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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

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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]	✓	

https://doi.org/10.1016/0899823X00085019

*For those recently exposed to the virus (including needlestick exposure), certain travelers to high-risk areas and neonates born of

Protection Against Hepatitis B

Lowest Cost Per Dose[2]

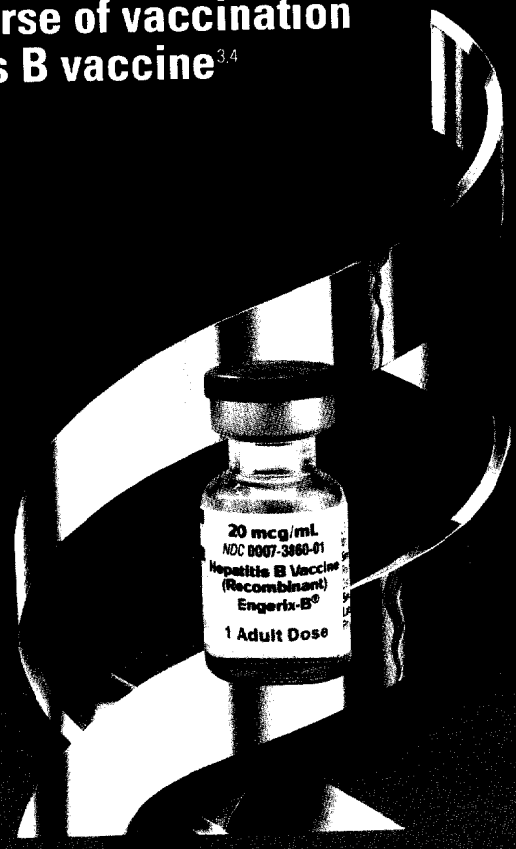
Extensively tested and well tolerated‡

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]



†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.

Visit us at APIC, Island G.

Engerix-B®

Hepatitis B Vaccine (Recombinant)

See complete prescribing information in SmithKline Beecham Pharmaceuticals 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 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 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 use in case of anaphylaxis M 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. Ge '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 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 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 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; 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 M 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 58160-860-01 (package of 1)
NDC 58160-860-11 (package of 10)
NDC 58160-860-16 (package of 25)

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

NDC 58160-859-01 (package of 1)

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

Manufactured by **SmithKline Biologicals**, Rixensart, Belgium
Distributed by **SmithKline Beecham Pharmaceuticals**, Philadelphia. PA 19101

Dated issuance Sept. 1990

BRS-EB:L8A

Engerix-B is a registered trademark of SmithKline Beecham.

References:
1. Poovorawan Y, Sanpavat S, Pongpunlert w. et al: Protective efficacy of a recombinant DNA hepatitis B vaccine in neonates of HBe ant'igen-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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Each summer, MDA camps provide a special outdoor world-without-barriers to children disabled by neuromuscular disorders. Despite leg braces and wheelchairs, these children swim and fish. They go boating. They horseback ride. They have cookouts and crafts. And each youngster shares a special friendship with a volunteer counselor who *works* one-on-one with the child.

Summer camps are just one way MDA serves patients with neuromuscular diseases. The Association also maintains some 230 clinics around the country to provide essential services like diagnosis, medical follow-up, physical therapy and counseling. And MDA provides orthopedic equipment and other aids for daily living, all free of charge to the patient and his family.

MDA receives no government grants or fees for services — its programs are funded entirely by private donations. For thousands of patients with neuromuscular diseases, you can be the best medicine. Please send a tax-deductible contribution today.

MDA®

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Jerry Lewis, National Chairman

To make a donation *or* bequest *to MDA, to receive an annual report or to obtain more information, write to: Muscular Dystrophy Association, 810* Seventh *Avenue, New York, NY 10019. Or contact your local MDA office.*

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OSHA VAPOR LIMIT

OSHA has set 0.2 ppm as the permissible exposure limit for glutaraldehyde.[1]

Sporicidin offers important advantages. When diluted for 100% hospital level disinfection, it contains 0.13% glutaraldehyde. With good cross-ventilation, this can avoid the need for special ventilation equipment to stay within the never-to-be exceeded ceiling of 0.2 ppm.

Greater ventilation and space areas are required when using 2% glutaraldehyde solutions. It is reported that a room volume of air 550 times greater than that of the soaking container is needed for 2% glutaraldehyde, while only 33 times greater is needed for Sporicidin.[2]

It's reassuring to know that you can lessen the risk of over-exposure to glutaraldehyde, offer greater protection to your staff and reduce your space and ventilation requirements as well by using

ANOTHER REASON TO DISINFECT WITH SPORICIDIN

References: 1. Federal *Register, Vol.* 54, No. *12, Jan.* 79, 7989 2. Hospital Hazardous Materials *Management, Vol. 3, No. 2, November 1989* Sporicidin International 5901 **Montrose** Rd., **Rockville,** Md. 20852

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