INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

Volume 11, Number 3 • March 1990

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‡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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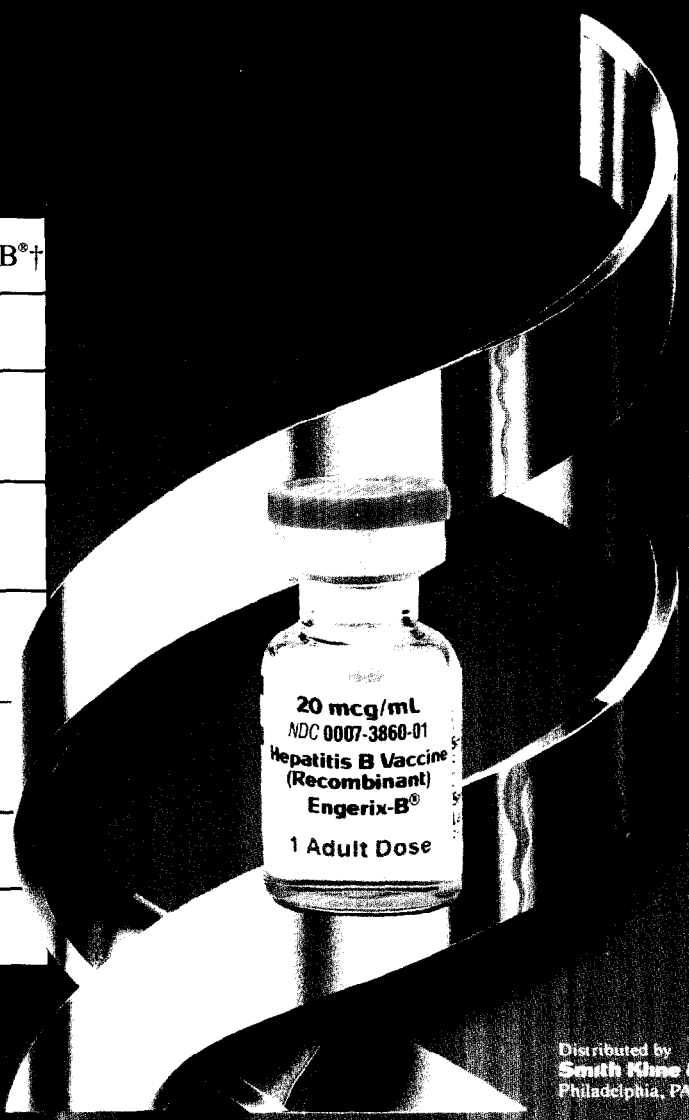
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	Yes	No
	Yes	Yes
	Yes	No
	Yes	No
	Yes	No



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INDICATIONS AND **USAGE:** 'Engerix-B' is indicated for immunization against infection caused by all know subtypes of hepatitis B virus. Immunization is recommended in parsons of all ages, especially those who are or will be, al increased risk d exposure to hepatitis B virus.

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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 al the time of vaccine administration Additionally, 1 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 of active infection

Pregnancy: Pregnancy Category C Animal reproduction studies have not been conducted with 'Engerix-B' Il is ako not known whether 'Engerix-B' can cause fetal harm when administered lo 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 hiih ly immunogenic in infants and children of all ages. Newborns also respond well; maternally transferred antibodies do not interfere with the active immune response lo 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 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 lo 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 di diverse experiences tended lo decrease with successive doses of 'Engerix-B' Using a symptom checklist," the mod frequently reported adverse reactions were injection site soreness (22%), and fatigue* (14%). Mher reactions are listed below

Incidence 1% **to 10%** et **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-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 011.10 and 25 vials.

NOC 0007-3860-01 (package of 1)
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† plasma-derived, Hepatitis B Vaccine, MSD.
‡ yeast-derived, Hepatitis B Vaccine, MSD

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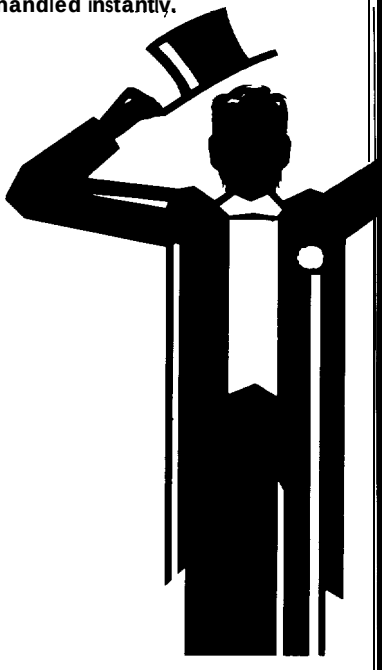
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The ideas and opinions expressed by contributing authors do not necessarily reflect those of the editors or publisher.

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*

https://doi.org/10.1086/646132 Published online by Cambridge University Press

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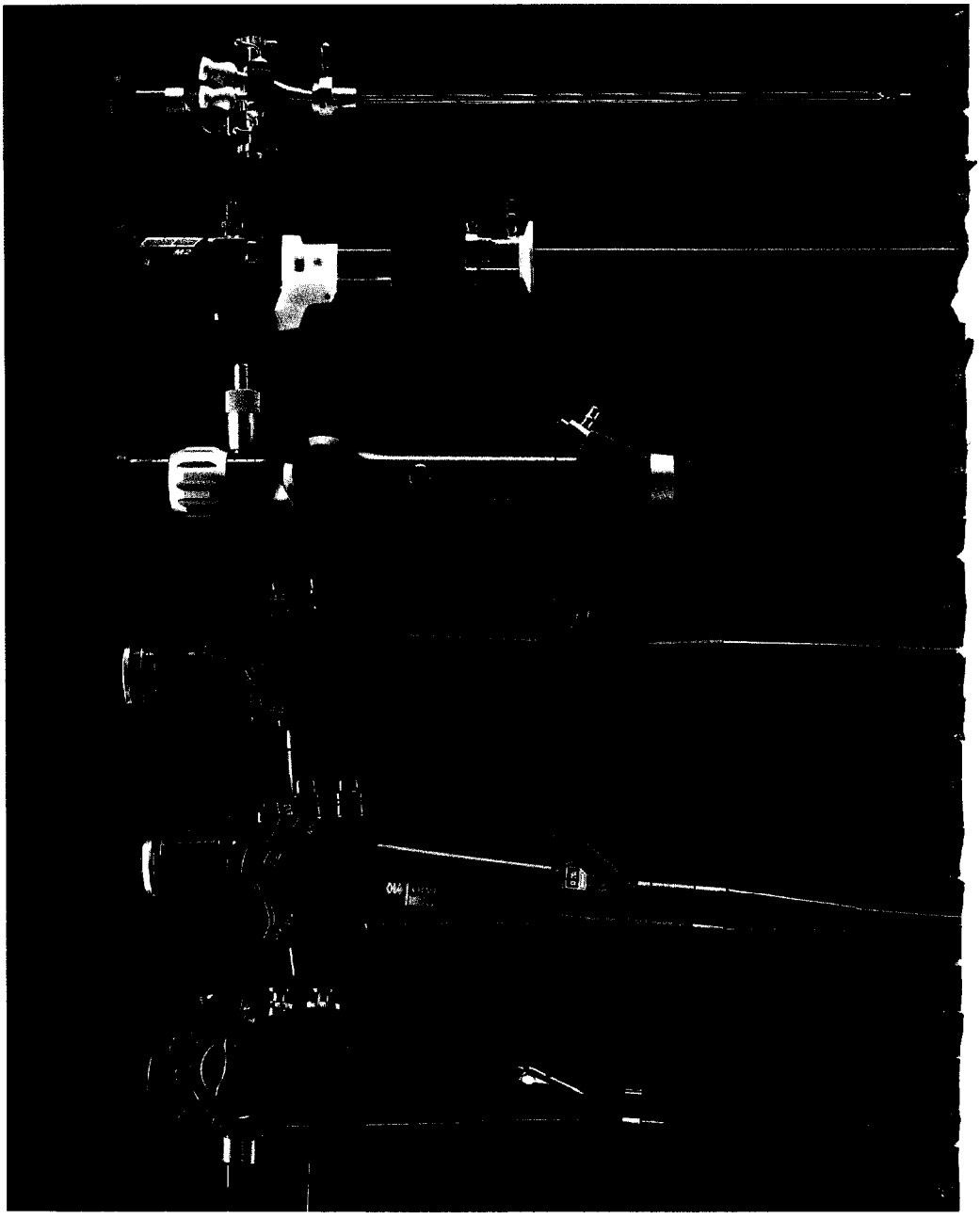
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