNOGENICITY AND SAFETY OF HEPLISAV-B[1]

IMMUNOGENICITY[2,3]

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	**90.1% - 95.4%** (N=7008)	**70.5% - 81.3%** (N=3163)
Rate of protective immunity across subpopulations of known hyporesponders in Trial 3	**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. 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

SAFETY[2]

- HEPLISAV-B is well tolerated with an overall safety profile similar to that of Engerix-B

"Based on the available immunogenicity evidence, a 2-dose schedule (0, 1 month) of [HEPLISAV-B] will be efficacious for the prevention of HBV infection."[1]

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%).

*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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Morbidity and Mortality Weekly Report

Recommendations of the Advisory Committee on Immunization Practices for Use of a Hepatitis B Vaccine with a Novel Adjuvant

Sarah Schillie, MD[1]; Aaron Harris, MD[1]; Ruth Link-Gelles, PhD[1]; José Romero, MD[2]; John Ward, MD[1]; Noele Nelson, MD[1]

Hepatitis B (HepB) vaccination is the primary means of preventing infections and complications caused by hepatitis B virus (HBV). On February 21, 2018, the Advisory Committee on Immunization Practices (ACIP) recommended Heplisav-B (HepB-CpG), a yeast-derived vaccine prepared with a novel [illegible]dministered as a 2-dose series (0, 1 month) for use [illegible]The ACIP Hepatitis Vaccines Work

HepB-CpG is available in single-dose 0.5 mL vials. Each dose contains 20 μg of HBsAg and 3,000 μg of 1018 adjuvant. HepB-CpG is formulated without preservatives and is administered as an intramuscular injection in the deltoid region of the upper arm (*1*).

HepB-CpG is the fifth inactivated HepB [illegible] recommended for use in [illegible]

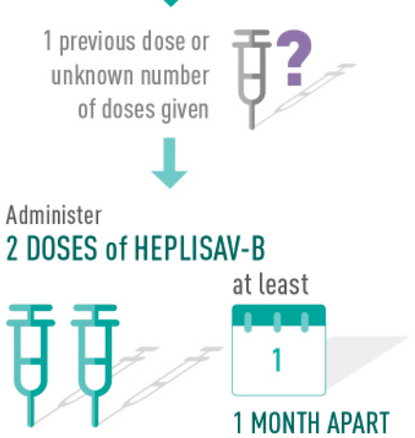
DOSING AND ADMINISTRATION

Hepatitis B vaccine-naïve adults[2]

Administer
2 DOSES of HEPLISAV-B

- 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

ACIP recommendation: Adults who have initiated a hepatitis B vaccine series that is unknown or unavailable[1]



- Whenever feasible, the same manufacturer's vaccine should be used to complete the series. However, vaccination should not be deferred when the manufacturer of the previously administered vaccine is unknown or when the vaccine from the same manufacturer is unavailable

ACIP RECOMMENDATIONS: ASSESSING RESPONSE[1]

- Postvaccination serologic testing 1-2 months after the final dose of vaccine is recommended for some persons (eg, hemodialysis patients, HIV-infected and other immunocompromised persons, healthcare personnel, and sex partners of HBsAg-positive persons)
- For specific information on revaccination with HEPLISAV-B, refer to the April 2018 edition of *MMWR*

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ACIP RECOMMENDATIONS FOR ADULTS AGED 18 YEARS AND OLDER INDICATED TO RECEIVE HEPATITIS B VACCINATION, INCLUDING[1]:

Persons at risk through sexual exposure:

- Sex partners of HBsAg-positive persons
- Sexually active persons not in a long-term, mutually monogamous relationship
- Persons seeking evaluation or treatment for a sexually transmitted infection
- Men who have sex with men

Persons at risk for infection by exposure to blood:

- Household contacts of HBsAg-positive persons
- Residents and staff of facilities for developmentally disabled persons
- Healthcare and public safety workers
- Dialysis patients
- Persons with diabetes mellitus aged <60 years

International travelers to certain countries

Incarcerated persons

Persons with hepatitis C virus infection or chronic liver disease

Anyone seeking protection from HBV, even without a specific risk factor

Persons with HIV infection

Persons with a history of current or recent injection drug use

"On February 21, 2018, the Advisory Committee on Immunization Practices (ACIP) recommended HEPLISAV-B..., a yeast-derived vaccine prepared with a novel adjuvant, administered as a 2-dose series (0, 1 month) for use in persons aged ≥18 years."[1]

INDICATION

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IMPORTANT SAFETY INFORMATION

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

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]. Berkeley, CA: Dynavax Technologies Corporation; 2017. **3.** 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.

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DYNAVAX

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