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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

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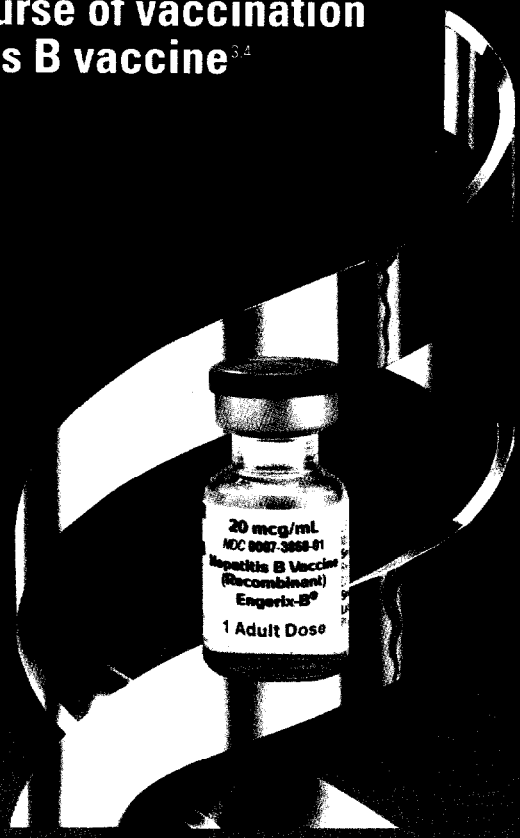
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‡Please see brief summary of prescribing information on adjacent page for a complete listing of adverse reactions, contraindications, warnings and precautions.

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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 uss 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 to 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 10,030 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 2,262 subjects showed no significant difference in the frequency or severity of adverse experiences between 'Engerix-B' and plasmaderived 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 19% **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-Barré syndrome and Bell's palsy; transverse myelitis; thrombocytopenia; eczema; purpura; herpes zoster; vertigo; conjunctivitis; keratitls; 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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NDC 58160-859-01 (package of 1)

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

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Date of issuance Sept. 1990

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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 1990. 3. Data on file, SmithKline Beecham Pharmaceuticals. 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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