

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BACTROBAN Ointment safely and effectively. See full prescribing information for BACTROBAN Ointment.

BACTROBAN (mupirocin) ointment, for topical use
Initial U.S. Approval: 1987

INDICATIONS AND USAGE

BACTROBAN ointment is an RNA synthetase inhibitor antibacterial indicated for the topical treatment of impetigo due to susceptible isolates of *Staphylococcus aureus* and *Streptococcus pyogenes*. (1)

DOSAGE AND ADMINISTRATION

- For Topical Use Only. (2)
- Apply a small amount of BACTROBAN ointment, with a cotton swab or gauze pad, to the affected area 3 times daily for up to 10 days. (2)
- Re-evaluate patients not showing a clinical response within 3 to 5 days. (2)
- Not for intranasal, ophthalmic, or other mucosal use. (2)

DOSAGE FORMS AND STRENGTHS

- Ointment: Each gram contains 20 mg mupirocin in a water-miscible ointment base supplied in 22-gram tubes. (3)

CONTRAINDICATIONS

- Known hypersensitivity to mupirocin or any of the excipients of BACTROBAN ointment. (4)

WARNINGS AND PRECAUTIONS

- Severe Allergic Reactions: Anaphylaxis, urticaria, angioedema, and generalized rash have been reported in patients treated with formulations of BACTROBAN, including BACTROBAN ointment. (5.1)
- Eye Irritation: Avoid contact with eyes. (5.2)

- Local Irritation: Discontinue in the event of sensitization or severe local irritation. (5.3)
- *Clostridium difficile*-Associated Diarrhea (CDAD): If diarrhea occurs, evaluate patients for CDAD. (5.4)
- Potential for Microbial Overgrowth: Prolonged use may result in overgrowth of nonsusceptible microorganisms, including fungi. (5.5)
- Risk Associated with Mucosal Use: BACTROBAN ointment is not formulated for use on mucosal surfaces. A separate formulation, BACTROBAN nasal ointment, is available for intranasal use. (5.6)
- Risk of Polyethylene Glycol Absorption: BACTROBAN ointment should not be used where absorption of large quantities of polyethylene glycol is possible, especially if there is evidence of moderate or severe renal impairment. (5.7)
- Risk Associated with Use at Intravenous Sites: BACTROBAN ointment should not be used with intravenous cannulae or at central intravenous sites because of the potential to promote fungal infections and antimicrobial resistance. (5.8)

ADVERSE REACTIONS

- The most frequent adverse reactions (at least 1%) were burning, stinging or pain, and itching. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

BACTROBAN[®] ointment is indicated for the topical treatment of impetigo due to susceptible isolates of *Staphylococcus aureus* (*S. aureus*) and *Streptococcus pyogenes* (*S. pyogenes*).

2 DOSAGE AND ADMINISTRATION

- For Topical Use Only.
- Apply a small amount of BACTROBAN ointment, with a cotton swab or gauze pad, to the affected area 3 times daily for up to 10 days.

- Cover the treated area with gauze dressing if desired.
- Re-evaluate patients not showing a clinical response within 3 to 5 days.
- BACTROBAN ointment is not for intranasal, ophthalmic, or other mucosal use [*see Warnings and Precautions (5.2, 5.6)*].
- Do not apply BACTROBAN ointment concurrently with any other lotions, creams or ointments [*see Clinical Pharmacology (12.3)*].

3 DOSAGE FORMS AND STRENGTHS

Each gram of BACTROBAN ointment contains 20 mg mupirocin in a water-miscible ointment base supplied in 22-gram tubes.

4 CONTRAINDICATIONS

BACTROBAN ointment is contraindicated in patients with known hypersensitivity to mupirocin or any of the excipients of BACTROBAN ointment.

5 WARNINGS AND PRECAUTIONS

5.1 Severe Allergic Reactions

Systemic allergic reactions, including anaphylaxis, urticaria, angioedema, and generalized rash, have been reported in patients treated with formulations of BACTROBAN, including BACTROBAN ointment [*see Adverse Reactions (6.2)*].

5.2 Eye Irritation

Avoid contact with the eyes. In case of accidental contact, rinse well with water.

5.3 Local Irritation

In the event of a sensitization or severe local irritation from BACTROBAN ointment, usage should be discontinued, and appropriate alternative therapy for the infection instituted.

5.4 *Clostridium difficile*-Associated Diarrhea

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

5.5 Potential for Microbial Overgrowth

As with other antibacterial products, prolonged use of BACTROBAN ointment may result in overgrowth of nonsusceptible microorganisms, including fungi [see *Dosage and Administration (2)*].

5.6 Risk Associated with Mucosal Use

BACTROBAN ointment is not formulated for use on mucosal surfaces. Intranasal use has been associated with isolated reports of stinging and drying. A separate formulation, BACTROBAN® (mupirocin calcium) nasal ointment, is available for intranasal use.

5.7 Risk of Polyethylene Glycol Absorption

Polyethylene glycol can be absorbed from open wounds and damaged skin and is excreted by the kidneys. In common with other polyethylene glycol-based ointments, BACTROBAN ointment should not be used in conditions where absorption of large quantities of polyethylene glycol is possible, especially if there is evidence of moderate or severe renal impairment.

5.8 Risk Associated with Use at Intravenous Sites

BACTROBAN ointment should not be used with intravenous cannulae or at central intravenous sites because of the potential to promote fungal infections and antimicrobial resistance.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in more detail in other sections of the labeling:

- Severe Allergic Reactions [see *Warnings and Precautions (5.1)*]
- Eye Irritation [see *Warnings and Precautions (5.2)*]
- Local Irritation [see *Warnings and Precautions (5.3)*]
- *Clostridium difficile*-Associated Diarrhea [see *Warnings and Precautions (5.4)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The following local adverse reactions were reported by at least 1% of subjects in connection with the use of BACTROBAN ointment in clinical trials: burning, stinging, or pain in 1.5% of

subjects; itching in 1% of subjects. Rash, nausea, erythema, dry skin, tenderness, swelling, contact dermatitis, and increased exudate were reported in less than 1% of subjects.

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following reactions have been identified during postmarketing use of BACTROBAN ointment. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These reactions have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal relationship to BACTROBAN ointment.

Immune System Disorders

Systemic allergic reactions, including anaphylaxis, urticaria, angioedema, and generalized rash [see *Warnings and Precautions (5.1)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B.

There are no adequate and well-controlled studies of BACTROBAN ointment 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.

Developmental toxicity studies have been performed with mupirocin administered subcutaneously to rats and rabbits at doses up to 160 mg per kg per day in both species. This dose is 22 and 43 times, respectively, the human topical dose (approximately 60 mg mupirocin per day) based on body surface area. There was no evidence of fetal harm due to mupirocin.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BACTROBAN ointment is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of BACTROBAN ointment have been established in the age range of 2 months to 16 years. Use of BACTROBAN ointment in these age-groups is supported by evidence from adequate and well-controlled trials of BACTROBAN ointment in impetigo in pediatric subjects studied as a part of the pivotal clinical trials [see *Clinical Studies (14)*].

11 DESCRIPTION

BACTROBAN (mupirocin) ointment, 2% contains the RNA synthetase inhibitor antibacterial, mupirocin. The chemical name is (*E*)-(2*S*,3*R*,4*R*,5*S*)-5-[(2*S*,3*S*,4*S*,5*S*)-2,3-epoxy-5-hydroxy-4-methylhexyl]tetrahydro-3,4-dihydroxy- β -methyl-2*H*-pyran-2-crotonic acid, ester with

9-hydroxynonanoic acid. The molecular formula of mupirocin is $C_{26}H_{44}O_9$, and the molecular weight is 500.6. The chemical structure is:

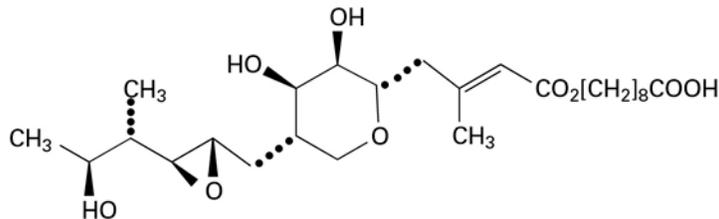


Figure 1. Structure of Mupirocin

Each gram of BACTROBAN ointment, 2% contains 20 mg mupirocin in a water-miscible ointment base (polyethylene glycol ointment, N.F.) consisting of polyethylene glycol 400 and polyethylene glycol 3350.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Mupirocin is an RNA synthetase inhibitor antibacterial [see *Microbiology (12.4)*].

12.3 Pharmacokinetics

Absorption

Application of ¹⁴C-labeled mupirocin ointment to the lower arm of normal male subjects followed by occlusion for 24 hours showed no measurable systemic absorption (less than 1.1 nanogram mupirocin per milliliter of whole blood). Measurable radioactivity was present in the stratum corneum of these subjects 72 hours after application.

The effect of the concurrent application of BACTROBAN ointment with other drug products has not been studied [see *Dosage and Administration (2)*].

Elimination

In a trial conducted in 7 healthy adult male subjects, the elimination half-life after intravenous administration of mupirocin was 20 to 40 minutes for mupirocin and 30 to 80 minutes for monic acid.

Metabolism: Following intravenous or oral administration, mupirocin is rapidly metabolized. The principal metabolite, monic acid, demonstrates no antibacterial activity.

Excretion: Monic acid is predominantly eliminated by renal excretion.

Special Populations

Renal Impairment: The pharmacokinetics of mupirocin have not been studied in individuals with renal insufficiency.

12.4 Microbiology

Mupirocin is an RNA synthetase inhibitor antibacterial produced by fermentation using the organism *Pseudomonas fluorescens*.

Mechanism of Action

Mupirocin inhibits bacterial protein synthesis by reversibly and specifically binding to bacterial isoleucyl-transfer RNA (tRNA) synthetase.

Mupirocin is bactericidal at concentrations achieved by topical administration. Mupirocin is highly protein bound (greater than 97%) and the effect of wound secretions on the minimum inhibitory concentrations (MICs) of mupirocin has not been determined.

Mechanism of Resistance

When mupirocin resistance occurs, it results from the production of a modified isoleucyl-tRNA synthetase, or the acquisition of, by genetic transfer, a plasmid mediating a new isoleucyl-tRNA synthetase. High-level plasmid-mediated resistance (MIC \geq 512 mcg/mL) has been reported in increasing numbers of isolates of *S. aureus* and with higher frequency in coagulase-negative staphylococci. Mupirocin resistance occurs with greater frequency in methicillin-resistant than methicillin-susceptible staphylococci.

Cross Resistance

Due to its mode of action, mupirocin does not demonstrate cross resistance with other classes of antimicrobial agents.

Antimicrobial Activity

Mupirocin has been shown to be active against susceptible isolates of *S. aureus* and *S. pyogenes*, both in vitro and in clinical trials [see *Indications and Usage (1)*]. The following in vitro data are available, but their clinical significance is unknown. Mupirocin is active against most isolates of *Staphylococcus epidermidis*.

Susceptibility Testing

High-level mupirocin resistance (\geq 512 mcg/mL) may be determined using standard disk diffusion or broth microdilution tests.^{1,2} Because of the occurrence of mupirocin resistance in methicillin-resistant *S. aureus* (MRSA), it is appropriate to test MRSA populations for mupirocin susceptibility prior to the use of mupirocin using a standardized method.^{3,4,5}

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate carcinogenic potential of mupirocin 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 genotoxicity: 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 with mupirocin administered subcutaneously to male and female rats at doses up to 100 mg per kg per day which is 14 times the human topical dose (approximately 60 mg mupirocin per day) based on body surface area. Neither evidence of impaired fertility nor impaired reproductive performance attributable to mupirocin was observed.

14 CLINICAL STUDIES

The efficacy of topical BACTROBAN ointment in impetigo was tested in 2 trials. In the first, subjects with impetigo were randomized to receive either BACTROBAN ointment or vehicle placebo 3 times daily for 8 to 12 days. Clinical efficacy rates at end of therapy in the evaluable populations (adults and pediatric subjects included) were 71% for BACTROBAN ointment (n = 49) and 35% for vehicle placebo (n = 51). Pathogen eradication rates in the evaluable populations were 94% for BACTROBAN ointment and 62% for vehicle placebo.

In the second trial, subjects with impetigo were randomized to receive either BACTROBAN ointment 3 times daily or 30 to 40 mg per kg oral erythromycin ethylsuccinate per day (this was an unblinded trial) for 8 days. There was a follow-up visit 1 week after treatment ended. Clinical efficacy rates at the follow-up visit in the evaluable populations (adults and pediatric subjects included) were 93% for BACTROBAN ointment (n = 29) and 78.5% for erythromycin (n = 28). Pathogen eradication rates in the evaluable populations were 100% for both test groups.

Pediatrics

There were 91 pediatric subjects aged 2 months to 15 years in the first trial described above. Clinical efficacy rates at end of therapy in the evaluable populations were 78% for BACTROBAN ointment (n = 42) and 36% for vehicle placebo (n = 49). In the second trial described above, all subjects were pediatric except 2 adults in the group receiving BACTROBAN ointment. The age range of the pediatric subjects was 7 months to 13 years. The clinical efficacy rate for BACTROBAN ointment (n = 27) was 96%, and for erythromycin it was unchanged (78.5%).

15 REFERENCES

1. Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Susceptibility Testing; Twenty-fifth Informational Supplement*. CLSI document M100-S25. Clinical and Laboratory Standards Institute, 950 West Valley Rd., Suite 2500, Wayne, PA 19087, USA, 2015.

2. Patel J, Gorwitz RJ, et al. Mupirocin Resistance. *Clinical Infectious Diseases*. 2009; 49(6): 935-41.
3. Clinical and Laboratory Standards Institute (CLSI). *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard – Tenth Edition*. CLSI document M07-A10. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA, 2015.
4. Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Disk Diffusion Susceptibility Tests; Approved Standard – Twelfth Edition*. CLSI document M02-A12. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA, 2015.
5. Finlay JE, Miller LA, Poupard JA. Interpretive criteria for testing susceptibility of staphylococci to mupirocin. *Antimicrob Agents Chemother* 1997;41(5):1137-1139.

16 HOW SUPPLIED/STORAGE AND HANDLING

BACTROBAN ointment, 2% is supplied in 22-gram tubes.

Each gram of BACTROBAN ointment contains 20 mg mupirocin in a water-miscible ointment base.

NDC 0029-1525-44 (22-gram tube)

Store at controlled room temperature 20°C to 25°C (68°F to 77°F).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Advise the patient to administer BACTROBAN ointment as follows:

- Use BACTROBAN ointment only as directed by the healthcare provider. It is for external use only. Avoid contact of BACTROBAN ointment with the eyes. If BACTROBAN ointment gets in the eyes, rinse thoroughly with water.
- Do not use BACTROBAN ointment in the nose.
- Wash your hands before and after applying BACTROBAN ointment.
- Use a gauze pad or cotton swab to apply a small amount of BACTROBAN ointment to the affected area. The treated area may be covered by gauze dressing if desired.
- Report to the healthcare provider any signs of local adverse reactions. BACTROBAN ointment should be stopped and the healthcare provider contacted if irritation, severe itching, or rash occurs.

- Report to the healthcare provider or go to the nearest emergency room if severe allergic reactions, such as swelling of the lips, face, or tongue, or wheezing occur [*see Warnings and Precautions (5.1)*].
- If impetigo has not improved in 3 to 5 days, contact the healthcare provider.

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BBM:3PI

PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

PATIENT INFORMATION
BACTROBAN® (BACK-troh-ban)
(mupirocin)
ointment

What is BACTROBAN ointment?

BACTROBAN ointment is a prescription medicine used on the skin (topical use) to treat a skin infection called impetigo that is caused by bacteria called *Staphylococcus aureus* and *Streptococcus pyogenes*. It is not known if BACTROBAN ointment is safe and effective in children under 2 months of age.

Who should not use BACTROBAN ointment?

Do not use BACTROBAN ointment if:

- you are allergic to mupirocin or any of the ingredients in BACTROBAN ointment. See the end of this Patient Information leaflet for a complete list of the ingredients in BACTROBAN ointment.

What should I tell my healthcare provider before using BACTROBAN ointment?

Before using BACTROBAN ointment, tell your healthcare provider about all of your medical conditions including if you:

- have kidney problems
- are pregnant or plan to become pregnant. It is not known if BACTROBAN ointment will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if BACTROBAN ointment passes into your breast milk. You and your healthcare provider should decide if you can use BACTROBAN ointment while breastfeeding.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not mix BACTROBAN ointment with other lotions, creams, or ointments.

How should I use BACTROBAN ointment?

- **BACTROBAN ointment is for use on the skin (topical).** Do not get BACTROBAN ointment in your eyes, nose, mouth, or vagina (mucosal surfaces).
- Use BACTROBAN ointment exactly as your healthcare provider tells you to use it.
- Apply a small amount of BACTROBAN ointment, with a cotton swab or gauze pad, to the affected area 3 times each day.
- It is important that you take the full course of BACTROBAN ointment. Do not stop early because your symptoms may disappear before the infection is fully cleared.
- Wash your hands **before and after** applying BACTROBAN ointment.
- After applying BACTROBAN ointment, you may cover the treated area with a clean gauze pad, unless your healthcare provider has told you to leave it uncovered.
- Talk to your healthcare provider if your skin does not improve after 3 to 5 days of treatment with BACTROBAN ointment.

What are the possible side effects of BACTROBAN ointment?

BACTROBAN ointment may cause serious side effects, including:

- **severe allergic reactions.** Stop using BACTROBAN ointment and call your healthcare provider or go to the nearest emergency room right away if you have any of the following signs or symptoms of a severe allergic reaction:
 - hives
 - swelling of your face, lips, mouth, or tongue
 - a rash over your whole body
 - trouble breathing or wheezing
 - dizziness, fast heartbeat or pounding in your chest
- **eye irritation.** Do not get BACTROBAN ointment in your eyes. If BACTROBAN ointment gets in your eyes, rinse your eyes well with water.
- **irritation in the area BACTROBAN ointment is used.** Stop using BACTROBAN ointment and call your healthcare provider if you develop an irritation, severe itching, or a rash while using BACTROBAN ointment.
- **a type of diarrhea called *Clostridium difficile*-associated diarrhea (CDAD).** CDAD may happen in people who use or have used medicine to treat bacterial infections. The severity of CDAD can range from mild diarrhea to severe diarrhea that may cause death (fatal colitis). Call your healthcare provider or go to the nearest emergency room right away if you have diarrhea while using or after you stop using BACTROBAN ointment.

- **risk of absorption of polyethylene glycol through the skin.** BACTROBAN ointment contains polyethylene glycol, which in large amounts can cause kidney damage. You should not apply BACTROBAN ointment to open skin wounds or damaged skin, especially if you have kidney problems.
- **increased risk of infection at IV (intravenous) sites.** BACTROBAN ointment should not be used on skin that is near an IV (intravenous) site.

The most common side effects of BACTROBAN ointment include:

- burning
- stinging or pain
- itching

These are not all the possible side effects of BACTROBAN ointment. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BACTROBAN ointment?

- Store BACTROBAN ointment at room temperature between 68°F to 77°F (20°C to 25°C).

Keep BACTROBAN ointment and all medicines out of the reach of children.

General information about the safe and effective use of BACTROBAN ointment

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use BACTROBAN ointment for a condition for which it was not prescribed. Do not give BACTROBAN ointment to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about BACTROBAN ointment that is written for health professionals.

What are the ingredients in BACTROBAN ointment?

Active Ingredient: mupirocin

Inactive Ingredients: polyethylene glycol 400 and polyethylene glycol 3350

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For more information, call 1-888-825-5249.