

Heplisav-B (hepatitis B vaccine [recombinant], adjuvanted)



NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Heplisav-B
- **Generic name:** Hepatitis B vaccine (recombinant), adjuvanted
- **Pharmacological class:** Hepatitis B vaccine
- **Strength and Formulation:** HBsAg 20mcg + CpG 1018 3000mcg per 0.5mL dose; soln for IM inj; preservative-free
- **Manufacturer:** Dynavax Technologies
- **How supplied:** Single-dose vials—1, 5
- **Legal Classification:** Rx

Indications

- Hepatitis B immunization

Dosage & Administration

- Give IM inj in deltoid muscle
- **≥18yrs:** 2 doses (0.5mL each) 1 month apart

Contraindications

- Yeast hypersensitivity

Considerations for Special Populations

- **Pregnancy:** No clinical studies in pregnant women
- **Nursing mothers:** Consider clinical need and potential adverse effects
- **Pediatric:** <18yrs: not established
- **Renal impairment:** Hemodialysis: not established

Warnings/Precautions

- Have appropriate medical treatment available to manage possible anaphylactic reactions
- Immunocompromised

Interactions

- Concomitant **immunosuppressants**:
may get sub-optimal response
- Concomitant **immune globulin**; give
separately using different syringes at
different inj sites
- May interfere with **lab tests**

Adverse Reactions

- Local reactions (eg, pain, redness, swelling)
- Fatigue
- Headache
- Malaise
- Anaphylaxis

Mechanism of Action

- Antibody concentrations ≥ 10 mIU/mL against HBsAg are recognized as conferring protection against hepatitis B virus infection

Clinical Studies

- Heplisav-B was compared with a licensed hepatitis B vaccine (Engerix-B) in 3 randomized, active-controlled, observer-blinded, multicenter Phase 3 trials of adults
- The trials compared **seroprotection rates** induced by Heplisav-B and Engerix-B

Clinical Studies

- **Study 1** analyzed seroprotection rates of patients who received Heplisav-B (N=1,511) at Week 12 vs Engerix-B (N=521) at Week 28
 - Study patients were aged 18–55 years
- Heplisav-B showed a noninferior seroprotection rate compared to Engerix-B
 - **95% vs 81.3%** (difference 13.7%, 95% CI: 10.4, 17.5)

Clinical Studies

- **Study 2** analyzed seroprotection rates of patients who received Heplisav-B (N=1,121) at Week 12 vs Engerix-B (N=353) at Week 32
 - Study patients were aged 40–70 years
- Heplisav-B showed a noninferior seroprotection rate compared to Engerix-B
 - **90.1% vs 70.5%** (difference 19.6%, 95% CI: 14.7, 24.8)

Clinical Studies

- **Study 3** analyzed seroprotection rates of patients with type 2 diabetes who received Heplisav-B (N=640) vs Engerix-B (N=321) at Week 28
 - Study patients were aged 18–70 years
- Heplisav-B showed a noninferior seroprotection rate compared to Engerix-B
 - **90.0% vs 65.1%** (difference 24.9%, 95% CI: 19.3, 30.7)
- For more information, see full labeling

New Product Monograph

- For more information view the product monograph available at:

<http://www.empr.com/heplisav-b/drug/34785/>