INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

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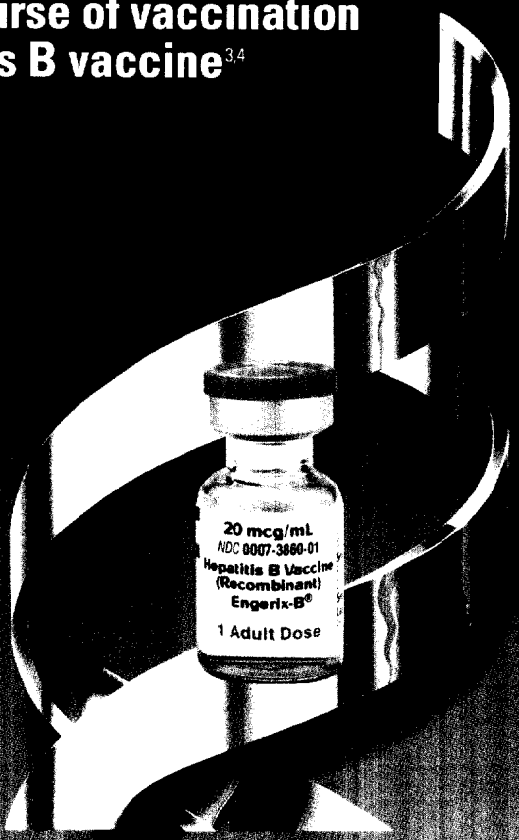
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Hepatitis B has a long incubation period. Hepatitis B vaccination may not prevent hepatitis B infection in individuals who had an unrecognized hepatitis B infection at the bme of vaccme administration Additionally, it may not prevent infection in individuals 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, 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 mlk, 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 10,000 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 weal 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 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; lever (> 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: P a m : 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; ngrrzane; syncope; paresis; neuropathy including hypoesthesia, paresthesia, Guiin-Barré syndrome and Belt'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 to physicians: Optic neuritis.

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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 Pricmg 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 vaccme and completing it with another. *Hepatology* 1989;10:689.

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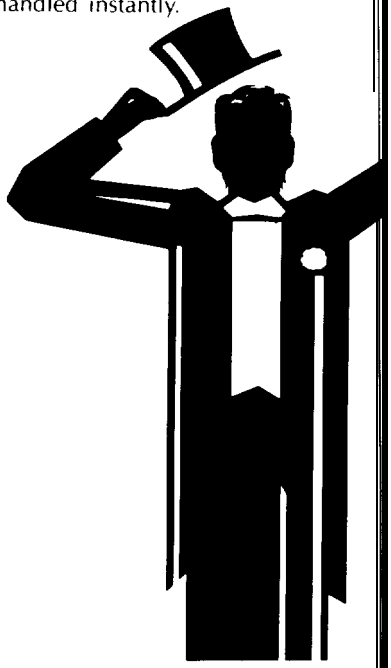
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