INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

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Lowest cost per dose[2]

*For those recently exposed to the virus (including needlestick exposure), certain travelers to high-risk areas, and neonates born of infected mothers. When prolonged maintenance of protective antibody titers is desired, a booster dose at month 12 is recommended.

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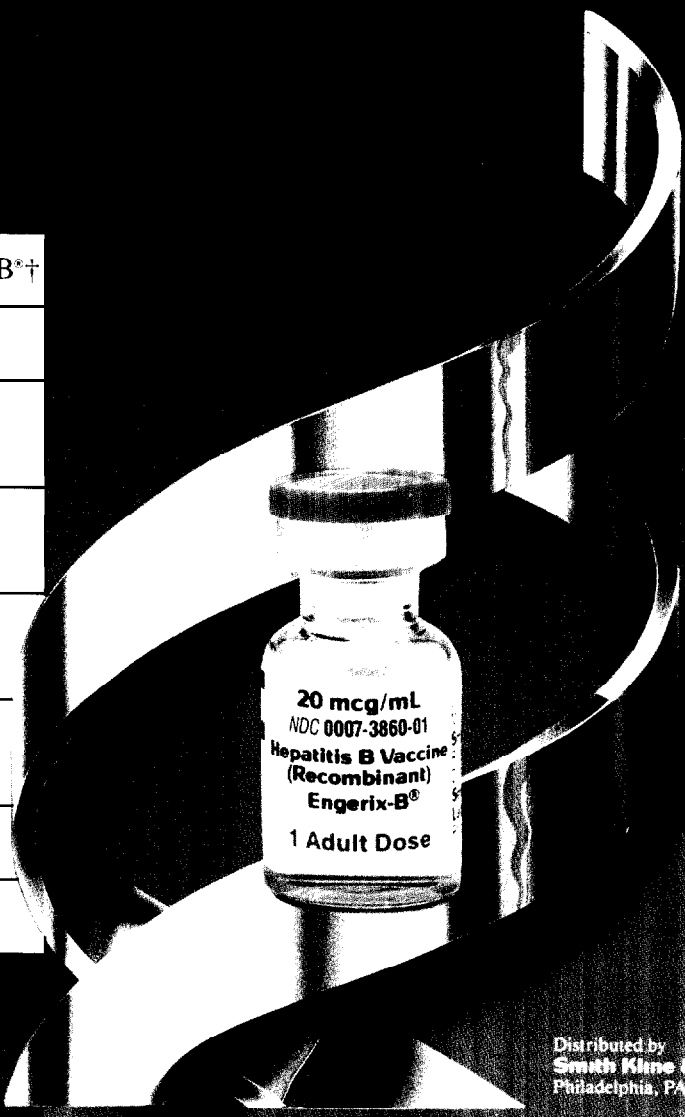
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Can be used to complete a course of vaccination initiated with another hepatitis B vaccine[3,4]

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



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Philadelphia, PA 19101

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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, al increased risk of exposure to hepatitis El virus

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 t o patients experiencing hypersensitivity alter 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 a* *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 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 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 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 were reported As with any vaccme, 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-dewed 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, fever (> 37.5%): 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, flushmg, 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 includm g 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

NDC 0007-3860-01 (package of 1)
NDC 0007-3860-11 (package of 10)
NDC 0007-3860-16 (package of 25)

10 mcgl0.5 mL in Single-Dose Vials in packages of 1 vial

NDC 0007-3859-01 (package Ot 1)

† *plasma-derived, Hepatitis B Vaccine*, MSD
‡ yeast-dewed. 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 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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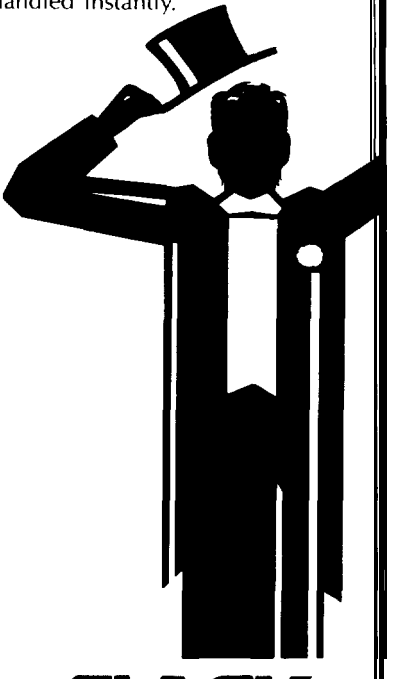
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* *Journal of Clinical Microbiology, November 1985, p. 735 - 739*



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