INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

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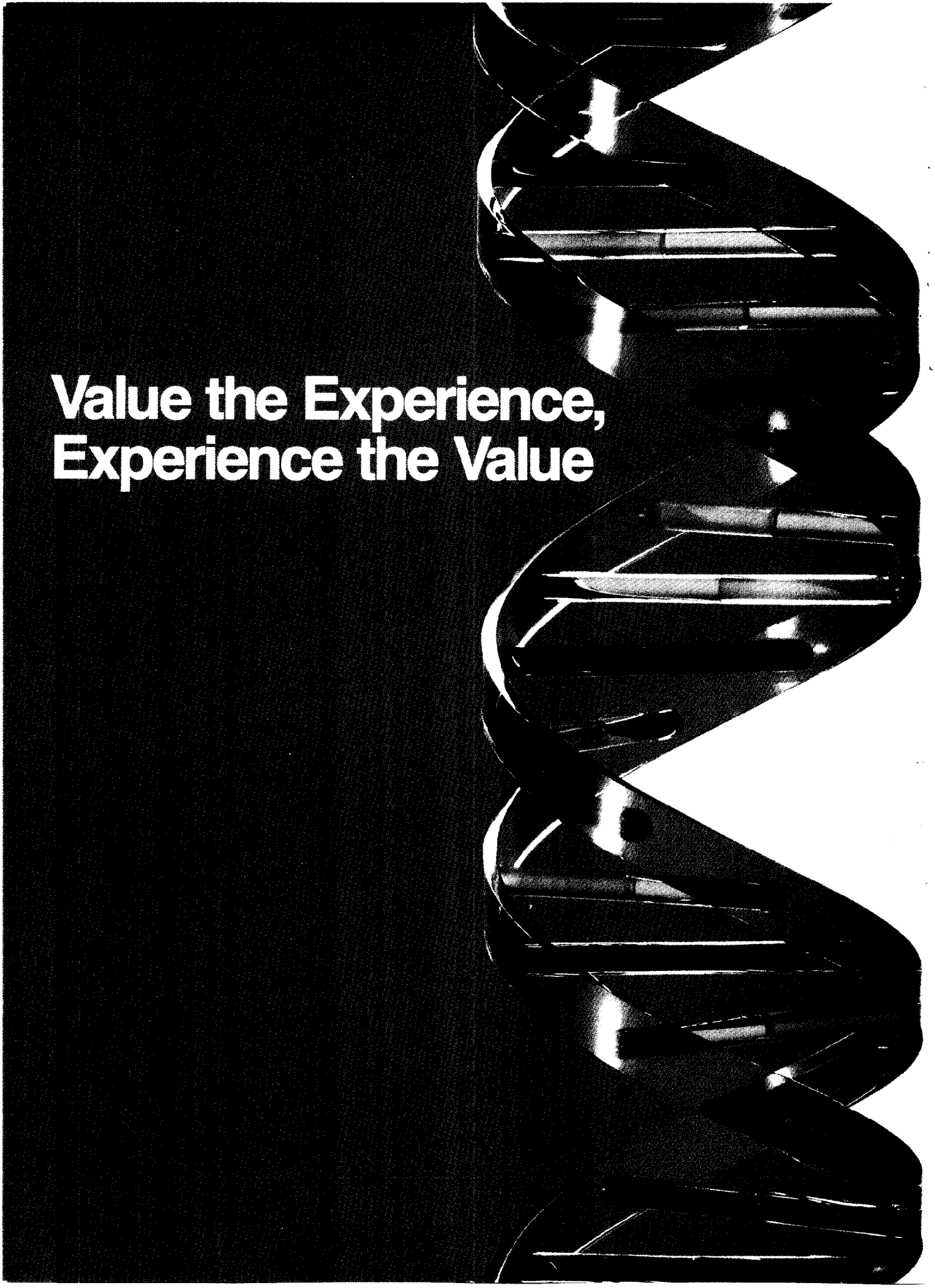

Value the Experience

. Over 2.6 million doses distributed in the United States

. In clinical trials, three IO-mcg doses induced protective levels of antibodies in 96% of healthy adults

. Contains no detectable yeast DNA and not more than 1% yeast protein

. Generally well tolerated in over three years of clinical use

Experience the Value

- Innovative services to help support your vaccination program

. Wide range of doses includes 40-mcg/mL Dialysis Formulation

. Now a 2.5-mcg pediatric dose may reduce vaccine costs by 50%

- Available in convenient multidose vials direct from MSD

Recombivax HB®

(Hepatitis B Vaccine [Recombinant] 1 MSD)

RECOMBIVAX HB is contraindicated in the presence of hypersensitivity to yeast or to any component of the vaccine.

Please see the following page for a Brief Summary of Prescribing Information for RECOMBIVAX HB.

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Value the Experience, Experience the Value

Recombivax HB®
(Hepatitis B Vaccine [Recombinant] | MSD)

INDICATIONS AND USAGE

RECOMBIVAX HB is indicated for vaccination against infection caused by all known subtypes of hepatitis B virus. RECOMBIVAX HB Dialysis Formulation is indicated for vaccination of adult predialysis and dialysis patients against infection caused by all known subtypes of hepatitis B virus.

Vaccination with RECOMBIVAX HB is recommended in persons of all ages who are or will be at increased risk of infection with hepatitis B virus. In areas with high prevalence of infection, most of the population are at risk of acquiring hepatitis B infection at a young age. Therefore, vaccination should be targeted to prevent such transmission. In areas of low prevalence, vaccination should be limited to those who are in groups identified as being at increased risk of infection.

CONTRAINDICATIONS

Hypersensitivity to yeast or any component of the vaccine.

WARNINGS

Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine (see CONTRAINDICATIONS).

Because of the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis Bin such patients.

PRECAUTIONS

General

As with any percutaneous vaccine, epinephrine should be available for immediate use should an anaphylactoid reaction occur.

Any serious active infection is reason for delaying use of the vaccine except when, in the opinion of the physician, withholding the vaccine entails a greater risk.

Caution and appropriate care should be exercised in administering the vaccine to individuals with severely compromised cardiopulmonary status or to others in whom a febrile or systemic reaction could pose a significant risk.

Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with the vaccine. It is also not known whether the vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The vaccine should be given to a oreanant woman only if clearly needed.

Nursing Mothers

It is not known whether the vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when the vaccine is administered to a nursina woman.

Pediatric Use

RECOMBIVAX HB has been shown to be usually 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. See DOSAGE AND ADMINISTRATION for recommended pediatric dosage and for recommended dosaae for infants born to HBsAg-positive mothers.

The safety and effectiveness of RECOMBIVAX HB Dialysis Formulation in children have not been established.

ADVERSE REACTIONS

RECOMBIVAX HB and RECOMBIVAX HB Dialysis Formulation are generally well tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. No adverse experiences were reported during clinical trials which could be related to changes in the titers of antibodies to yeast. As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

In a group of studies. 3,258 doses of RECOMBIVAX HB were administered to 1.252

healthy adults who were monitored for 5 days after each dose. Injection-site and systemic complaints were reported following 17% and 15% of the injections, respectively.

The following adverse reactions were reported:

Incidence Equal to or Greater Than 1% of Injections

LOCAL REACTION (INJECTION SITE)

Injection-site reactions consisting principally of soreness and including pain, tenderness, pruritus, erythema, ecchymosis, swelling, warmth, and nodule formation.

BODY AS A WHOLE

The most frequent systemic complaints include fatigue/weakness; headache; fever (≥100°F); malaise.

DIGESTIVE SYSTEM

Nausea; diarrhea.

RESPIRATORY SYSTEM

Pharyngitis; upper respiratory infection.

Incidence Less Than 1% of Injections

BODY AS A WHOLE

Sweating; achiness; sensation of warmth; lightheadedness: chills: flushino.

DIGESTIVE SYSTEM -

Vomiting; abdominal pains/cramps; dyspepsia; diminished appetite.

RESPIRATORY SYSTEM

Rhinitis; influenza; cough.

NERVOUS SYSTEM

Vertigo/dizziness; paresthesia.

INTEGUMENTARY SYSTEM

Pruritus; rash (non-specified); angioedema; urticaria.

MUSCULOSKELETAL SYSTEM

Arthralgia including monoarticular; myalgia; back pain; neck pain; shoulder pain; neck stiffness.

HEMIC/LYMPHATIC SYSTEM

Lymphadenopathy.

PSYCHIATRIC/BEHAVIORAL

Insomnia/disturbed sleep.

SPECIAL SENSES

Earache.

UROGENITAL SYSTEM

Dysuria.

CARDIOVASCULAR SYSTEM

Hypotension.

The following additional adverse reactions have been reported with use of the marketed vaccine. In many instances, the relationship to the vaccine was unclear.

Hypersensitivity: Anaphylaxis and symptoms of immediate hypersensitivity reactions including rash, pruritus, urticaria, edema, angioedema, dyspnea, chest discomfort, bronchial spasm, palpitation, or symptoms consistent with a hypotensive episode have been reported within the first few hours after vaccination. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including arthralgia/arthritis (usually transient), fever, and dermatologic reactions such as urticaria. erythema multiforme, ecchymoses, and erythema nodosum (see WARNINGS and PRECAUTIONS).

Nervous System: Peripheral neuropathy including Bell's Palsy; muscle weakness: Guillain-Barré syndrome.

Special *Senses:* Optic neuritis.

Potential ADVERSE EFFECTS

In addition, a variety of adverse effects not observed in clinical trials with RECOMBIVAX HB or RECOMBIVAX HB Dialysis Formulation have been reported with HEPTAVAX-B® (Hepatitis B Vaccine, MSD)(plasma-derived hepatitis B vaccine). Those listed below are to serve as alerting information to physicians:

Nervous System: Neurological disorders such as myelitis including transverse myelitis; acute radiculoneuropathy; herpes zoster.

Hematologic: Thrombocytopenia.

Special Senses: Tinnitus; visual disturbances.

RECOMBIVAX HB®
(Hepatitis B Vaccine [Recombinant], MSD)

DOSAGE AND ADMINISTRATION

Do not inject *intravenously or intradermally.*

RECOMBIVAX HB DIALYSIS FORMULATION (40 mcg/mL) IS INTENDED ONLY FOR ADULT PREDIALYSIS/DIALYSIS PATIENTS.

RECOMBIVAX HB (10 mcg/mL) IS NOT INTENDED FOR USE IN PREDIALYSIS/DIALYSIS PATIENTS.

RECOMBIVAX HB and RECOMBIVAX HB Dialysis Formulation are for intramuscular injection. The *deltoid muscle* is the preferred site for intramuscular injection in adults. Data suggest that injections given in the buttocks are frequently given into fatty-tissue instead of into muscle. Such injections have resulted in a lower seroconversion rate than was expected. The *anterolateral thigh* is the recommended site for intramuscular injection in infants and young children.

For persons at risk of hemorrhage following intramuscular injection, RECOMBIVAX HB may be administered subcutaneously. However, when other aluminum-adsorbed vaccines have been administered subcutaneously, an increased incidence of local reactions including subcutaneous nodules has been observed. Therefore, subcutaneous administration should be used only in persons (e.g., hemophiliacs) who are at risk of hemorrhage following intramuscular injections.

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

The RECOMBIVAX HB vaccination regimen consists of 3 doses of vaccine. The volume of vaccine to be given on each occasion is as follows:

Age group	Initial	1 month	6 months
Birth* through 10 years of age	0.25 mL (2.5 mcg)	0.25 mL (2.5 mcg)	0.25 mL (2.5 mcg)
11-19 years of age	0.5 mL (5 mcg)	0.5 mL (5 mcg)	0.5 mL (5 mcg)
≥20 years	1 mL (10 mcg)	1 mL (10 mcg)	1 mL (10 mcg)

'Infants born of HBsAg-negative mothers.

The recommended RECOMBIVAX HB Dialysis Formulation vaccination regimen for predialysis/dialysis patients is as follows:

Group	Formulation	Initial	1 month	6 months
Predialysis and Dialysis Patients	Dialysis 40 mcg/mL	1 mL	1 mL	1 mL

Whenever revaccination or administration of a booster dose is appropriate, RECOMBIVAX HB may be used.

The recommended regimen for infants born of HBsAg-positive mothers is as follows:

	Birth	Within 7 days	1 month	6 months
RECOMBIVAX HB		0.5 mL (5 mcg)	0.5 mL (5 mcg)	0.5 mL (5 mcg)
HEPATITIS B IMMUNE GLOBULIN	0.5 mL	—	—	—

Storage

Store vials at 2°–8°C (36°–46°F). Storage above or below the recommended temperature may reduce potency.

Do not freeze since *freezing destroys potency*

For more detailed information! consult your MSD Representative or see Prescribing Information. Merck Sharp & Dohme, Division of Merck & Co., INC., West Point, PA 19466. J9RX08 (206)

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

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