

INFECTION CONTROL^{AND}

HOSPITAL EPIDEMIOLOGY

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EDITORIAL

- Hospital-Based Routine HIV Testing Programs** 625
Frank Rhame, MD

ORIGINAL ARTICLES

- Evaluation of a Hospital Admission HIV Antibody Voluntary Screening Program** 628
Richard L. Harris, MD; Eugene V. Boisaubin, MD;
Pamela D. Salyer, MSRN;
Denise F Semands, MSRN

- An Effective Educational Program to Reduce the Frequency of Needle Recapping** 635
Bruce S. Ribner, MD, MPH;
Barbara S. Ribner, RN, BSN, MBA

- Increasing Prevalence of Methicillin-Resistant *Sfaphylococcus aureus* in the United States** 639
John M. Boyce, MD

- Postoperative Group A β -Hemolytic Streptococcus Outbreak With the Pathogen Traced to a Member of a Healthcare Worker's Household** 643
Sindy M. Paul, MD;
C(arol) Genese, MT, (ASCP), MBA;
Kenneth Spitalny, MD

AIDS

- Position Paper: The HIV-Infected Healthcare Worker** 647
Association for Practitioners in Infection Control:
Society of Hospital Epidemiologists of America

- ANNUAL INDEX** 657

LETTERS TO THE EDITOR

- Surveillance of Hospital Infections in the United Kingdom** 622
Helen Glenister; Lynda Taylor;
Craig Mackintosh; E. Mary Cooke;
Christopher Barlett; Anne Mulhall

- SHEA NEWSLETTER** 673

From SmithKline Biologicals



Hepatitis B Vaccine (Recombinant)

Choice of dosing regimens

Alternate 0, 1, 2 month dosing regimen for certain populations*

20 mcg recombinant dose

Helps to ensure immune response in adult patients of all ages

	Engerix-B®	Recombivax HB®†
Adult dose (mcg)	20	10
Standard dosing regimen (0, 1 and 6 months)	✓	✓
Alternate 0, 1, 2 month dosing regimen for certain populations*	✓	
Published efficacy data: Neonates born of infected mothers ⁷	✓	✓
VACTRAC™—computer software for vaccination tracking and compliance	✓	
Bar-coded, unit-dose vials	✓	
Lowest cost per dose ²	✓	

*For those recently exposed to the virus (including needlestick exposure), certain travelers to high-risk areas and neonates born of infected mothers. When prolonged maintenance of protective antibody titers is desired, a booster dose at month 12 is recommended.

Lowest Cost Per Dose²

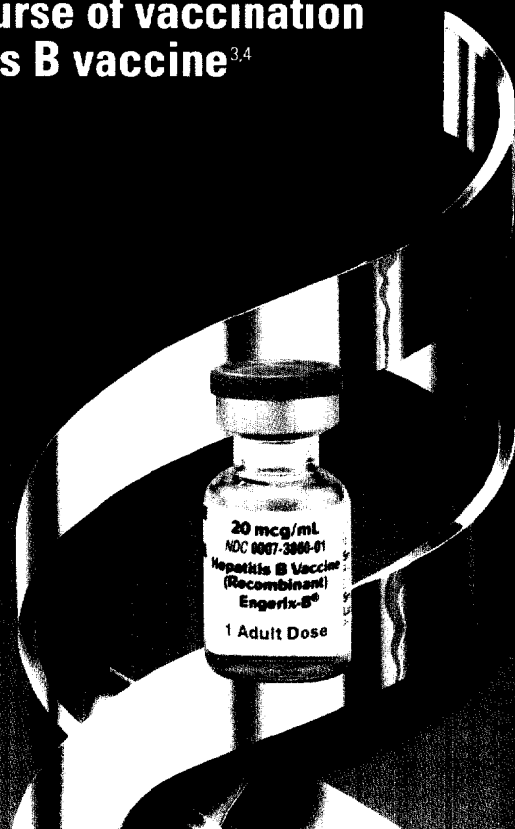
Extensively tested and well tolerated[‡]

State-of-the-art recombinant technology

14 million doses distributed in over 87 countries³

Switch to Engerix-B[®]

Can be used to complete a course of vaccination initiated with another hepatitis B vaccine^{3,4}



¹Hepatitis B Vaccine (Recombinant), MSD.

[‡]Please see brief summary of prescribing information on adjacent page for a complete listing of adverse reactions, contraindications, warnings and precautions.

©SmithKline Beecham, 1990

Engerix-B®

Hepatitis B Vaccine (Recombinant)

See complete prescribing information in SK&F literature or PDR. The following is a brief summary.

INDICATIONS AND USAGE: Engerix-B is indicated for immunization against infection caused by all known subtypes of hepatitis B virus. Immunization is recommended in persons of all ages, especially those who are, or will be, at increased risk of exposure to hepatitis B virus.

CONTRAINDICATIONS: Hypersensitivity to yeast or any other component of the vaccine is a contraindication for use of the vaccine.

WARNINGS: Do not give additional injections to patients experiencing hypersensitivity after an Engerix-B injection. (See CONTRAINDICATIONS.)

Hepatitis B has a long incubation period. Hepatitis B vaccination may not prevent hepatitis B infection in individuals who had an unrecognized hepatitis B infection at the time of vaccine administration. Additionally, it may not prevent infection in individuals who do not achieve protective antibody titers.

PRECAUTIONS: General: As with any percutaneous vaccine, keep epinephrine available for use in case of anaphylaxis or anaphylactoid reaction.

As with any vaccine, delay administration, if possible, in persons with any febrile illness or active infection.

Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with Engerix-B. It is also not known whether Engerix-B can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Give Engerix-B to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether Engerix-B is excreted in human milk. Because many drugs are excreted in human milk, use caution when giving Engerix-B to a nursing woman.

Pediatric Use: Engerix-B has been shown to be well tolerated and highly immunogenic in infants and children of all ages. Newborns also respond well; maternally transferred antibodies do not interfere with the active immune response to the vaccine.

ADVERSE REACTIONS: Engerix-B is generally well tolerated. During clinical studies involving over 10,000 individuals distributed over all age groups, no serious adverse reactions attributable to vaccine administration were reported. As with any vaccine, however, it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions not observed in clinical studies.

Ten double-blind studies involving 2,252 subjects showed no significant difference in the frequency or severity of adverse experiences between Engerix-B and plasma-derived vaccines. In 36 clinical studies a total of 13,495 doses of Engerix-B were administered to 5,071 healthy adults and children who were initially seronegative for hepatitis B markers, and healthy neonates. All subjects were monitored for 4 days post-administration. Frequency of adverse experiences tended to decrease with successive doses of Engerix-B. Using a symptom checklist, the most frequently reported adverse reactions were injection site soreness (22%), and fatigue (14%). Other reactions are listed below:

Incidence 1% to 10% of injections: Induration; erythema; swelling; fever ($>37.5^{\circ}\text{C}$); headache; dizziness.*

*Parent or guardian completed forms for children and neonates. Neonatal checklist did not include headache, fatigue or dizziness.

Incidence < 1% of injections: Pain; pruritus; ecchymosis; sweating; malaise; chills; weakness; flushing; tingling; hypotension; influenza-like symptoms; upper respiratory tract illnesses; nausea, anorexia; abdominal pain/cramps; vomiting; constipation; diarrhea; lymphadenopathy; pain/stiffness in arm, shoulder or neck; arthralgia; myalgia; back pain; rash; urticaria; petechiae; erythema; somnolence; insomnia; irritability; agitation.

Additional adverse experiences have been reported with the commercial use of Engerix-B outside the United States. Those listed below are to serve as alerting information to physicians: Anaphylaxis; erythema multiforme including Stevens-Johnson syndrome; angioedema; arthritis; tachycardia/palpitations; bronchospasm including asthma-like symptoms; abnormal liver function tests; migraine; syncope; paresis; neuropathy including hypoesthesia, paresthesia, Guillain-Barré syndrome and Bell's palsy; transverse myelitis; thrombocytopenia; eczema; purpura; herpes zoster; vertigo; conjunctivitis; keratitis; visual disturbances.

Potential Adverse Experiences: In addition, certain other adverse experiences not observed with Engerix-B have been reported with Hepavax-B®† and/or Recombivax HB®‡. Those listed below are to serve as alerting information to physicians: Optic neuritis.

HOW SUPPLIED: 20 mcg/mL in Single-Dose Vials in packages of 1, 10 and 25 vials.

NDC 0007-3860-01 (package of 1)
NDC 0007-3860-11 (package of 10)
NDC 0007-3860-16 (package of 25)

10 mcg/0.5 mL in Single-Dose Vials in packages of 1 vial

NDC 0007-3859-01 (package of 1)

† plasma-derived, Hepatitis B Vaccine, MSD

‡ yeast-derived, Hepatitis B Vaccine, MSD.

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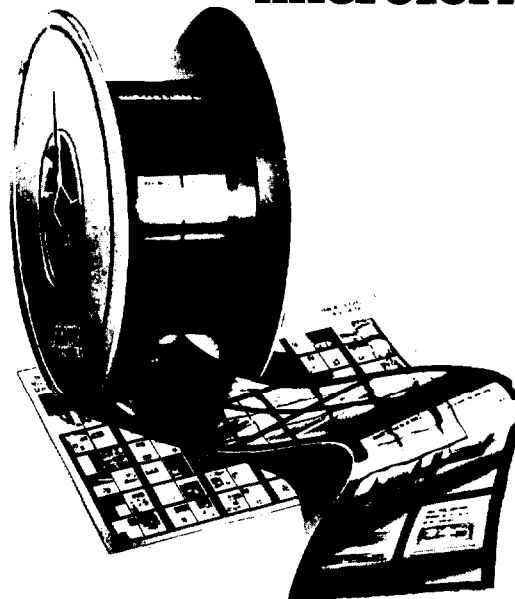
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References:

1. Poovorawan Y, Sanpavat S, Pongpunlert W, et al: Protective efficacy of a recombinant DNA hepatitis B vaccine in neonates of HBe antigen-positive mothers. *JAMA* 1989; 261(22):3278-3281.
2. Based on Medi-Span® Hospital Formulary Pricing Guide, December 1989.
3. Data on file, SK&F.
4. Bush L, Moonsammy G, Boscia J: Evaluation of initiating a hepatitis B vaccination schedule with one vaccine and completing it with another. *Hepatology* 1989; 10:689.

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EDITORIAL	Hospital-Based Routine HIV Testing Programs Frank Rhame, MD	625
ORIGINAL ARTICLES	Evaluation of a Hospital Admission HIV Antibody Voluntary Screening Program Richard L. Harris, MD; Eugene V. Boisauvin, MD; Pamela D. Salyer, MSRN; Denise F. Semands, MSRN	628
	An Effective Educational Program to Reduce the Frequency of Needle Recapping Bruce S. Ribner, MD, MPH; Barbara S. Ribner, RN, BSN, MBA	635
	Increasing Prevalence of Methicillin-Resistant Staphylococcus aureus in the United States John M. Boyce, MD	639
	Postoperative Group A β-Hemolytic Streptococcus Outbreak With the Pathogen Traced to a Member of a Healthcare Worker's Household Sindy M. Paul, MD; Carol Genese, MT, (ASCP), MBA; Kenneth Spitalny, MD	643
SPECIAL SECTIONS	AIDS Position Paper: The HIV-Infected Healthcare Worker Association for Practitioners in Infection Control; Society of Hospital Epidemiologists of America	647
	Annual Index	657
DEPARTMENTS	Letters to the Editor	622
	Calendar of Events	672
	SHEA Newsletter	673
	Information for Authors	675
	Classified Marketplace	676

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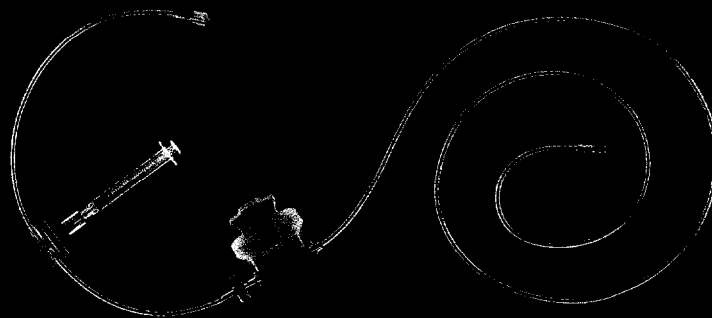
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