In the NEW era of universal adult hepatitis B vaccination[1*]

PROTECTING YOUR ADULT PATIENTS IS AS EASY AS 1-2-3

HEPLISAV-B is the first and only adult hepatitis B vaccine that provides series completion with just **2 DOSES IN 1 MONTH.**[2,3]

* The CDC ACIP voted to recommend hepatitis B vaccination for all adults aged 19-59. The ACIP also voted to recommend that all adults aged 60 and over with risk factors for hepatitis B infection should be vaccinated. Adults aged 60 and over without known risk factors may receive a hepatitis B vaccination.[1]

ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention.

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.

Please see additional Important Safety Information throughout this brochure and click here for full Prescribing Information.

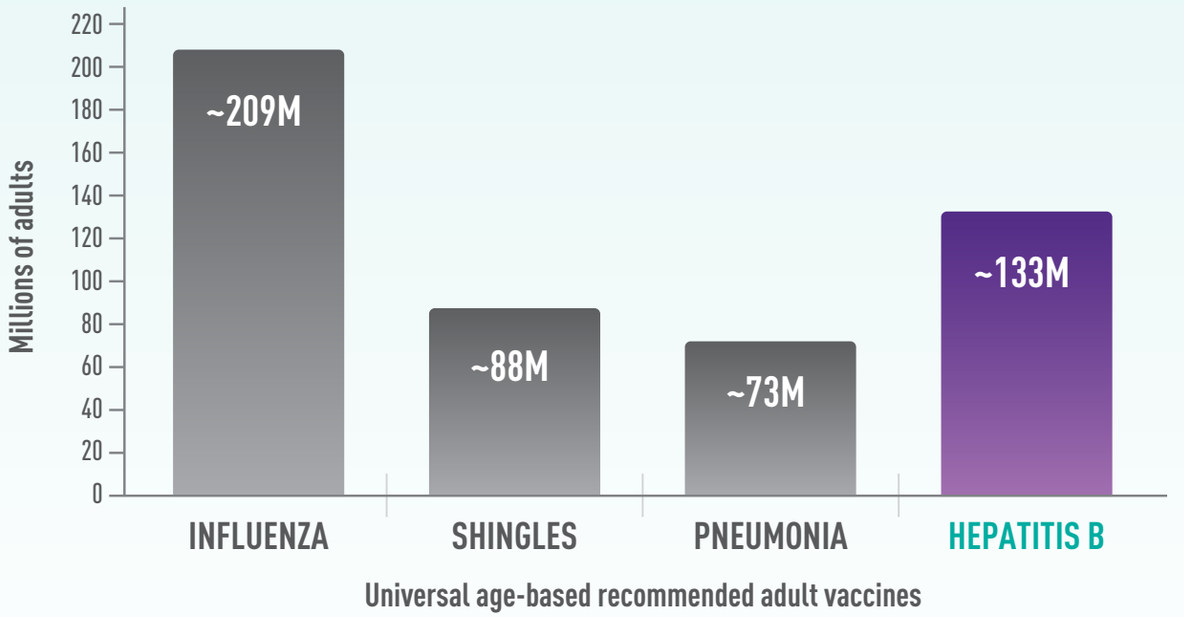
HEPLISAV-B®
Hepatitis B Vaccine (Recombinant), Adjuvanted

2 DOSES. 1 MONTH. DONE.[2]

WHAT YOU KNOW ABOUT HEPATITIS B VACCINATION IS CHANGING

Hepatitis B vaccines are likely to become the **second most widely used adult vaccines in your healthcare system**[4]

HOW MANY ADULTS ARE RECOMMENDED FOR VACCINATION IN 2022?[4]*



- CDC ACIP has voted to recommend that **all adults aged 19-59 receive hepatitis B vaccination**[1†]
- ACIP-recommended vaccines are **eligible for first-dollar coverage**[5]

THE CDC IS COUNTING ON HEALTHCARE SYSTEMS LIKE YOURS TO VACCINATE MORE ADULTS[1]

* Adults eligible for influenza vaccines calculated from population aged 18+ in 2022; adults eligible for shingles vaccines calculated using adults turning 50 years old in 2022, adults aged >50 who are unvaccinated based on CDC coverage rates, and immunocompromised adults aged 19-49; adults eligible for pneumonia vaccines included adults aged 65+ and at-risk adults aged 18-64 excluding smokers, patients with chronic heart disease, and patients who are immunocompromised; adults eligible for hepatitis B vaccines included general population aged ≤59 and at-risk adults aged 19+ calculated based on CDC ACIP assessment, converted to patient numbers using compliance data from Nelson et al.[4]

† The ACIP also voted to recommend that all adults aged 60 and older with risk factors for hepatitis B infection should be vaccinated. Adults aged 60 and older without known risk factors may receive a hepatitis B vaccination.[1]

3-DOSE HEPATITIS B VACCINES MAY CREATE CHALLENGES FOR ADULT IMMUNIZATION PROGRAMS

Many adult vaccinations **require fewer than 3 doses**[6]

	1 DOSE*	2 DOSES	3 DOSES
Influenza	✓		
Tetanus, diphtheria, pertussis	✓		
Measles, mumps, rubella	✓	✓	
Varicella		✓	
Herpes zoster		✓	

Low series completion can be a problem with 3-dose adult hepatitis B vaccines[7]

~75% of adults aged 19+ did **not receive all 3 doses**[8]

EFFICIENT SERIES COMPLETION IS MORE CRITICAL THAN EVER IN THE ERA OF UNIVERSAL ADULT HEPATITIS B VACCINATION[1,7]

*The CDC recommends 1 dose annually of the influenza vaccine and 1 dose followed by boosters every 10 years of the tetanus, diphtheria, and pertussis vaccine.[6]

SERIES COMPLETION IS ESSENTIAL FOR PROTECTION

Failed series completion **can lead to consequences**

Most patients do not achieve protective immunity **without series completion**[9]

Increased number of patients will **compound operational inefficiencies with 3-dose vaccines**[1,7]

2-DOSE HEPLISAV-B CAN MAKE SERIES COMPLETION EASIER AND PROTECT PATIENTS FASTER[2,10]

IMPORTANT SAFETY INFORMATION

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.

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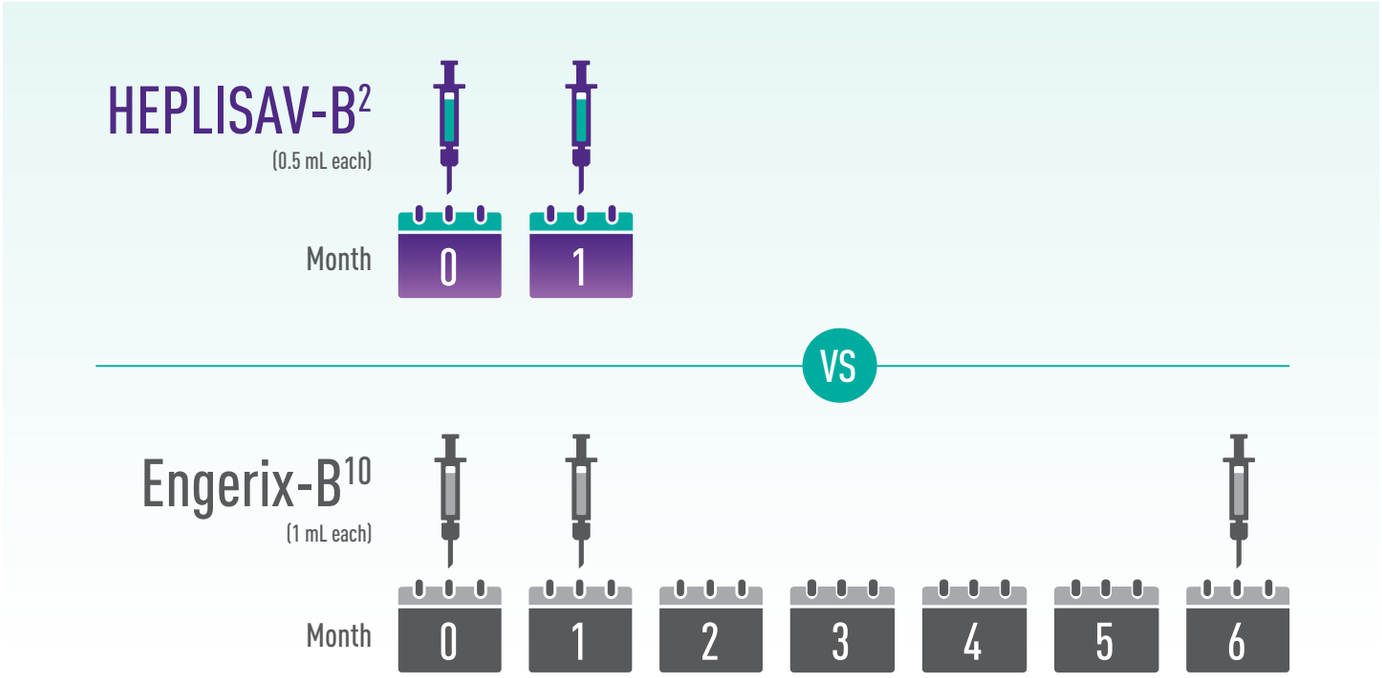
INCOMPLETE

2-DOSE HEPLISAV-B MAKES SERIES COMPLETION MORE EFFICIENT

A complete series of HEPLISAV-B is **just 2 doses in 1 month**[2]



In a **real-world study**, a large healthcare system evaluated the impact of simply switching to **HEPLISAV-B** and found that...

2X MORE
ADULTS COMPLETED THE
HEPLISAV-B SERIES
THAN THOSE STARTING WITH ENGERIX-B[11]

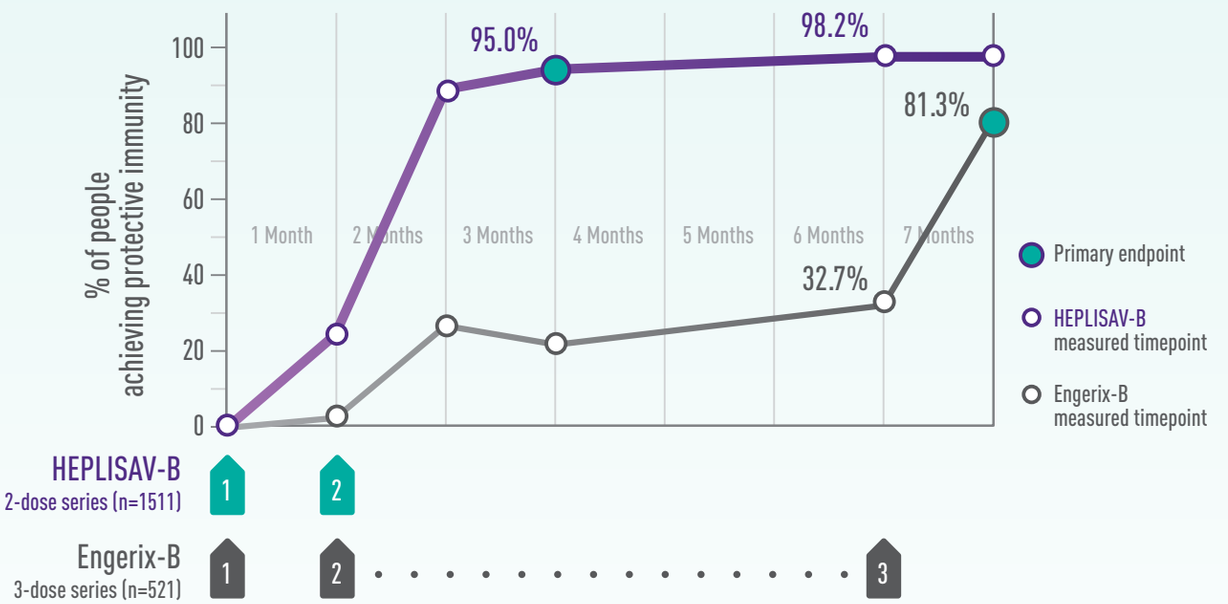
HEPLISAV-B®
Hepatitis B Vaccine (Recombinant), Adjuvanted

UNPROTECTED

FASTER PROTECTION WITH HEPLISAV-B

95% of those who received HEPLISAV-B were **protected after just 2 doses in 1 month**[2,12]*

TRIAL 1 **PERCENTAGE OF PEOPLE AGED 18 TO 55 ACHIEVING PROTECTIVE IMMUNITY†**



- 13.7% difference (95% CI, 10.4 to 17.5) in protective immunity between patient groups at primary endpoint[2]
- The primary analysis compared the rate of protective immunity at week 12 for HEPLISAV-B with that at week 28 for Engerix-B[2]
- Statistical significance was met; however, statistical significance was not prespecified in trial 1[12]
- Noninferiority was met because the 95% CI lower bound of the difference in SPRs was greater than -10%[2]

* Compared to 81.3% who received 3 doses of Engerix-B.[2]

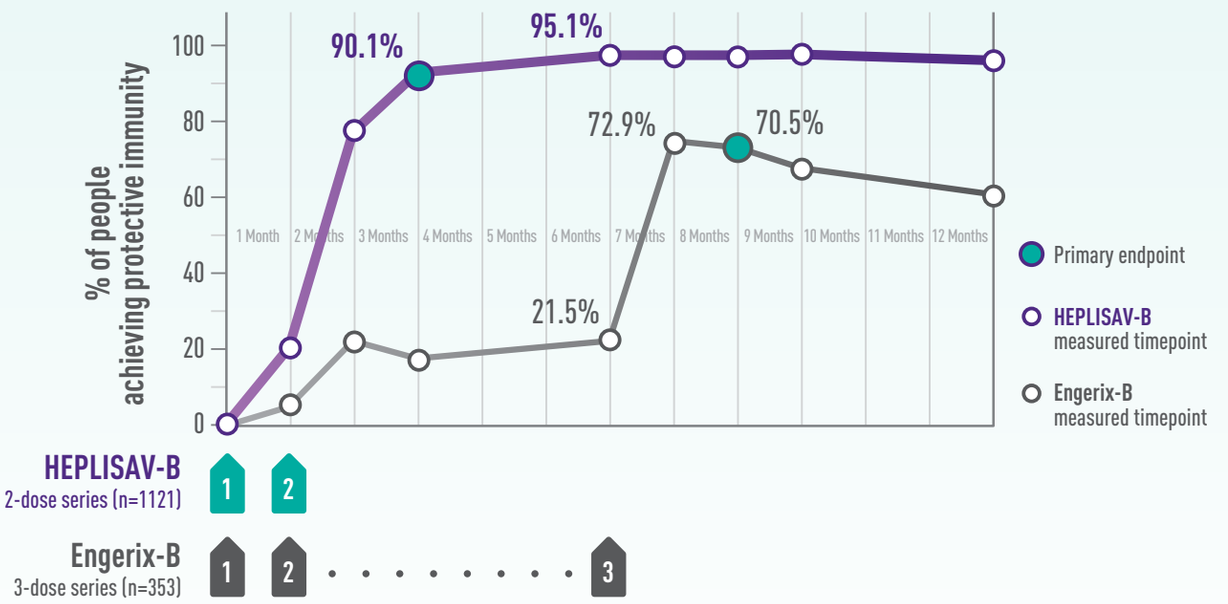
† Protective immunity defined as antibody concentration ≥10 mIU/mL.[13]

CI, confidence interval; SPRs, seroprotection rates.

FASTER AND HIGHER RATES OF PROTECTION WITH HEPLISAV-B

Statistically **significantly higher rates of protection with HEPLISAV-B** vs Engerix-B at every timepoint in adults aged 40 to 70 years[2,12]

TRIAL 2 **PERCENTAGE OF PEOPLE AGED 40 TO 70 ACHIEVING PROTECTIVE IMMUNITY***



- 19.6% (95% CI, 14.7 to 24.8) difference in protective immunity between patient groups at primary endpoint[2,12]
- The primary analysis compared the rate of protective immunity at week 12 for HEPLISAV-B with that at week 32 for Engerix-B[2]

*Protective immunity defined as antibody concentration ≥10 mIU/mL.[13]

IMPORTANT SAFETY INFORMATION

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%).

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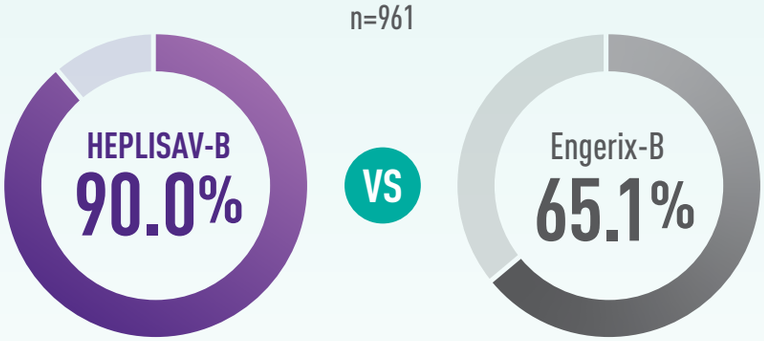
HEPLISAV-B®
Hepatitis B Vaccine (Recombinant), Adjuvanted

HIGHER RATES OF PROTECTION IN HYPORESPONSIVE POPULATIONS

HEPLISAV-B provided statistically **significantly higher rates of protection in people with diabetes and other known hyporesponsive populations**[2,14]

TRIAL 3 **PERCENTAGE OF PEOPLE AGED 18 TO 70 ACHIEVING PROTECTIVE IMMUNITY***

PATIENTS WITH DIABETES
n=961



	TOTAL TRIAL POPULATION N=6665	MALE n=3353	AGED 40 TO 70 n=5434	OBESITY n=3241	SMOKERS n=2082
HEPLISAV-B	95.4%	94.5%	94.6%	94.7%	95.9%
VS	VS	VS	VS	VS	VS
Engerix-B	81.3%	78.8%	78.7%	75.4%	78.6%

Trial 3 study design: 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), diabetes, and smoking status among adults aged 18 to 70 years.[14]

* Protective immunity defined as antibody concentration ≥10 mIU/mL.[13]

IMPORTANT SAFETY INFORMATION

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%).

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INEFFICIENT

2-DOSE HEPLISAV-B CAN DECREASE COSTS AND INCREASE EFFICIENCY

HEPLISAV-B was found to be economically dominant* vs Engerix-B across populations, including[15]:

- Patients with **diabetes**
- Patients with **CKD**
- **Older adults**
- Patients with **obesity**
- Patients with **HIV**
- People who **inject drugs**

*"Vaccination using **HEPLISAV-B is a cost-saving strategy** compared to Engerix-B for adults with diabetes, chronic kidney disease, obesity, and HIV; older adults; and [people who inject drugs]."*[15]

—Rosenthal et al. 2020.

In the era of **universal adult hepatitis B vaccination...**[1]

=

Less staff time[11]
Fewer wasted doses[2,11,16]
Easier for patients[2]

* No cost benefit was demonstrated for non-responders. "Economically dominant" indicates that the intervention strategy had lower costs and higher quality-adjusted life years than the baseline strategy.[15]

CKD, chronic kidney disease; HIV, human immunodeficiency virus.

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

SAFETY PROFILE DEMONSTRATED ACROSS TRIALS IN MORE THAN 10,000 PATIENTS[12]

Data derived from the largest clinical trial safety database (N=14,238) for a hepatitis B vaccine[12]

PERCENTAGE WITH LOCAL OR SYSTEMIC REACTIONS WITHIN 7 DAYS OF VACCINATION[2]

TRIAL 1	HEPLISAV-B post dose		Engerix-B post dose		
	1	2	1	2	3
LOCAL REACTIONS	n=1810	n=1798	n=605	n=603	n=598
Injection-site pain	**38.5%**	**34.8%**	33.6%	24.7%	20.2%
Injection-site redness*	**4.1%**	**2.9%**	0.5%	1.0%	0.7%
Injection-site swelling*	**2.3%**	**1.5%**	0.7%	0.5%	0.5%
SYSTEMIC REACTIONS					
Fatigue	**17.4%**	**13.8%**	16.7%	11.9%	10.0%
Headache	**16.9%**	**12.8%**	19.2%	12.3%	9.5%
Malaise	**9.2%**	**7.6%**	8.9%	6.5%	6.4%
	n=1784	n=1764	n=596	n=590	n=561
Fever†	**1.1%**	**1.5%**	1.8%	1.7%	1.8%

PERCENTAGE WITH LOCAL OR SYSTEMIC REACTIONS WITHIN 7 DAYS OF VACCINATION[2]

TRIAL 2	HEPLISAV-B post dose		Engerix-B post dose		
	1	2	1	2	3
LOCAL REACTIONS	n=1952	n=1905	n=477	n=464	n=448
Injection-site pain	**23.7%**	**22.8%**	18.4%	15.9%	13.8%
Injection-site redness*	**0.9%**	**0.7%**	0.6%	0.2%	0.2%
Injection-site swelling*	**0.9%**	**0.6%**	0.6%	0.6%	0.2%
SYSTEMIC REACTIONS					
Fatigue	**12.6%**	**10.8%**	12.8%	12.1%	9.4%
Headache	**11.8%**	**8.1%**	11.9%	9.5%	8.5%
Malaise	**7.7%**	**7.0%**	8.6%	7.1%	5.1%
Myalgia	**8.5%**	**6.4%**	9.6%	8.0%	4.5%
	n=1923	n=1887	n=472	n=459	n=438
Fever†	**0.6%**	**0.6%**	0.6%	0.9%	0.7%

* Redness and swelling ≥2.5 cm.[2]

† Oral temperature ≥100.4°F (38.0°C).[2]

SAFETY PROFILE DEMONSTRATED ACROSS 3 TRIALS WITH 12 MONTHS OF FOLLOW-UP[12]

Unsolicited adverse events reported in 3 pivotal clinical trials

PERCENTAGE WHO EXPERIENCED ADVERSE EVENTS AFTER VACCINATION[2]

			Unsolicited adverse events*		Serious adverse events	Immune-mediated adverse events†
TRIAL 1	**HEPLISAV-B** (n=1810)	Within 28 days of any injection	**42.0%**	Within 7 months of the first vaccine dose	**1.5%**	**0.2%**
	Engerix-B (n=605)		41.3%		2.1%	0.7%
TRIAL 2	**HEPLISAV-B** (n=1968)	Within 28 days of any injection	**35.4%**	Within 12 months of the first vaccine dose	**3.9%**	**0.2%**
	Engerix-B (n=481)		36.2%		4.8%	0.0%
TRIAL 3	**HEPLISAV-B** (n=5587)	Within 28 days of any injection	**20.1%**	Within 13 months of the first vaccine dose	**6.2%**	**0.1%**
	Engerix-B (n=2781)		20.1%		5.3%	0.0%

* For trial 3, only unsolicited medically attended adverse events, those for which a subject sought medical care, were captured.[2]

† For trials 2 and 3, new-onset autoimmune adverse events are listed. Herpes zoster was reported in 0.7% of HEPLISAV-B patients and 0.3% of patients receiving Engerix-B.[2]

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

EFFICIENCY FOR YOUR STAFF WITH PREFILLED SYRINGES

Latex-free HEPLISAV-B **prefilled syringes offer convenience**[2]

1 PREFILLED SYRINGE (0.5 mL)

NDC: 43528-003-01

PACKAGE OF 5 SINGLE-DOSE PREFILLED SYRINGES

NDC: 43528-003-05

CPT CODE	DESCRIPTION	ADMINISTRATION CODE FOR MEDICARE PART B	DIAGNOSIS CODE (ICD-10-CM)
90739	Hepatitis B vaccine (Hep B), adult dosage, 2-dose schedule, for IM use	G0010	Z23

CPT, current procedural terminology; IM, intramuscular.

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.

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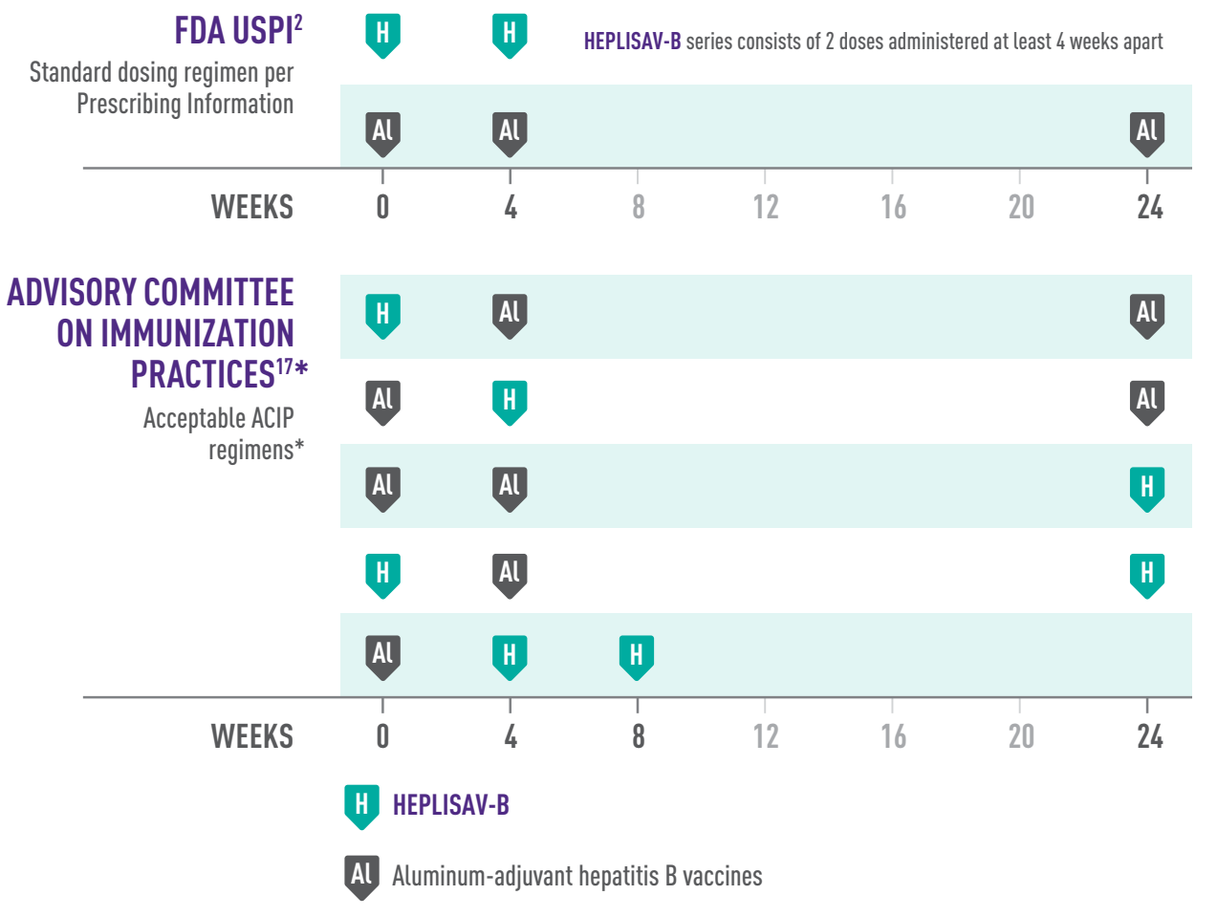
UNANIMOUSLY RECOMMENDED BY THE ACIP[17]

DON'T DELAY THE SWITCH TO HEPLISAV-B

The CDC ACIP provides the following dosing regimens when the manufacturer of the previously administered vaccine is unknown or when the vaccine from the same manufacturer is unavailable[17]



* 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, and 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.[17]

USPI, United States prescribing information.

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

The CDC ACIP voted to recommend universal adult hepatitis B vaccination[1]*

THE TIME FOR A DIFFERENT APPROACH IS NOW

AND IT STARTS WITH YOU

Give your healthcare system the 2-dose HEPLISAV-B advantage[2,11,12]

INCOMPLETE series

UNPROTECTED patients

INEFFICIENT workflow

Learn more at **HEPLISAVB.com**

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Please click here for full Prescribing Information.

DYNAVAX

February 2022 US-22-00-00025

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

2 DOSES. 1 MONTH. DONE.[2]