

**HEPLISAV-B- hepatitis b vaccine (recombinant) adjuvanted injection, solution**  
**Bamboo US BidCo LLC**

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**These highlights do not include all the information needed to use HEPLISAV-B<sup>®</sup> safely and effectively. See full prescribing information for HEPLISAV-B.**

**HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted] Solution for Intramuscular Injection**  
**Initial U.S. Approval: 2017**

**Principal Panel - Carton - Vials**

**Rx only**

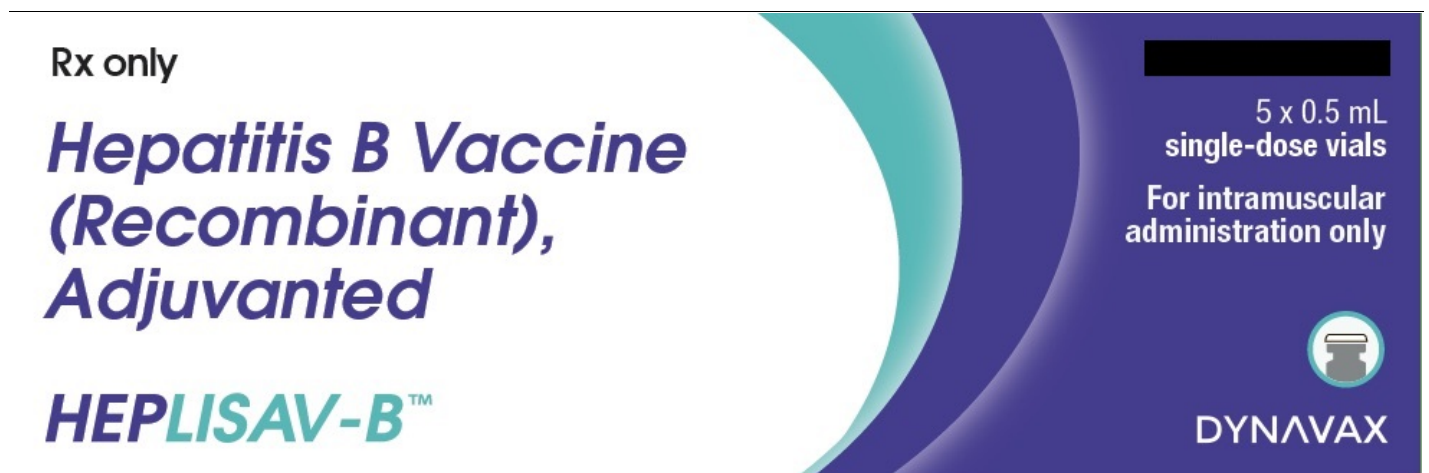
**Hepatitis B Vaccine  
(Recombinant),  
Adjuvanted**

**HEPLISAV-B<sup>™</sup>**

5 x 0.5 mL  
**single-dose vials**

**For intramuscular  
administration only**

**DYNAVAX**



**Principal Panel - Carton - Prefilled Syringes**

**Rx only**

**Hepatitis B Vaccine  
(Recombinant),  
Adjuvanted**

**HEPLISAV-B<sup>®</sup>**

5 x 0.5 mL single-dose syringes

**For intramuscular  
administration only**

**For Adult Use Only**

**NEEDLES NOT INCLUDED**

DYNAVAX



**Principal Panel - Label - Prefilled Syringes**

**HEPLISAV-B®**

**1 dose (0.5 mL)**

*Hepatitis B Vaccine  
(Recombinant), Adjuvanted*

For IM use only DO NOT FREEZE  
Store at 2-8°C (36-46°F)  
Mfd. by Dynavax Tech. Corp.



## HEPLISAV-B

hepatitis b vaccine (recombinant) adjuvanted injection, solution

### Product Information

<b>Product Type</b>	VACCINE	<b>Item Code (Source)</b>	NDC:83703-048
<b>Route of Administration</b>	INTRAMUSCULAR		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HEPATITIS B VIRUS SUBTYPE ADW HBSAG SURFACE PROTEIN ANTIGEN</b> (UNII: XL4HLC6JH6) (HEPATITIS B VIRUS SUBTYPE ADW HBSAG SURFACE PROTEIN ANTIGEN - UNII:XL4HLC6JH6)	HEPATITIS B VIRUS SUBTYPE ADW HBSAG SURFACE PROTEIN ANTIGEN	20 ug in 0.5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>1018 ISS</b> (UNII: 25DT549L0G)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM PHOSPHATE, DIBASIC, DODECAHYDRATE</b> (UNII: E1W4N241FO)	
<b>SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE</b> (UNII: 5QWK665956)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-048-05	5 in 1 CARTON		
1	NDC:83703-048-01	0.5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125428	01/01/2018	

**Labeler** - Bamboo US BidCo LLC (119087615)

**Registrant** - Dynavax Technologies Corporation (964173801)

Revised: 6/2024

Bamboo US BidCo LLC