INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

Volume 11, Number 12 • December 1990

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The Official Journal of The Society of Hospital Epidemiologists of America

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From SmithKline Biologicals

20 mcg/mL

Engerix-B®

Hepatitis B Vaccine (Recombinant)

Choice of dosing regimens

Alternate 0, 1, 2 month dosing regimen for certain populations*

20 mcg recombinant dose

Helps to ensure immune response in adult patients of all ages

	Engerix-B®	Recombivax HB®†
Adult dose (mcg)	20	10
Standard dosing regimen (0, 1 and 6 months)	✓	✓
Alternate 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.

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Lowest Cost Per Dose[2]

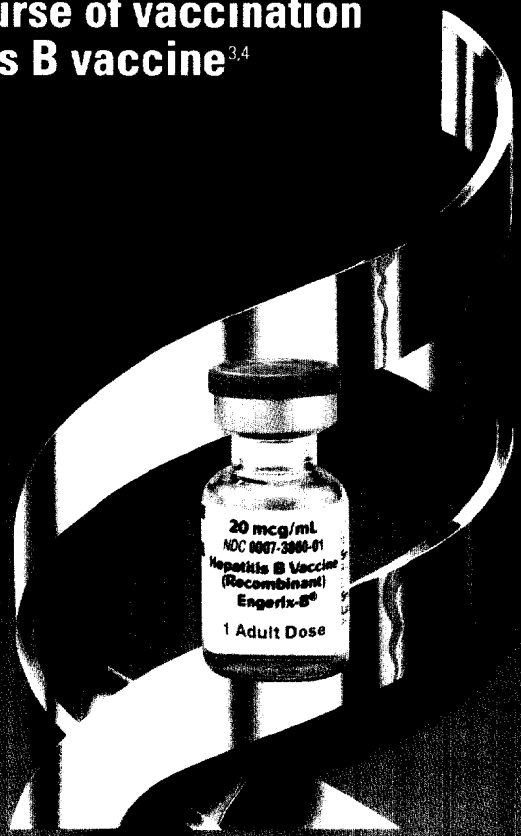
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State-of-the-art recombinant technology

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]



†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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Engerix-B®

Hepatitis B Vaccine (Recombinant)

See complete prescribing information In **SK&F literature** or ***PDR***. **The** following **is a brief summary.**

INDICATIONS A N D **USAGE:** 'Engerix-B' i s 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 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** pabents **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 an **unrecognized hepatitis B infection** al the bme **of vaccine administration. Additionally, it** may not **pre**vent **infection in individuals** who do not **achieve protective antibody titers**

PREUUTIDNS: **General:** As with any **percutaneous vaccine,** keep **epi**nephrine **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 repro**duction 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 **10,000 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 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** seventy **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** Ail **subjects** were monitored **for** 4 days **post-administration. Fre**quency of adverse experiences tended lo decrease **with successive** doses **of** 'Engerix-B'. Using a symptom checklist.' the **most** frequently reported **ad**verse **reactions** were **injection** site soreness **(22%),** and fatigue' (14%) Other reactions are listed **below:**

Incidence 1% lo **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% o f In **ections:** Pain; pruritus; ecchymosis; sweating; malaise; chills; weakness; **flushing; tingling; hypotension; influenza-like symp**toms; upper **respiratory tract** illnesses; nausea, **anorexia; abdominal pain/** cramps: **vomiting; constipation; diarrhea; lymphadenopathy; pain/stiffness** in am, shoulder or neck. **arthralgia; myalgia;** back **pain;** rash; **urticaria; pete**chiae; **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 includ**ing Stevens-Johnson syndrome; **angioedema; arthritis; tachycardia/palpita**tions; **bronchospasm including asthma-like** symptoms. **abnormal liver func**tion tests: **migraine; syncope; paresis; neuropathy** Including **hypoesthesia, paresthesia, Guiin-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.

NOC **0007-3860-01** (package **of** 1)
NDC 0007.3860-I 1 (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.

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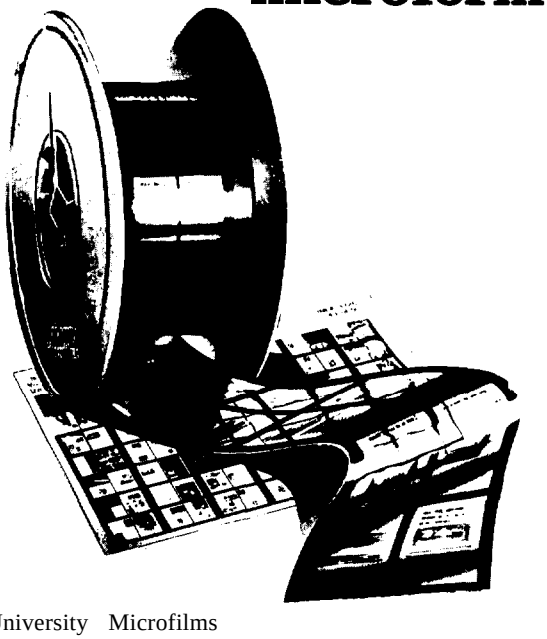
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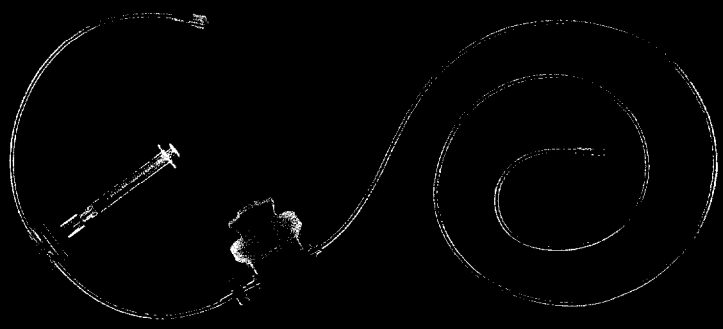
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