INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

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From SmithKline Biologicals/
Smith Kline &French Laboratories

Engerix-B®

Hepatitis B Vaccine (Recombinant)

0, 1, 2 Month Dosing Regimen for Certain Populations*

20 mcg recombinant dose helps to ensure immune response in adult patients of all ages

Choice of dosing regimens

Adult dose (mcg)
Standard dosing regimen (0, 1 and 6 months)
New 0, 1, 2 month dosing regimen for certain populations*
Published efficacy data: Neonates born of infected mothers'
VACTRAC™—computer software for vaccination tracking and compliance
Bar-coded, unit-dose vials
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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Lowest Cost Per Dose[2]

Extensively Tested and Well Tolerated‡

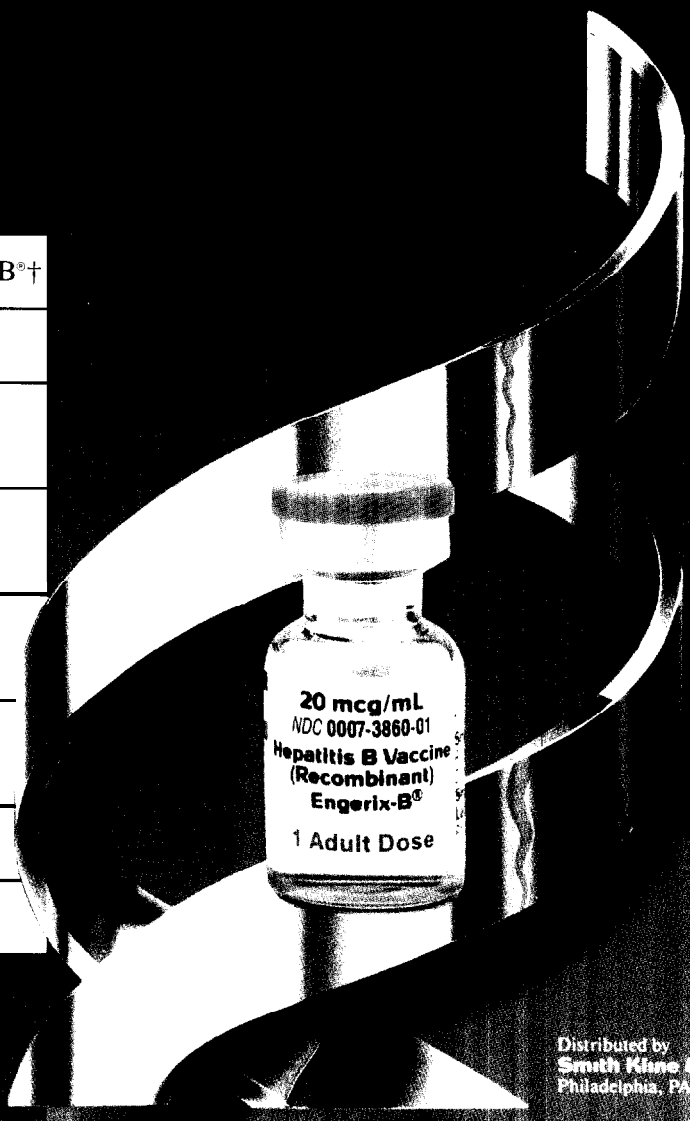
State-of-the-art recombinant technology

14 million doses distributed in over 87 countries[3]

Switch to 'Engerix-B'

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

Engerix-B®	Recombivax HB®†
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 hepabbs B 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 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 hepabbs 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 use 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 Uu: '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-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% Ia **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, 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 Stales 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 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 mcg/0 5 mL in Single-Dose Vials in packages of 1 vial

NDC 0007-3859-01 (package of 1)

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

Manufactured by **SmithKline Biologicals**, Rixensart, Belgium
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Date of issuance Aug. 1989

BRS-EB L6

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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. Damon 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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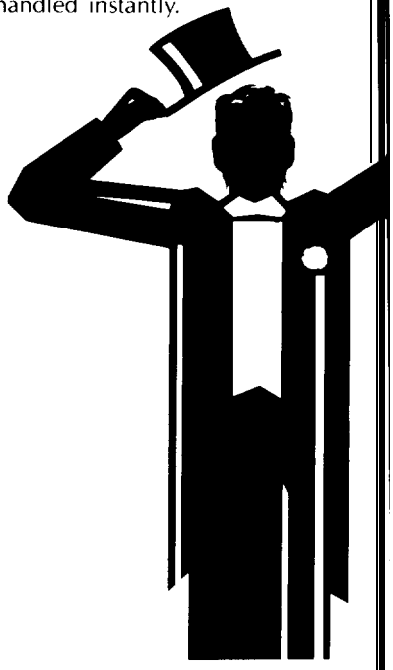

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* *Journal of Clinical Microbiology, November 1985, p. 735 - 739*

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