INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

Volume 11, Number 4 • April 1990

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The Official Journal of The Society of Hospital Epidemiologists of America

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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.

†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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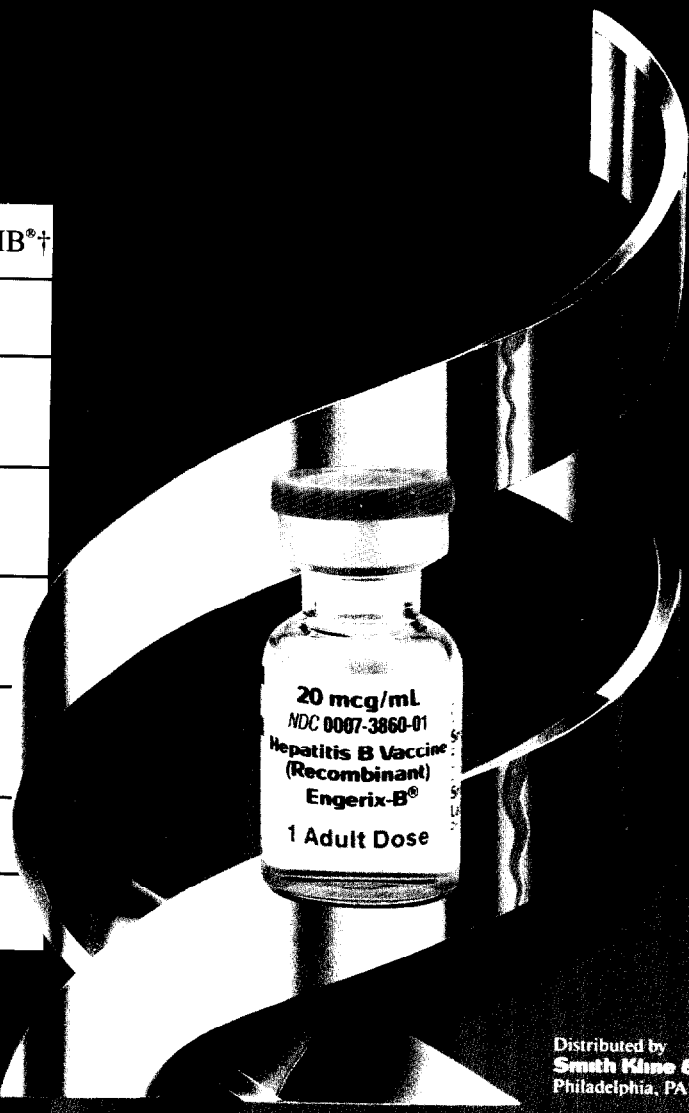
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Engerix-B®	Recombivax HB®†
20	10
Yes	Yes
Yes	No
Yes	Yes
Yes	No
Yes	No
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Sos **complete prescribing information** In **SK&F literature** or ***PDR.*** **The following** IS **abrief summary.**

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 ivgive' aoaral injections* I · *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 hepatibs B infection al the bme 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, 1 possible, in persons with any febrile illness or active infection

Pregnancy: Pregnancy Ctegory 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: il is not known whether 'Engerix-B' is excreted in human milk Because many drugs are excreted in human mitk, use caution when giving 'Engerix-B' lo a nursing woman

Pediatric Use: 'Engerix-B' has been shown lo 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' 6 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 d 13.496 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: *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 am. shod&r *or* neck. *arthralgia; myalgia;* back *pain;* rash; *urticaria; petechiae;* erythema; somnolence; insomnia; irritability; agitation

Additional adverse experiences have been reported with the commercial "se d '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, Guäin-Barré syndrome and Bell'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 lo physicians Optic neuritis.

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

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NOC 0007-3859-01 (package d 1)

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

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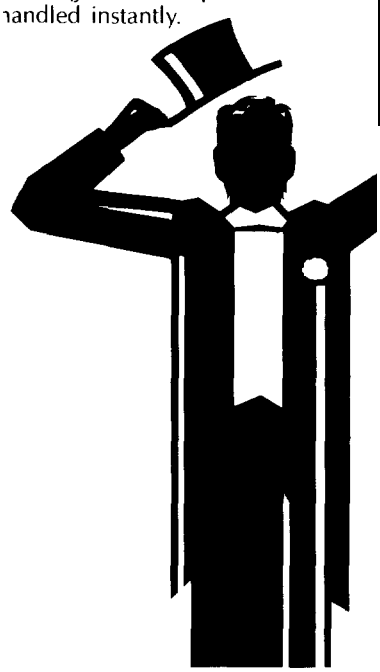
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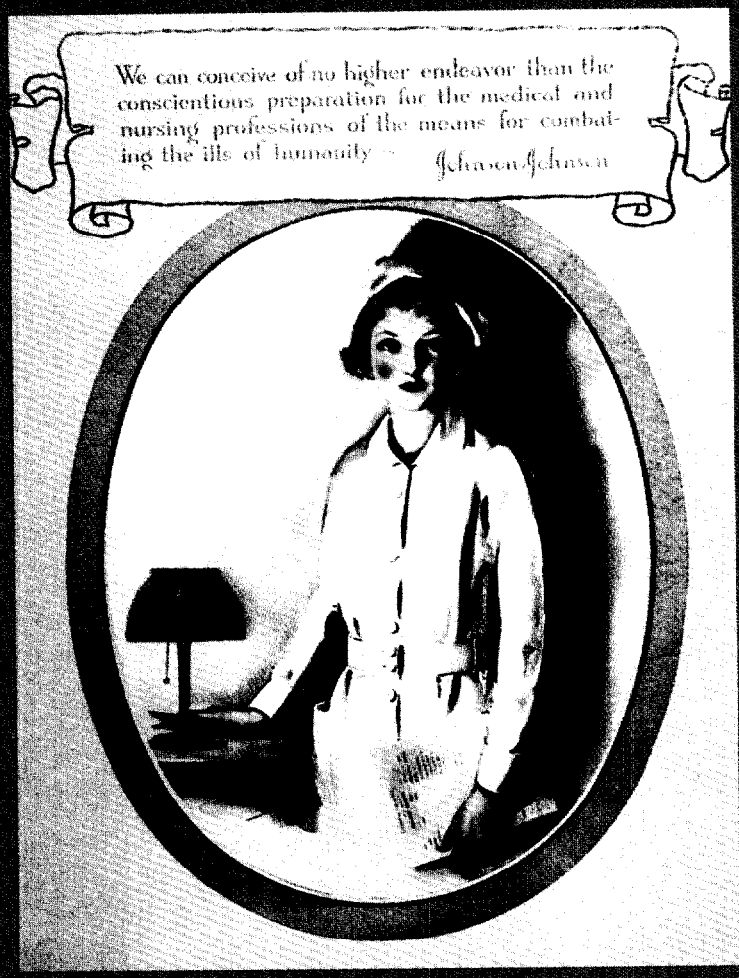
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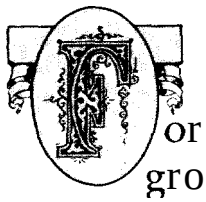
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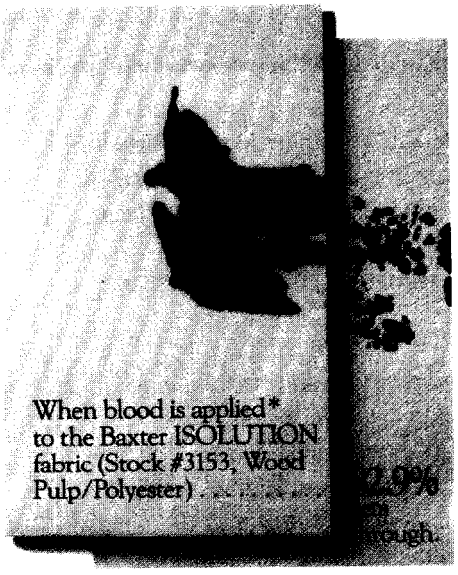
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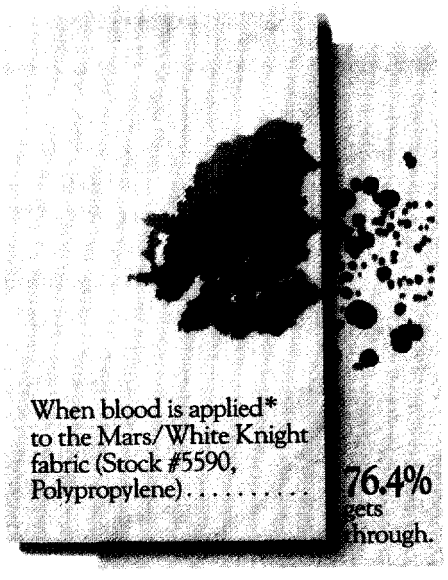
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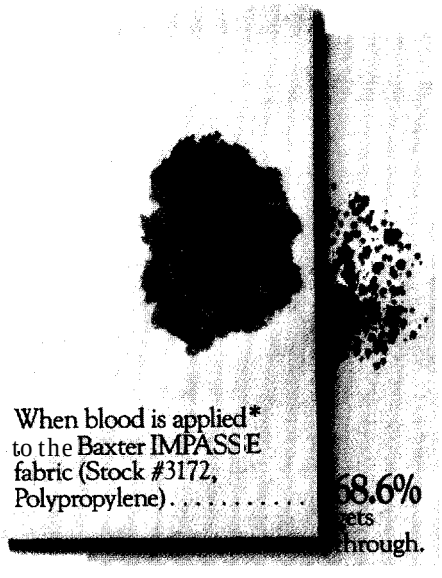
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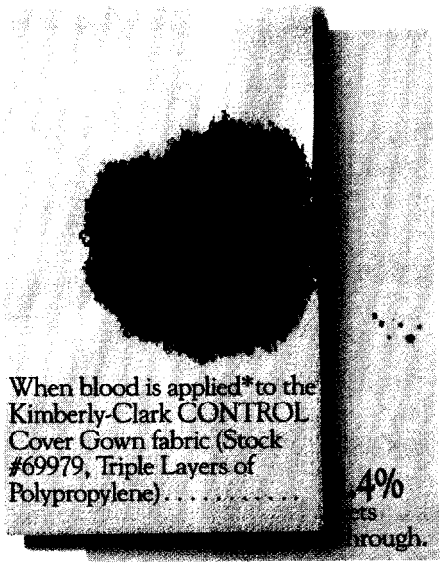
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2 Klein, B.S., W.H. Perloff, and D.G. Maki. 1989. Reduction of nosocomial infection during pediatric intensive care by protective isolation. N. Engl. J. Med. 320: 1714-1721.

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Two major independent studies support CONTROL Cover Gowns' superior performance.

In a study at Arkansas Children's Hospital, CONTROL Cover Gowns were shown to be more protective against contaminated body fluids! And a study published in The New England Journal of Medicine showed that CONTROL Cover Gowns and gloves significantly reduced nosocomial infection in pediatric intensive care!



Cross-section of CONTROL Cover Gown Fabric

The key is CONTROL Cover Gowns' unique, three-layer laminated fabric with an inner layer of polypropylene microfibers. This inner layer forms a barrier to screen out bacteria and resist fluid penetration. Yet, this remarkable cloth-like fabric is also highly breathable and tear resistant.

Get the best for your staff and patients. For more information on CONTROL Cover Gowns, call 1-800-KC HELPS, or 1-800-524-3572

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