INFECTION CONTROL

HOSPITAL EPIDEMIOLOGY

Volume 11, Number 11 • November 1990

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Lee Benson; Lee Bush, PhD; Destin LeBlanc

EDITORIAL

From SmithKline Biologicals

SENGERIXB

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)	J	✓
Alternate 0, 1, 2 month dosing regimen for certain populations*	1	
Published efficacy data: Neonates born of infected mothers'	√.	✓
VACTRAC TM—computer software for vaccination tracking and compliance	√	
Bar-coded, unit-dose vials	1	
Lowest cost per dose ²	1	

^{*}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 Dose

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}



†Hepatitis 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.

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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 inlection caused by all known subtypes of hepatitis B wrus immuni zation is recommended in persons of all ages. especially those who are. Or will be, at increased risk of exposure to hepatitis B wrus.

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

WARNINGS: Do not give additional injections to palients experienci 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 profective 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 Calegory C: Animal reproduction studies have not been conducted with 'Engerix B'. It is also not known whether Engerix B cause letal 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 inlants and children of all ages. Newborns also respond well, maternally transferred antibodies do not interfere with the active immune

ADVERSE REACTIONS: E erx: B' is generally well tolerated. During clinical studies involving .cupr. 10% 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 ram 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 Engerus 8 and plasma-derived vaccines. In 36 clinical studies a total of 13,495 doses of Engerus 8 were administered to 5.071 healthy adults and children who were initially seronegative for hepatitis 8 markers, and healthy neonates All subjects were monitored for 4 days post-administration. Frequency of adverse experiences tended to decrease with successive doses of Engerus B. Using a symptom checklist, "the most frequently reported adverse eactions were injectionsite soveness (2296), and tatigue" (14%) Other reactions are listed below

Incidence 1% la 10% of injections: induration; erythema; swelling: fever (>37.5°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, lingling; 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 expenences have been reported with the commercial use of Engenx B outside the United Stales Those listed below are to serve as alerting information to physicians Anaphylaxis, crythema multiforme including Stevens-Johnson syndrome; angioedema; arthritis, tachycardia/palpitations, bronchospasm including asthma-fike symptoms, abnormal liver function lests; migraine; syncope, paresis; neuropathy including hypoeshesia, Guillain-Barré syndrome and Bell's palsy: transverse myelitis; thrombocytopenia; eczema, purpura; herpes zoster; vertigo; conjunctivitis; keratitis; visual disturbances.

Polential Adverse Experiences. In addition, certain other adverse experiences not observed with "Rogerix Bhave been reported with Heptavax 8% and/or Recombivax H8% ‡ 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

NDC **0007-3860-01** (package 011) NOC **0007-3860-11** (package **of 10)** NOC **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 ‡ yeasl-derived, Hepatitis B Vaccine, MSD.

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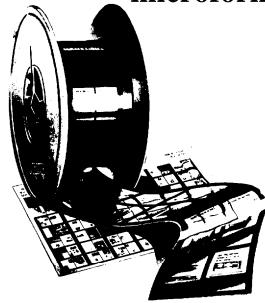
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I. Poovorawan Y, Sanpavat S. Pongnunlert W. et al: Protective efficacy of a recombinant DNA hepatitis B vaccine in neonates of HBe antigen-positive mothers. *JAMA* 1989; 261(22):3278–3281. Based& Medi-Span* Hospital Formulary Pricing Guide,
December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

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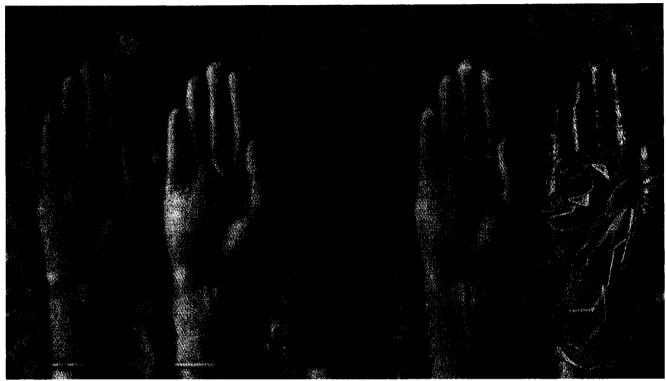
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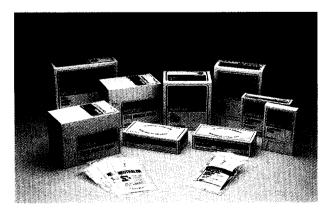
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