INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

Volume 11, Number 8 • August 1990

Special Update

The Fifth Consensus Conference on Testing for Human Retroviruses

Sponsored by the Association of State and Territorial Public Health Laboratories

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†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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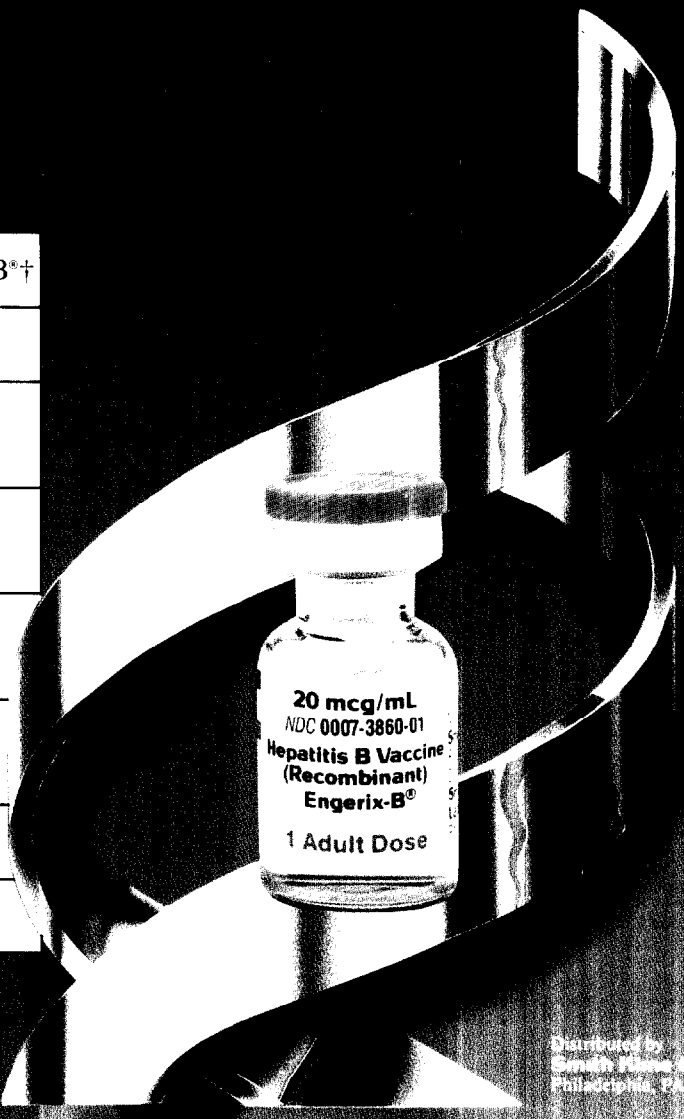
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Can be used to complete a course of vaccination initiated with another hepatitis B vaccine[3,4]

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20	10
Yes	Yes
Yes	No
Yes	Yes
Yes	No
Yes	No
Yes	No



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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 hepatitis B virus.

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

WARNINGS: Da not give additional injections to patients experiencing hypersensitivity after an 'Engerix-B' injection (See CONTRAINDICATIONS)

Hepatitis B has a long incubation period Hepabbs B vaccination may not revent hepabbs B infection in individuals who had an unrecognized hepatitis 6 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 vaccme. delay administration, 1 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 'Engenx 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 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 vaccme. 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-dewed vaccines In 36 clinical studies a total of 13,495 doses of 'Engenx 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, Hushing; 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; Luck 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 Slates. 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; eczema, purpura; herpes zoster, vertigo; conjunctivitis; keratitis; visual disturbances

Potential Adverse Experiences: In addrbon, certain other adverse experiences not observed with 'Engenx 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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† plasm&derived, Hepatitis B Vaccine, MSD
‡ yeast-derived, Hepatitis B Vaccine, MSD

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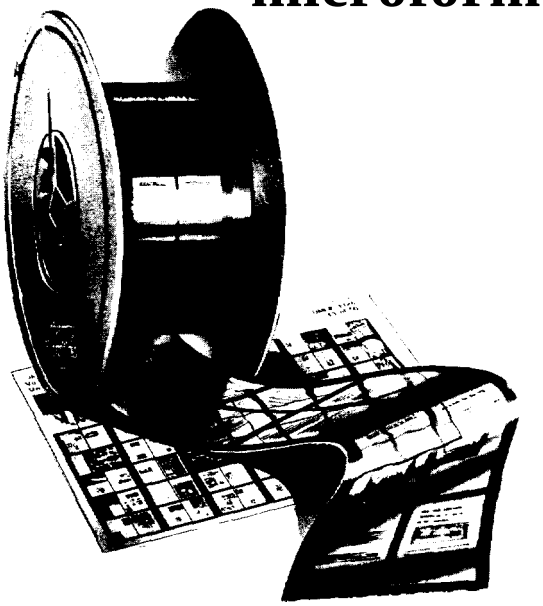
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1. Poovorawan Y, Sanpavat S, Pongpunlert W, et al: Protective efficacy of a recombinant DNA hepatitis B vaccine in neonates of HBe antigen-positive mothers. *JAMA* 1989; 261(22):3278–3281. 2. Based on Medi-Span* Hospital Formulary Pricing Guide, December 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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* *Journal of Clinical Microbiology, November 1985, p. 735 - 739*



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