INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

Volume 11, Number 10 • October 1990

The Official Journal of The Society of Hospital Epidemiologists of America

https://doi.org/10.1017/S0899823X00083938 Published online by Cambridge University Press

From SmithKline Biologicals

20 mcg/mL

Engerix-B®

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'	✓	✓
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.

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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 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 hepabtis B virus.

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 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 bme of vaccme 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 vaccme. 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 mlk, 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 weal 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°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: Pam: 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; ngrraine; syncope; paresis; neuropathy including hypoesthesia, paresthesia, Guiin-Barré syndrome and Belt's palsy transverse myelitis; thrombocytopenia; eezema; 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 Heptavax-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.

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

10 mcgD.5 mL in Single-Dose Vials in packages of 1 vial

NOC 0007-3859-01 (package of 1)

† plasma-derived, Hepatitis B Vaccine, MSD
‡ yeast-derived, Hepatitis B Vaccine, MSD.

Manufactured by **SmithKline Biologicals**, Rixensart, Belgium
Distributed by **Smith Kline & French Laboratories**
Division of SmithKline Beckman Corp., Philadelphia, PA 19101

Oate of issuance Aug. 1989

BRS--EB:L6

Engerix-B is a registered trademark of SmithKline Beecham

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 Pricmg 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 vaccme and completing it with another. *Hepatology* 1989;10:689.

https://doi.org/10.1017/S0899823X00083938 Published online by Cambridge University Press

VOLUME 11, NUMBER 10 OCTOBER 1990

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

The ideas and opinions expressed by contributing authors do not necessarily reflect those of the editors or publisher.

Publisher: Infection Control and Hospital Epidemiology (ISSN-0899-823X) is published monthly by SLACK Incorporated. 6900 Grove Road Thorofare New Jersey 08086 Telephone (609) 848-1000

Subscriptions: Requests should be addressed to the publisher (except Japan) In Japan contact Woodbell Incorporated 4-22-11 Kitakasai, Edogawaku Tokyo 134. Japan Subscription rates in the US and possessions Individual One year-$60 00 Two years-$95 00, Three years-$125.00 Institutional One year-$70 00. Two years-$110 00, Three years-$150 00, Canada $16 00 additional each year all other countries $30 00 additional each year Single copies of current issues may be obtained for $8 00 United States and possessions. $16 00 all other countries

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As of Volume 1. Number 1, INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY is listed in *Index Medicus, Current Contents—Clinical Practice Hospital Literature Index. Cumulative Index to Nursing and Allied Health Literature,* and *Nursing Abstracts*

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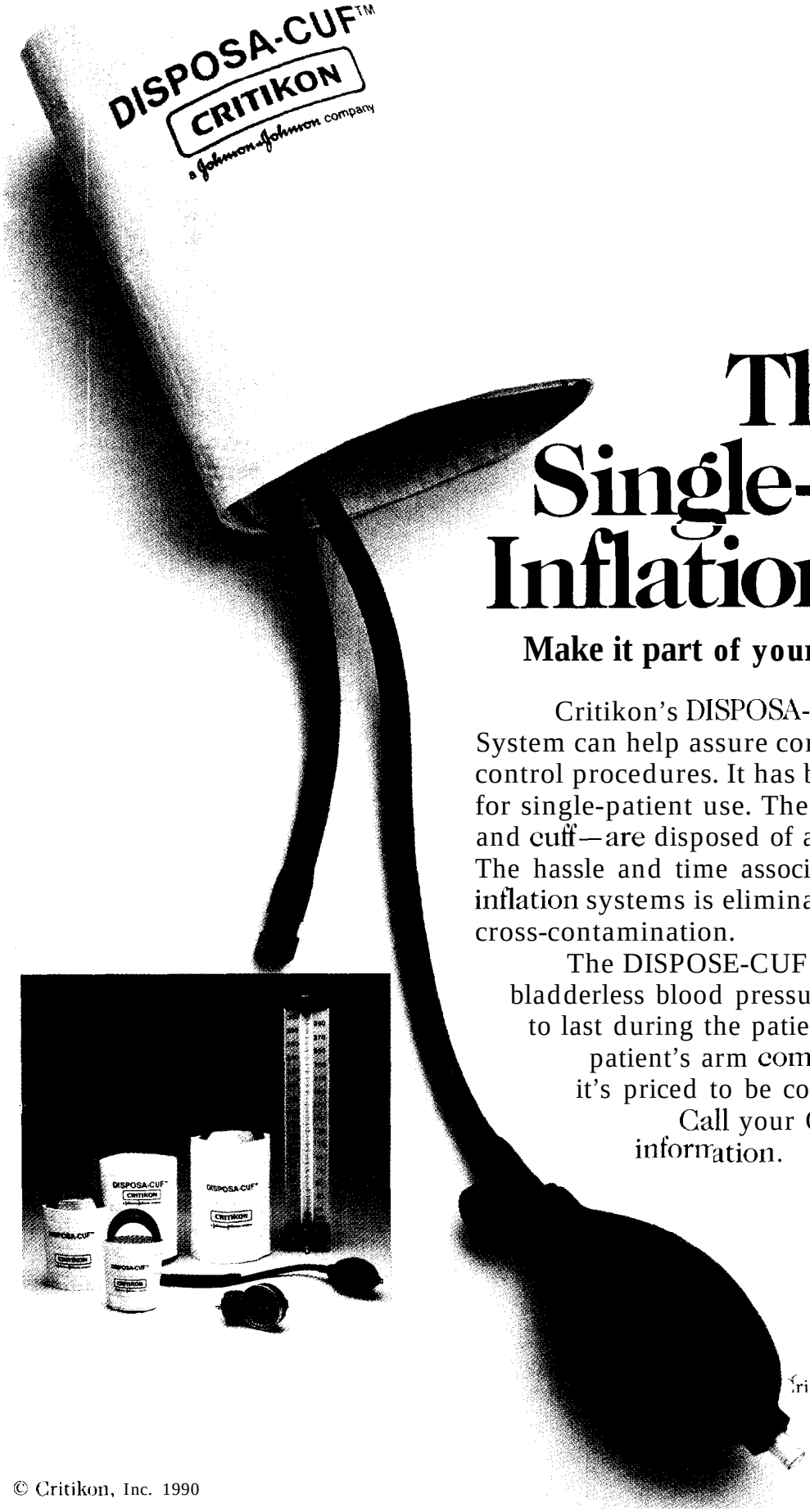

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