Mupirocin Ointment Indications

To the Editor:

In the recent article by Cederna, et al. (1990;11:13-16), mupirocin ointment was used successfully to treat nasal colonization with *Staphyloccocus aureus* in the nursing home setting. The formulation used in this study was mupirocin 2% ointment in a polyethylene glycol base. Professor Neu, in his editorial (1990;11:11-12), pointed out that this formulation is indicated for topical skin use but not for nasal use. Professor Neu also makes a plea that the study by Cederna, et al. should not be duplicated with unapproved medication.

SmithKline Beecham, as manufacturers of mupirocin, would wholeheartedly concur with Professor Neu's comments.

Mupirocin in a polyethylene glycol base is not indicated for topical application to nasal mucous membranes. Another more appropriate formulation of mupirocin in a white soft paraffin base (without polyethylene glycol) is undergoing clinical trials in the United States and other countries, and already is available for general prescribing in the United Kingdom as Bactroban Nasal (SmithKline Beecham Pharmaceuticals, London, England).

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Letters to the Editor should be addressed to INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY Editorial Offices, C41 General Hospital, University of Iowa Hospitals and Clinics, Iowa City, IA 52242. All letters must be typed, double spaced, and may not exceed four pages nor include more than one figure or table. The editors reserve the right to edit for purposes of clarity or brevity.

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

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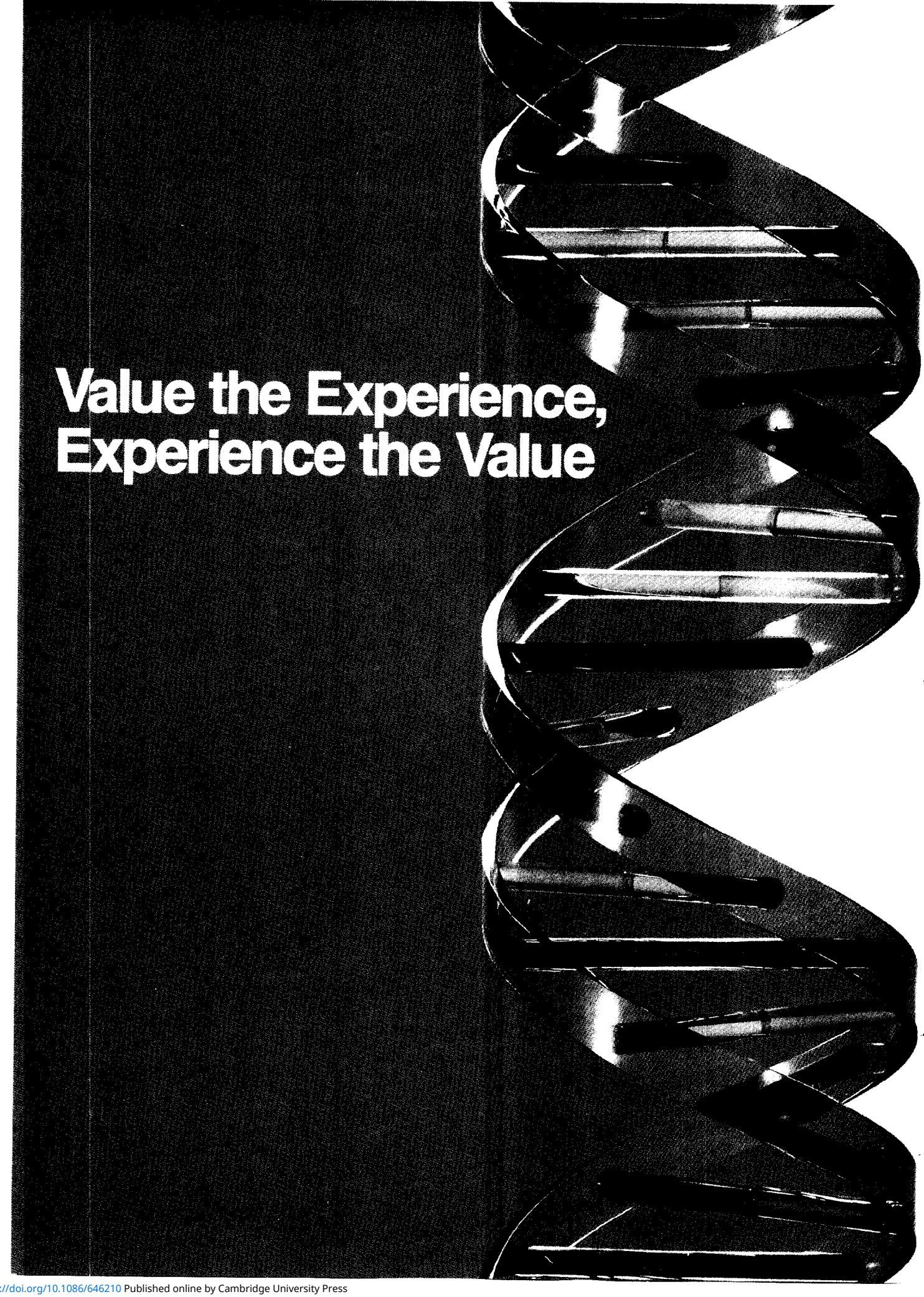

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RECOMBIVAX HB is contraindicated in the presence of hypersensitivity to yeast or to any component of the vaccine.

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 B in 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 ohvsician. withholdina 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 pregnant 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 nursing 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 dosage 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

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

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, flushing.

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.

UROGENITALSYSTEM

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 reactionssuch as urticaria, erythema multiforme, ecchymoses. and erythema nodosum (see WARNINGS and PRECAUTIONS).

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

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(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 PATIFNTS.

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 19486. **J9RX08** (206)

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