INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

Volume 11, Number 9 • September 1990

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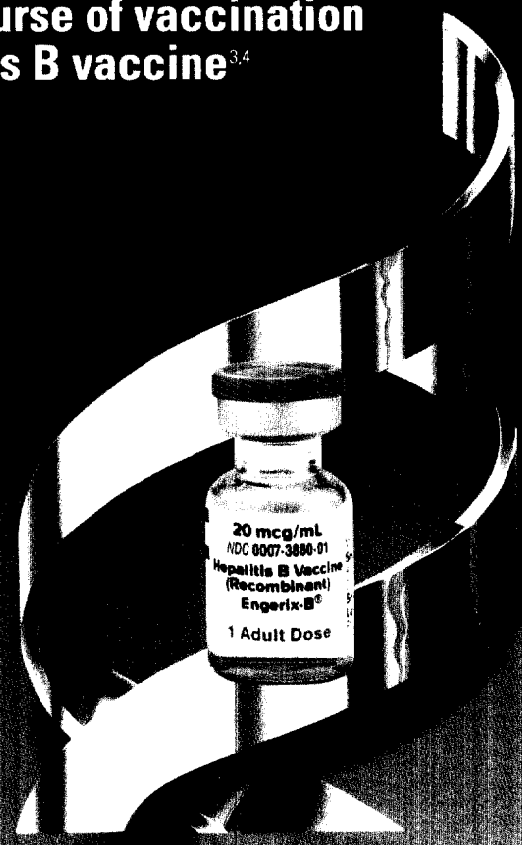
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Hepatitis B has a long incubation period Hepatitis B vaccination may not prevent hepatitis B infection in individuals who had an unrecognized hepatitis B infection at the time of vaccine administration Additionally, it may not prevent infection in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

PRECAUTIONS: General: As with any percutaneous vaccme, 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 lo a pregnant woman or can affect reproduction capacity Give 'Engerix-B' lo 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 Uu: 'Engerix-B' has been shown to be well tolerated and highly immunogenic in infants and children of att ages. Newborns also respond welt, maternally transferred antibodies do not interfere with the active immune response to the vaccme

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 we reported As with any vaccine, however, d 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 expenences 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 torms 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 patsy, 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

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

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NOC 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.

NOC 0007 3859-01(package of 1)

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

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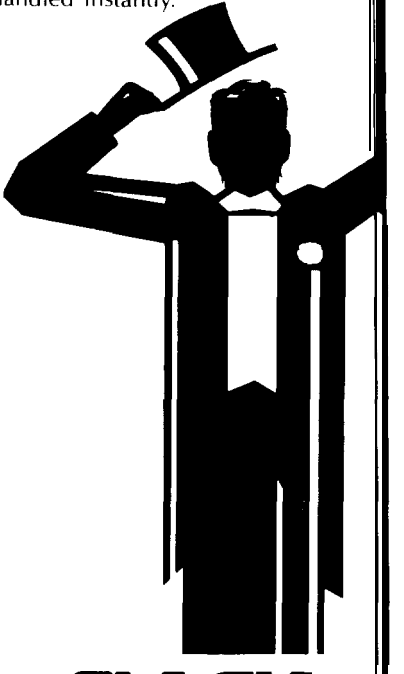
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The ideas and opinions expressed by contributing authors do not necessarily reflect those of the editors or publisher.

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

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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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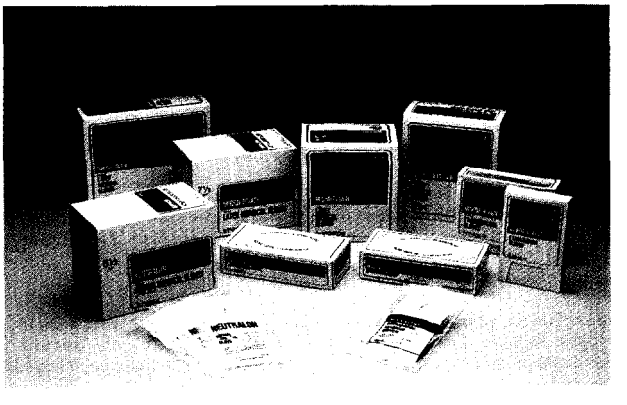
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