

DATA SHEET

BACTROBAN™

Mupirocin

Presentation

BACTROBAN Ointment 2% contains 20mg mupirocin per gram in a bland water soluble ointment base consisting of polyethylene glycol 400 and polyethylene glycol 3350 (polyethylene glycol ointment NF).

Clinical Particulars

Therapeutic Indications

BACTROBAN Ointment is indicated for the topical treatment of the following primary and secondary skin infections due to susceptible pathogens: primary pyodermas such as impetigo, folliculitis, furunculosis, ecthyma; secondary infected dermatoses such as eczema, psoriasis, atopic dermatitis, herpes, epidermolysis bullosa, ichthyosis, and infected traumatic lesions such as ulcers, minor burns, cuts, abrasions, lacerations, wounds, biopsy sites, surgical incisions and insect bites.

Prophylactically, BACTROBAN Ointment may be used to prevent bacterial contamination in minor burns, biopsy sites, incisions and other clean lesions. For abrasions, minor cuts and wounds the prophylactic use of BACTROBAN may prevent the development of infection and permit wound healing.

Posology and Method of Administration

A small amount of BACTROBAN Ointment should be applied to the affected area three times daily. The area treated may be covered with a gauze dressing if required.

Any product remaining at the end of treatment should be discarded.

Do not mix with other preparations as there is a risk of dilution, resulting in a reduction in the antibacterial activity and potential loss of stability of the mupirocin in the ointment.

Contraindications

BACTROBAN ointment should not be given to patients with a history of hypersensitivity to any of its constituents.

Special Warnings and Special Precautions for Use

Patients with renal impairment

Elderly patients: No restrictions unless the condition being treated could lead to absorption of polyethylene glycol and there is evidence of moderate or severe renal impairment.

This mupirocin ointment formulation is not suitable for:

- ophthalmic use.
- intranasal use (in neonates or infants).
- use in conjunction with cannulae.
- at the site of central venous cannulation

Avoid contact with eyes. If contaminated, the eyes should be thoroughly irrigated with water until the ointment residues have been removed.

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, mupirocin 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.

In the rare event of a possible sensitisation reaction or severe local irritation occurring with the use of mupirocin ointment, treatment should be discontinued, the product should be rinsed off and appropriate alternative therapy for the infection instituted.

As with other antibacterial products, prolonged use may result in overgrowth of non-susceptible organisms.

Interaction with Other Medicaments and Other Forms of Interaction

No drug interactions have been reported.

Pregnancy and Lactation

Pregnancy:

Adequate human data on use during pregnancy are not available. However, animal studies have not identified any risk to pregnancy or embryo-foetal development.

Lactation:

Adequate human and animal data on use during lactation are not available. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast feeding .

Effect on Ability to Drive and Use Machines

No adverse effects on the ability to drive or operate machinery have been observed.

Undesirable Effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1000$), very rare ($< 1/10,000$), including isolated reports. Common and uncommon adverse reactions were determined from pooled safety data from a clinical trial population of 1573 treated patients encompassing 12 clinical studies. Very rare adverse reactions were primarily determined from post-marketing experience data and therefore refer to reporting rate rather than true frequency.

Immune system disorders:

Very rare: Systemic allergic reactions have been reported with BACTROBAN ointment.

Skin and subcutaneous tissue disorders:

Common: Burning localised to the area of application.

Uncommon: Itching, erythema, stinging and dryness localised to the area of application.

Uncommon: Cutaneous sensitisation reactions to mupirocin or the ointment base.

Overdose

Not applicable.

Pharmacological Properties

Pharmacodynamic Properties

General Properties

Mupirocin is a novel antibiotic produced through fermentation of *Pseudomonas fluorescens*. Mupirocin inhibits isoleucyl transfer-RNA synthetase, thereby arresting bacterial protein synthesis.

Due to this particular mode of action and its unique chemical structure, mupirocin does not show any cross-resistance with other clinically available antibiotics.

Mupirocin shows little risk of selection of resistant bacteria if used as prescribed.

Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bactericidal properties at the higher concentrations reached when applied locally.

Following intravenous or oral administration, mupirocin is rapidly metabolised to the inactive monic acid.

Activity

BACTROBAN ointment shows *in vivo* activity against *Staphylococcus aureus* (including methicillin-resistant strains), *S. epidermidis* and beta-haemolytic *Streptococcus* species.

The *in vitro* spectrum of activity includes the following bacteria:

Aerobic Gram-positive:

- *Staphylococcus aureus* (including beta-lactamase producing strains and methicillin resistant strains)
- *Staphylococcus epidermidis*
- Other coagulase negative *Staphylococci* (including methicillin resistant strains)
- *Streptococcus* species

Anaerobic Gram-negative:

- *Haemophilus influenzae*
- *Neisseria gonorrhoeae*
- *Neisseria meningitidis*
- *Branhamella catarrhalis*
- *Pasteurella multocida*
- *Proteus mirabilis*
- *Proteus vulgaris*
- *Enterobacter cloacae*
- *Enterobacter aerogenes*
- *Citrobacter freundii*

- *Bordetella pertussis*

Susceptibility:

Susceptible:

- *Staphylococcus aureus**
- *Staphylococcus epidermidis**
- *Coagulase-negative staphylococci**
- *Streptococcus species**
- *Haemophilus influenzae*
- *Neisseria gonorrhoeae*
- *Neisseria meningitidis*
- *Moraxella catarrhalis*
- *Pasteurella multocida*

* Clinical efficacy has been demonstrated for susceptible isolates in approved clinical indications.

Insusceptible

- *Corynebacterium species*
- *Enterobacteriaceae*
- Gram negative non-fermenting rods
- *Micrococcus species*
- Anaerobes

Cross-resistance:

Mupirocin does not demonstrate cross-resistance with any other known antimicrobial.

Resistance mechanisms:

Low-level resistance in staphylococci (MICs 8-256 mcg/ml) has been shown to be due to changes in the native isoleucyl tRNA synthetase enzyme. High-level resistance in staphylococci (MICs \geq 512 mcg/ml) has been shown to be due to a distinct, plasmid encoded isoleucyl tRNA synthetase enzyme. Intrinsic resistance in Gram negative organisms such as the *Enterobacteriaceae* could be due to poor penetration into the bacterial cell.

Pharmacokinetic Properties

1. **Absorption:** Mupirocin is poorly absorbed through intact human skin. However, if it is absorbed (e.g. through broken/diseased skin) or it is given systemically, it is metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted.
2. **Excretion:** Mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is excreted mainly by the kidney (90%).

Preclinical Safety Data

No further information of relevance.

Pharmaceutical Particulars

Incompatibilities

None reported.

Shelf Life

Two years when stored below 25°C.

Special precautions for storage

BACTROBAN ointment may be stored at room temperature (below 25°C) up to the expiry date.

Instructions for Use/Handling

Wash your hands after application.

Medicine Classification

Prescription Medicine.

Packaging Quantities

BACTROBAN Ointment 2% is supplied in 15g tubes.

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