

Bactrocin[®] 2% Ointment

Mupirocin USP 2% Ointment

Prescribing Information

Composition

Each gram of **Bactrocin[®]** 2% Ointment contains Mupirocin USP 20 mg.

Pharmacology

Mupirocin is a naturally occurring antibiotic. It is an antibacterial agent produced by fermentation using the organism *Pseudomonas fluorescens*. It is active against a wide range of bacteria those responsible for the majority of skin infections, e.g. *Staphylococcus aureus* including methicillin-resistant *Staphylococcus aureus* (MRSA), other staphylococci and streptococci. It is also active against certain gram-negative pathogens, like *Escherichia coli* and *Haemophilus influenzae*. Mupirocin inhibits bacterial protein synthesis by reversibly and specifically binding to bacterial isoleucyl transfer-RNA synthetase. Due to this unique mode of action, Mupirocin demonstrates no in vitro cross resistance with other classes of antimicrobial agents. Mupirocin is bactericidal at concentrations achieved by topical administration. However, the minimum bactericidal concentration (MBC) against relevant pathogens is generally eight-fold to thirty-fold higher than the minimum inhibitory concentration (MIC).

Indication

Bactrocin[®] (Mupirocin) Ointment is indicated for the topical treatment of impetigo due to:

Staphylococcus aureus and
Streptococcus pyogenes

Dosage and administration

A small amount of Bactrocin[®] (Mupirocin) Ointment should be applied to the affected area three times daily. The area treated may be covered with gauze dressing if desired. Patients not showing a clinical response within 3 to 5 days should be re-evaluated.

Contraindication

This drug is contraindicated in individuals with a history of sensitivity reactions to any of its components.

Precaution

Bactrocin[®] (Mupirocin) Ointment is not for ophthalmic or intra-nasal use. If a reaction suggesting sensitivity or chemical irritation should occur with the use of **Bactrocin[®]** (Mupirocin) Ointment, treatment should be discontinued and appropriate alternative therapy for the infection instituted. As with other antibacterial products, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. When **Bactrocin[®]** (Mupirocin) is used on the face care should be taken to avoid the eyes.

Drug Interaction

The effect of the concurrent application of **Bactrocin[®]** (Mupirocin) and other drug products has not been studied.

Use in Pregnancy

The drug is classified in Pregnancy Category B. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Use in Lactation

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 **Bactrocin[®]** (Mupirocin) is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of **Bactrocin[®]** (Mupirocin) have been established in the age range of 2 months to 16 years. Use of the ointment in these age groups is supported by evidence from adequate and well-controlled studies of Mupirocin in impetigo in pediatric patients.

Adverse effects

The following local adverse reactions have been reported in connection with the use of **Bactrocin[®]** (Mupirocin) Ointment: burning, stinging, or pain in 1.5% of patients; itching in 1% of patients; rash, nausea, erythema, dry skin, tenderness, swelling, contact dermatitis, and increased exudate in less than 1% of patients.

How supplied

Bactrocin[®] 2% Ointment: Each pack has a tube containing 10 gm ointment.