INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

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From SmithKline Biologicals/SK&F

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‡

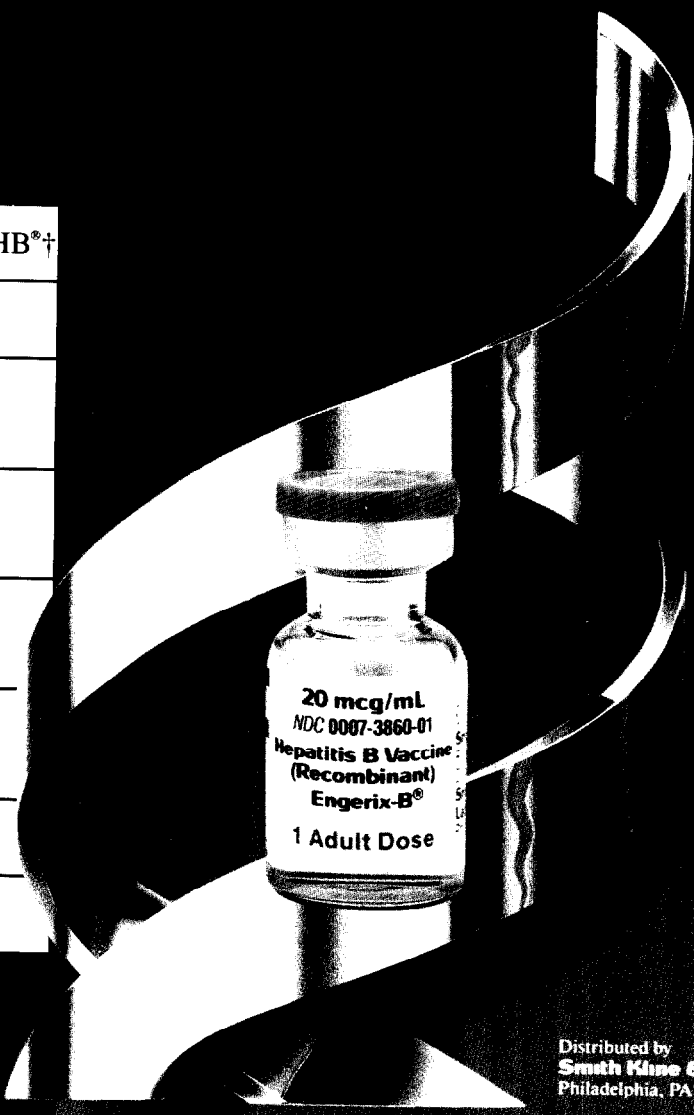
State-of-the-art recombinant technology

10 million doses distributed in over 80 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



Manufactured by
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Rixensart, Belgium

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Smith Kline &French Laboratories
Philadelphia, PA 19101

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Engerix-B®

Hepatitis B Vaccine (Recombinant)

Sos **complete prescribing information** In **SK&F literature** or ***PDR.*** **The following** IS **abrief 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 ivgive' aoaral injections* I · *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 hepatibs B infection al the bme 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, 1 possible, in persons with any febrile illness or active infection

Pregnancy: Pregnancy Ctegory 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: il is not known whether 'Engerix-B' is excreted in human milk Because many drugs are excreted in human mitk, use caution when giving 'Engerix-B' lo a nursing woman

Pediatric Use: 'Engerix-B' has been shown lo 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' 6 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 plasma-derived vaccines. In 36 clinical studies a total d 13.496 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 am. shod&r *or* neck. *arthralgia; myalgia;* back *pain;* rash; *urticaria; petechiae;* erythema; somnolence; insomnia; irritability; agitation

Additional adverse experiences have been reported with the commercial "se d 'Engerix-B' outside the United States Those listed below are to serve as alerting information to physicians: Anaphytaxis; 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, Guäin-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 lo 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)
NOC 0007-3860-16 (package of 25)

10 mcg/0.5 mL in Single-Dose Vials in packages of 1 vial.

NOC 0007-3859-01 (package d 1)

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t plasma-derived, Hepatitis B Vaccine, MSD
‡ yeast-derived, Hepatitis 6 Vaccine, MSD.

Manufactured by **SmithKline Biologicals**, Rixensart, Belgium
Distributed by **Smith Kline & French Laboratories**
Division of SmithKline Beckman Corp., Philadelphia, PA 19101

Date of issuance Aug. 1989

BRS—EB:L6

Engerix-B is a registered trademark of SmithKline Beckman Corporation.

References:
1. Poovorawan Y, Sanpavat S, Pongpunlert W, et al: Protective efficacy cd a recombinant DNA hepatitis B vaccine in neonates cd HBe antigen-positive mothers. *JAMA* 1989; 261(22):3278–3281. 2. Based on Medi-Span® Hospital Formulary Pricing Guide, December 1989. 3. Data on tile, SK&F. 4. Bush L, Moonsammy G, Boscia 1: Evaluation of initiating a hepatitis B vaccination schedule with one vaccine and completing it with another. *Hepatology* 1989;10:689.

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

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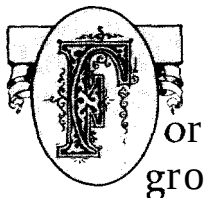

or over a century, that philosophy has guided the growth of the largest and most diversified health care company in the world. Today, as we continue to grow in response to a health care marketplace where the need for effective infection control and wound care products, as well as efficient, specialized services, has never been greater, we can still conceive of no higher purpose.

Johnson &Johnson Medical Inc. was created to better meet your needs in the coming decade. Over the years, ***Johnson &Johnson Patient*** Care, *Surgikos* ***and Sterile Design*** have provided health care professionals with a wide range of products and a valuable body of knowledge in the critical area of infection control. Now, they come together as Johnson & Johnson Medical Inc., giving you a single source of continued support in the vital areas of infection control and wound care, while responding to the ever-increasing need for economic efficiencies. We dedicate Johnson & Johnson Medical Inc. to you, the health care professional, as we prepare to meet the special challenges of the 1990s together.

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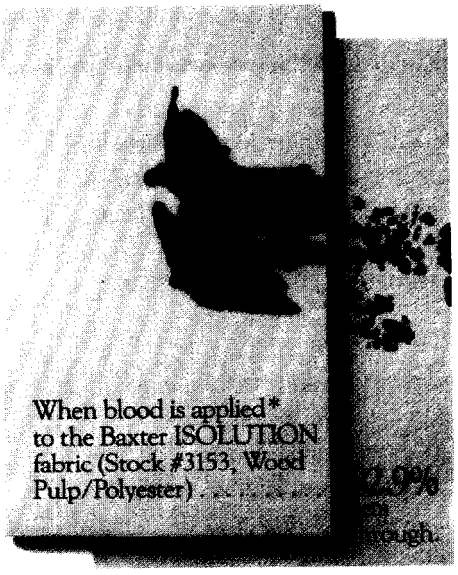
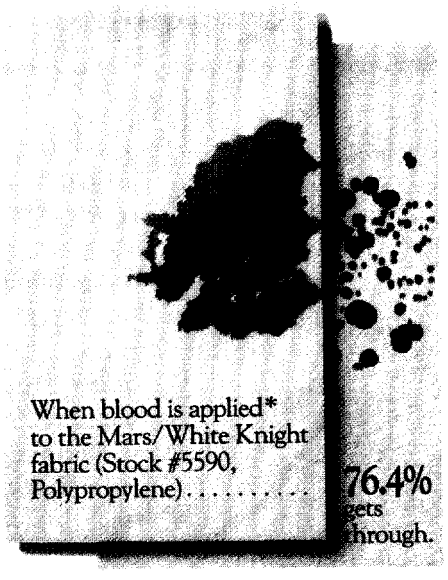
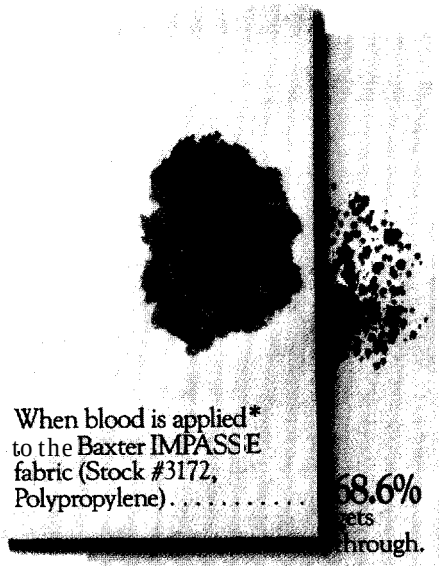
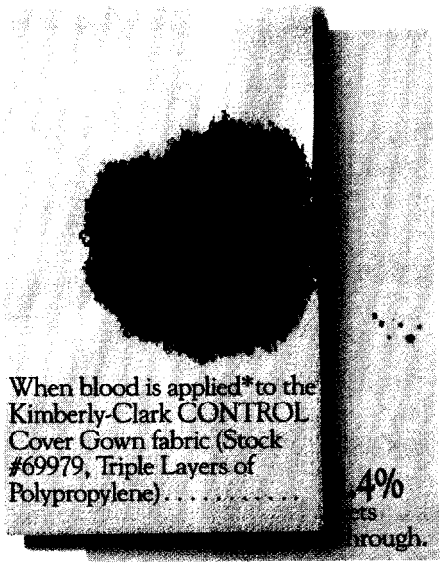
SPOT THE #1 COVER GOWN









*applied at 0.5 psi of pressure

1 Eisenach, K., T. Yamauchi, B. Johnson, and R. Clarke. 1989. Resistance of cover gowns to microbially contaminated human body fluids. Abstr. Annu. Meet. of Interscience Conf. on Antimicrob. Agents and Chemother., 604, p.202.

2 Klein, B.S., W.H. Perloff, and D.G. Maki. 1989. Reduction of nosocomial infection during pediatric intensive care by protective isolation. N. Engl. J. Med. 320: 1714-1721.

CONTROL" Cover Gowns from Kimberly-Clark are the #1 choice for many reasons, but none more critical than the superior barrier protection shown in these unretouched photos. Simply put, they far outperform other gowns.

Two major independent studies support CONTROL Cover Gowns' superior performance.

In a study at Arkansas Children's Hospital, CONTROL Cover Gowns were shown to be more protective against contaminated body fluids! And a study published in The New England Journal of Medicine showed that CONTROL Cover Gowns and gloves significantly reduced nosocomial infection in pediatric intensive care!

Cross-section of CONTROL Cover Gown Fabric

The key is CONTROL Cover Gowns' unique, three-layer laminated fabric with an inner layer of polypropylene microfibers. This inner layer forms a barrier to screen out bacteria and resist fluid penetration. Yet, this remarkable cloth-like fabric is also highly breathable and tear resistant.

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