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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

Continued inside.

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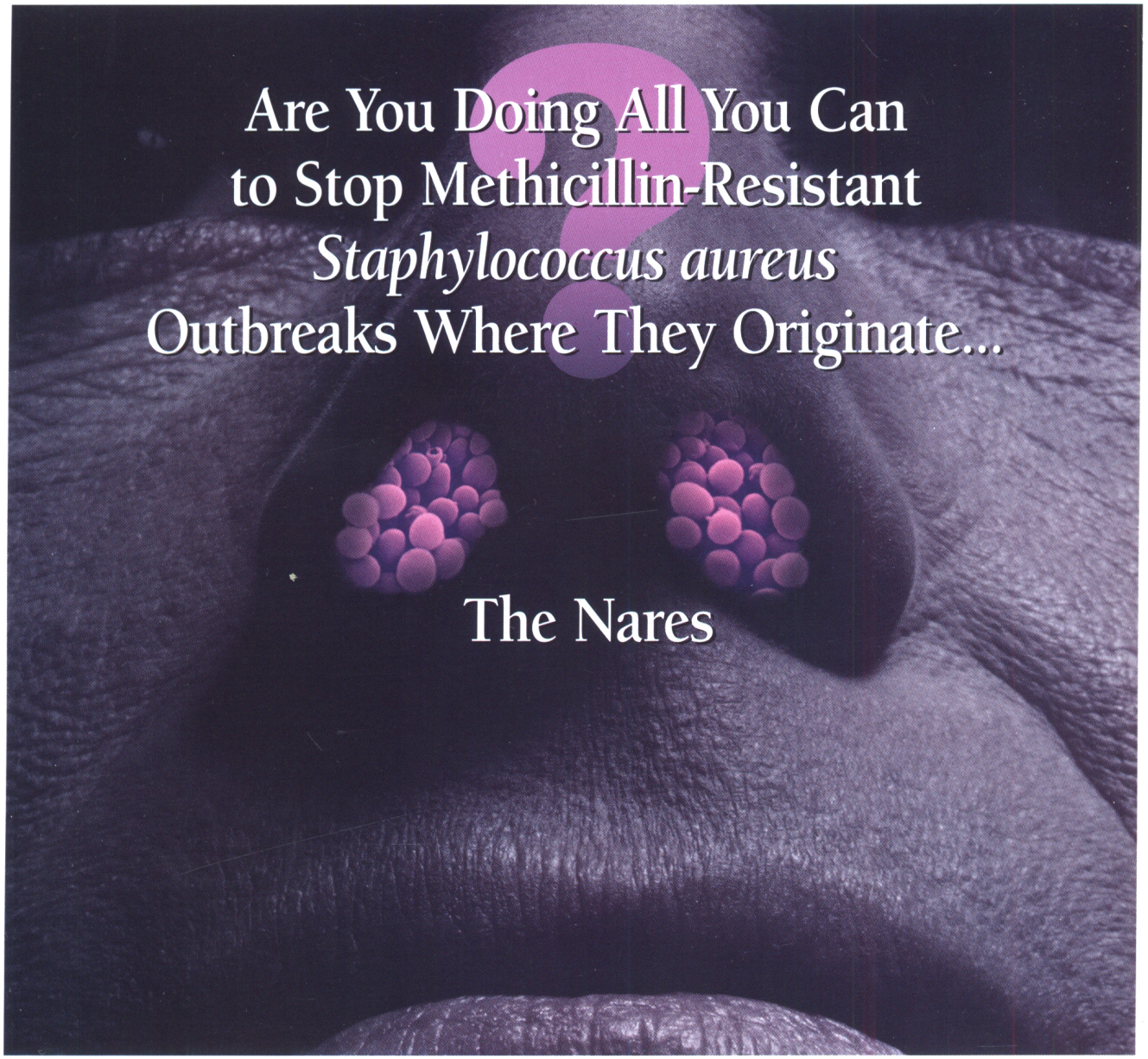
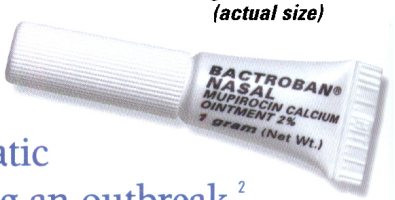


- *Bactroban* Nasal is indicated for eradication of nasal colonization with methicillin-resistant *S. aureus* (MRSA) in adult patients and healthcare workers as part of a comprehensive infection control program to reduce the risk of infection among high-risk patients during MRSA outbreaks.[1]

Single-use tube (actual size)



- In a hospital study, *Bactroban* Nasal contributed to a dramatic reduction in MRSA infections and vancomycin costs during an outbreak.[2]
- Excellent safety profile[1]

Please see brief summary of prescribing information on adjacent page.

References: 1. Bactroban® Nasal prescribing information, 1995. **2.** Reagan DR, Dula RT, Palmer BH, et al. Control of MRSA in a VAMC with limited resources. Prog Abstr 31st Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, U.S.A., Sept. 29-Oct. 2, 1991, p 104.

Bactroban® Nasal mupirocin calcium

2% ointment for intranasal use

SB SmithKline Beecham Pharmaceuticals

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BACTROBAN® NASAL (mupirocin calcium ointment), 2%

Brief summary. For complete prescribing information, see package insert.

INDICATIONS AND USAGE

Bactroban Nasal is indicated for eradication of nasal colonization with methicillin-resistant *Staphylococcus aureus* in adult patients and health care workers as part of a comprehensive infection control program to reduce the risk of infection among patients at high risk of methicillin-resistant *S. aureus* infection during institutional outbreaks of infections with this pathogen.

NOTE:

(1) There are insufficient data at this time to establish that this product is safe and effective as part of an intervention program to prevent autoinfection of high-risk patients from their own nasal colonization with *S. aureus*.

(2) There are insufficient data at this time to recommend use of *Bactroban* Nasal for general prophylaxis of any infection in any patient population.

(3) Greater than 90% of subjects/patients in clinical trials had eradication of nasal colonization 2 to 4 days after therapy was completed. Approximately 30% recolonization was reported in one domestic study within 4 weeks after completion of therapy. These eradication rates were clinically and statistically superior to those reported in subjects/patients in the vehicle-treated arms of the adequate and well-controlled studies. Those treated with vehicle had eradication rates of 5% to 30% at 2 to 4 days post-therapy with 85% to 100% recolonization within 4 weeks.

CONTRAINDICATIONS

Bactroban Nasal is contraindicated in patients with known hypersensitivity to any of the constituents of the product.

WARNINGS

AVOID CONTACT WITH THE EYES. Application of *Bactroban* Nasal to the eye under testing conditions has caused severe symptoms such as burning and tearing. These symptoms resolved within days to weeks after discontinuation of the ointment.

In the event of a sensitization or severe local irritation from *Bactroban* Nasal, usage should be discontinued.

PRECAUTIONS

General: As with other antibacterial products, prolonged use may result in overgrowth of nonsusceptible microorganisms, including fungi. (See DOSAGE AND ADMINISTRATION in complete prescribing information.)

Information for Patients: Patients should: apply approximately one-half of the ointment from the single-use tube directly into one nostril and the other half into the other nostril; avoid contact of the medication with the eyes; discard the tube after using; press the sides of the nose together and gently massage after application to spread the ointment throughout the inside of the nostrils; and discontinue using *Bactroban* Nasal and call a health care practitioner if sensitization or *severe local irritation occurs.*

Drug Interactions: The effect of the concurrent application of intranasal mupirocin calcium and other intranasal products has not been studied. Do not apply mupirocin calcium ointment, 2% concurrently with any other intranasal products.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals to evaluate carcinogenic potential of mupirocin calcium have not been conducted. Results of the following studies performed with mupirocin calcium or mupirocin sodium *in vitro* and *in vivo* did not indicate a potential for mutagenicity: rat primary hepatocyte unscheduled DNA synthesis, sediment analysis for DNA strand breaks, *Salmonella* reversion test (Ames), *Escherichia coli* mutation assay, metaphase analysis of human lymphocytes, mouse lymphoma assay, and bone marrow micronuclei assay in mice. Reproduction studies were performed in rats with mupirocin administered subcutaneously at doses up to **40** times the human intranasal dose (approximately 20 mg mupirocin per day) on a mg/m^2 basis and revealed no evidence of impaired fertility from mupirocin sodium.

Pregnancy: Teratogenic Effects. Pregnancy Category B. Reproduction studies have been performed in rats and rabbits with mupirocin administered subcutaneously at doses up to 65 and 130 times, respectively, the human intranasal dose *(approximately 20 mg mupirocin per day) on a mg/m^2 basis* and revealed no evidence of harm to the fetus due to mupirocin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when *Bactroban* Nasal is administered to a nursing woman.

Pediatric Use: Safety in children under the age of 12 years has not been established. (See CLINICAL PHARMACOLOGY in complete prescribing information.)

ADVERSE REACTIONS

Clinical Trials: In clinical trials, 210 domestic and 2,130 foreign adult subjects/patients received *Bactroban* Nasal ointment. Less than 1% of domestic or foreign subjects and patients in clinical trials were withdrawn due to adverse events. In domestic clinical trials, 17% (36/210) of adults treated with *Bactroban* Nasal ointment reported adverse events thought to be at least possibly drug-related. The incidence of adverse events thought to be at least possibly drug-related that were reported in at least 1% of adults enrolled in domestic clinical trials were as follows: headache, 9%; rhinitis, 6%; *respiratory disorder, including upper respiratory tract congestion,* 5%; pharyngitis, 4%; taste perversion, 3%; burning/stinging, 2%; cough, 2%; and pruritus, 1%.

The following events thought possibly drug-related were reported in less than 1% of adults enrolled in domestic clinical trials: blepharitis, diarrhea, dry mouth, ear pain, epistaxis, nausea and rash. All adequate and well-controlled clinical trials have been performed using *Bactroban* Nasal ointment, 2% in one arm and the vehicle ointment in the other arm of the study.

OVERDOSAGE

Following single or repeated intranasal applications of *Bactroban* Nasal to adults, no evidence for systemic absorption of mupirocin was obtained.

Manufactured by **DPT Laboratories, Inc.**, San Antonio, TX 78215

Distributed by **SmithKline Beecham Pharmaceuticals**, Philadelphia, PA 19101

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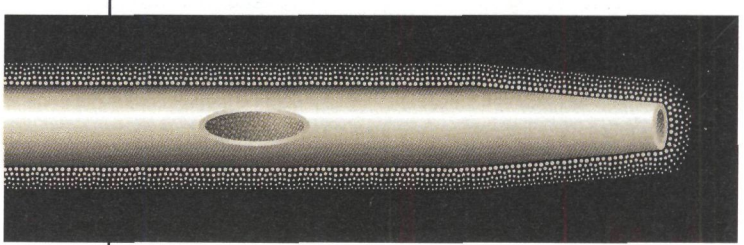
An extensive new study just published in *The New England Journal of Medicine* concludes that catheters impregnated with minocycline and rifampin are **twelve times less likely** to cause bloodstream infections than catheters impregnate with chlorhexidine and silver sulfadiazine.[1]



Central venous catheters are vital to patient care, but they are also the leading cause of primary nosocomial bloodstream infection.[2]

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[1] R. Darouiche, I. Raad, S. Heard, J. Thornby, O. Wenker, A. Gabrielli, J. Berg, N. Khardori, H. Hanna, R. Hachem, R. Harris, and G. Mayhall for the Catheter Study Group: "A Comparison of Two Antimicrobial-Impregnated Central Venous Catheters," *New England Journal of Medicine*, Volume 340, Issue 1, (1999), 1-8.

[2] I. Raad, R. Darouiche, J. Dupuis, D. Abi-Said, A. Gabrielli, R. Hachem, M. Wall, R. Harris, J. Jones, A. Buzaid, C. Robertson, S. Shenaq, P. Curling, T. Burke, C. Ericsson, Texas Medical Center Catheter Study Group: "Central Venous Catheters Coated with Minocycline and Rifampin for the Prevention of Catheter-Related Colonization and Bloodstream Infections: A Randomized, Double-Blind Trial," *Annals of Internal Medicine*, 127 (1997), 267-274.

[3] D. Pittet, R. Wenzel: "Nosocomial Bloodstream Infections in the Critically Ill, Letter to the Editor," *Journal of the American Medical Association*, 272 (1994), 1819-1820.

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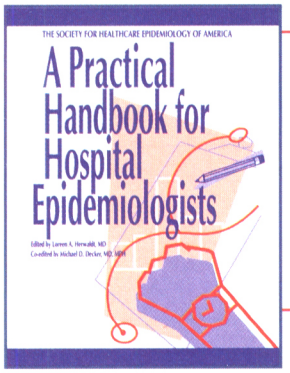

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