INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

Volume 11, Number 5 • May 1990

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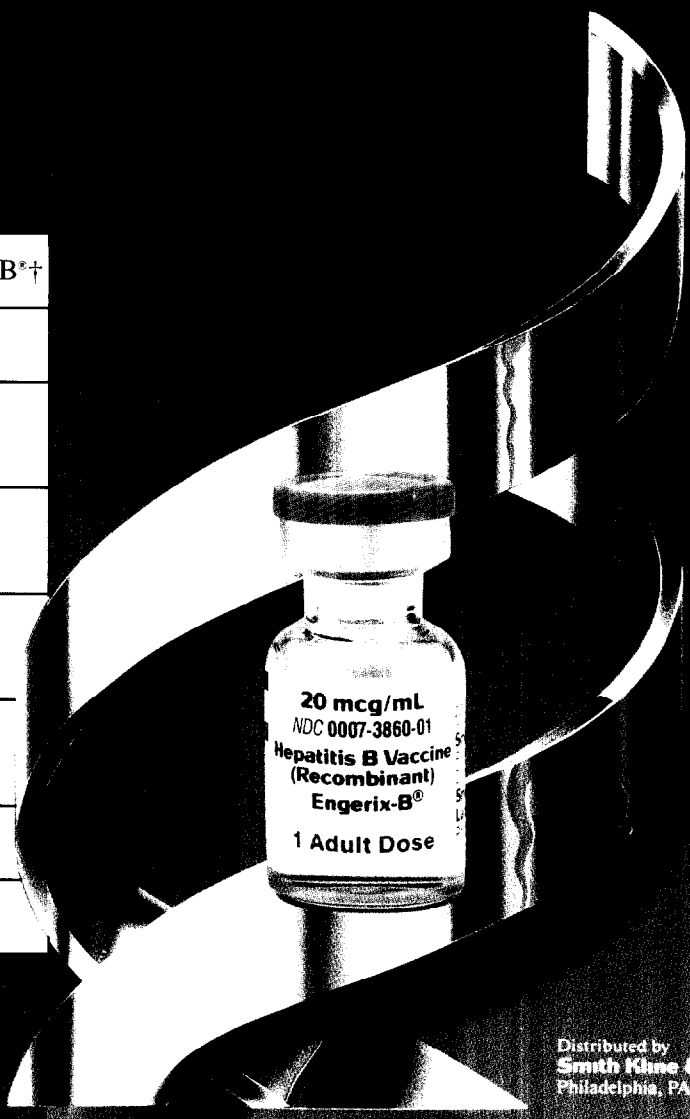
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CONTRAINDICATIONS: Hypersensitivity to yeast or any other component of the vaccine is a contraindication for use of the vaccine

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 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' 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, 1 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 ES and plasma dewed 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: *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 Barre 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 Heptavax B®† and/or Recombivax HB® ‡ Those listed below are to serve as alerting information to physicians Optic neuritis

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‡ yeast-dewed, Hepatitis B Vaccine, MSD

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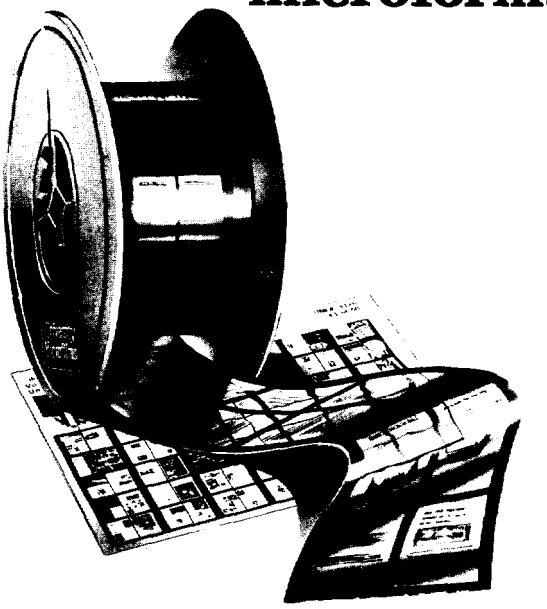
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1. Poovorawan Y, Sanpavat S, Pongpunlert W, et al: Protective efficacy of a recombinant DNA hepatitis B vaccine in neonates of HBe antigen-positive mothers *JAMA* 1989; 261(22):3278–3281.
2 Based on Medi-Span* Hospital Formulary Pricing Guide, December 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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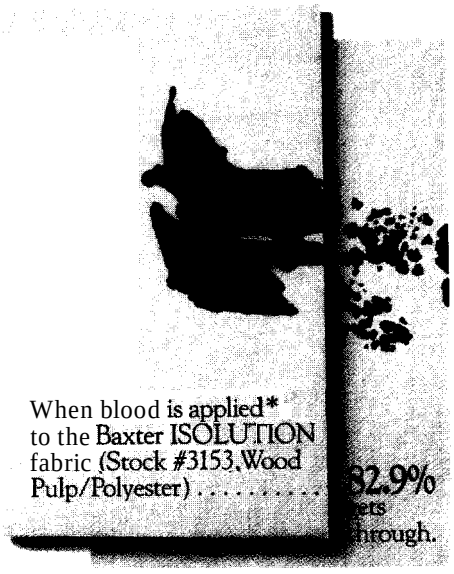


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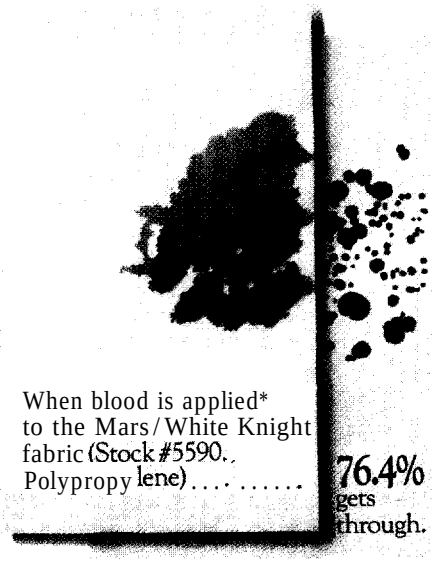
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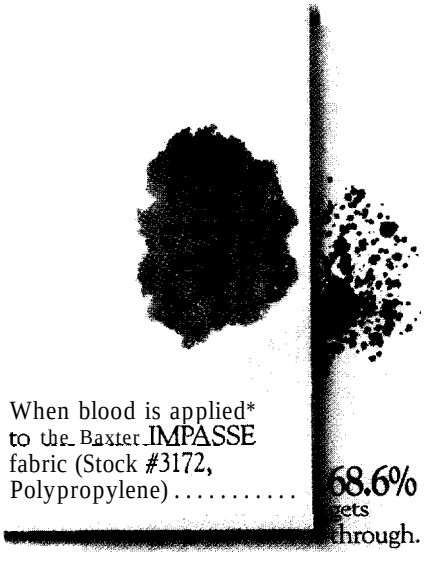
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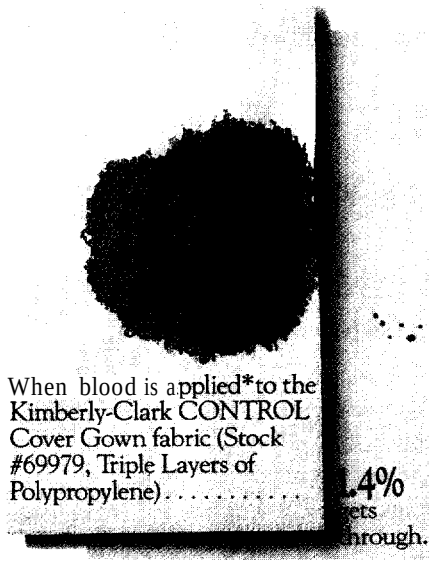
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2 Klein, B.S., W.H. Perloff, and D.G. Maki. 1989. Reduction of nosocomial infection during pediatric intensive care by protective isolation. N. Engl. J. Med. 320: 1714-1721.

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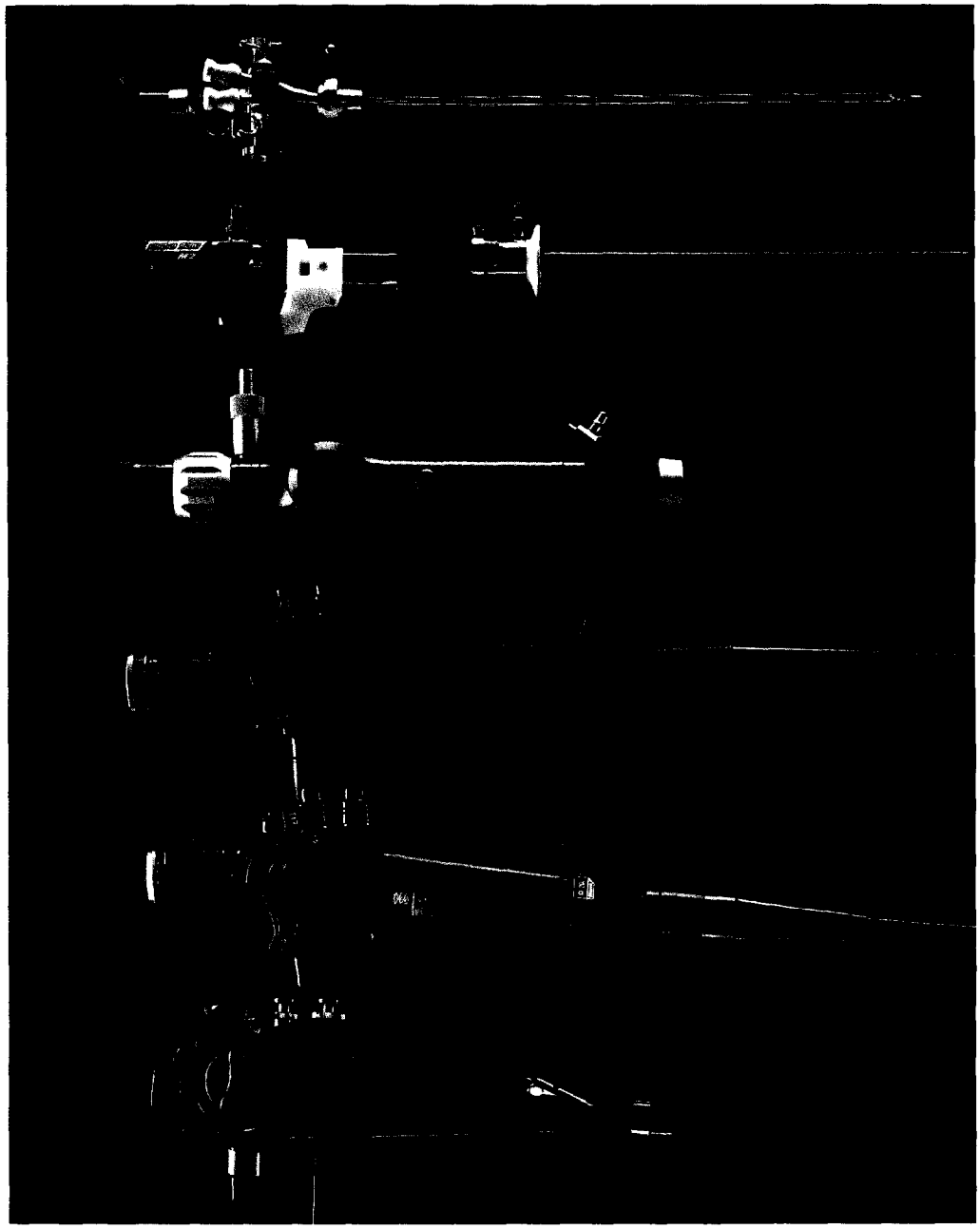
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