BACTROBAN® NASAL 2% OINTMENT

PRODUCT INFORMATION

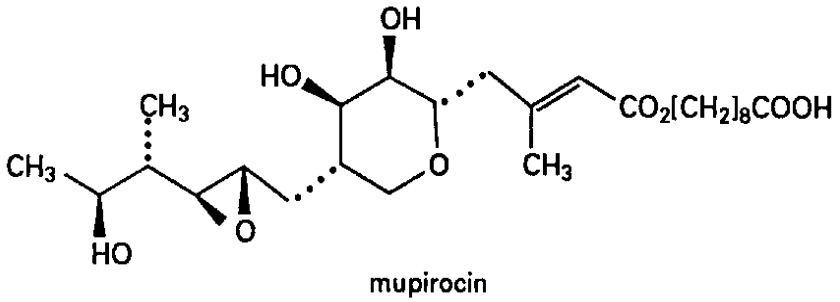
For Intranasal Use

NAME OF THE MEDICINE

Bactroban Nasal Ointment contains mupirocin calcium 2% w/w as the active ingredient.

DESCRIPTION

Mupirocin is a naturally occurring antibiotic, produced by fermentation of the organism *Pseudomonas fluorescens*. The chemical name is: 9-4-{5S-(2S,3S-epoxy-5S-hydroxy-4S-methylhexyl)-3R,4R-dihydroxytetrahydropyran-2S-y1}-3-methylbut-2-(E)-enoyloxy- nonanoic acid.



mupirocin

The CAS number for mupirocin is 12550-69-0.

Each gram of BACTROBAN Nasal Ointment 2% contains 20mg mupirocin as the calcium salt in a white soft paraffin based ointment containing a glycerin ester (bis-diglyceryl polyacyladipate-2).

PHARMACOLOGY

Microbiology

Mupirocin inhibits bacterial protein synthesis by reversibly and specifically binding to bacterial isoleucyl transfer - RNA synthetase. It shows no cross resistance with other commonly used and clinically important antibiotics.

In vitro mupirocin is active mainly against Gram positive aerobes including *Staphylococcus aureus* (including MRSA positive strains), *Staphylococcus saprophyticus, Staphylococcus epidermidis, Streptococcus pyogenes, Streptococcus viridans, Streptococcus agalactiae, and* Streptococcus *pneumoniae*.

Group D Streptococci (including *S. faecalis* and *S. faecium*), are much less sensitive to mupirocin. Most Gram negative organisms (except for *H.influenzae*, Neisseria and Branhamella) and anaerobes (including *Propionibacterium acnes*) are not sensitive to mupirocin.

Clinical Pharmacology

This formulation has been designed as appropriate for use in the interior nares. Limited data are available on the absorption of mupirocin following intranasal application in adults. Adverse effects from continued absorption from the nose cannot be ruled out.

Mupirocin is absorbed in neonates and premature infants following intranasal administration of mupirocin ointment. In clinical studies of neonates, intranasal administration of mupirocin for up to 5 days was well tolerated. The safety of courses lasting longer than 5 days in neonates and infants has not been studied.

If absorption occurs, mupirocin will be quickly hydrolysed to the antimicrobially inactive metabolite monic acid which is rapidly cleared from the body.

No evidence of contact sensitization has been demonstrated with the white soft paraffin ointment formulation of mupirocin (BACTROBAN Nasal Ointment).

Whilst mupirocin successfully eradicates *S. aureus* colonisation of the nasal mucosa there are currently insufficient data to determine the frequency of, and time to, recolonisation.

INDICATIONS

BACTROBAN (mupirocin) Nasal Ointment is indicated for the elimination of nasal carriage of staphylococci including methicillin resistant *Staphylococcus aureus* (MRSA).

CONTRAINDICATIONS

BACTROBAN Nasal Ointment is contraindicated in patients who have demonstrated hypersensitivity to mupirocin calcium or any components of the formulation.

PRECAUTIONS

If a reaction suggesting sensitivity or chemical irritation should occur with the use of BACTROBAN Nasal Ointment, treatment should be discontinued, the product should be wiped off and appropriate alternative therapy for the infection instituted.

BACTROBAN nasal ointment formulation is not suitable for ophthalmic use.

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

As with other antibacterial products, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

The occurrence of resistance to topical mupirocin has occasionally been reported. The possibility of the development of resistance following intranasal use should therefore be borne in mind, particularly in treatment courses lasting longer than 5-7 days. Long term, continuous use of BACTROBAN Nasal ointment should be avoided to minimise this possibility, particularly in the hospital environment.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. Although this is less likely to occur with topically applied mupirocin, if prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

Use in pregnancy

Reproduction studies have been performed in rats and rabbits at systemic doses up to 160mg/kg and have revealed no evidence of impaired fertility or harm to the foetus due to mupirocin.

Adequate human data on use during pregnancy are not available. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Use in lactation

Adequate human data on use during lactation are not available. Caution should be exercised when BACTROBAN Nasal Ointment is administered to a nursing woman.

OVERDOSAGE

There is currently limited experience with overdosage of BACTROBAN.

There is no specific treatment for an overdose of BACTROBAN. In the event of overdose, the patient should be treated supportively with appropriate monitoring as necessary. Further management should be as clinically indicated or as recommended by the Poison Information Centre on 131126 (Australia).

INTERACTIONS WITH OTHER MEDICINES

BACTROBAN Nasal Ointment should not be mixed 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.

ADVERSE EFFECTS

The following local adverse reactions with an overall incidence of approximately 2%, have been reported in connection with the use of this product: irritation, itching, tingling, burning, stinging, soreness, facial pain over maxillae, post nasal drip, sinusitis, rhinitis and conjunctivitis. However, less than 0.2% of patients withdrew due to adverse experiences.

Systemic allergic reactions including anaphylaxsis, generalised rash, urticaria and angioedema have been reported very rarely.

DOSAGE AND ADMINISTRATION

Adults and children: BACTROBAN Nasal Ointment should be applied to the anterior nares two to three times a day, as follows:

A small amount of the ointment about the size of a match head is placed on the little finger and applied to the inside of each nostril. The nostrils are closed by pressing the side of the nose together; this will spread the ointment throughout the nares. A swab may be used for application to infants or patients who are very ill.

Nasal carriage should normally clear within 5 - 7 days of commencing treatment. Treatment should not continue for more than 10 days.

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

PRESENTATION AND STORAGE CONDITIONS

Presentation

BACTROBAN (mupirocin) Nasal Ointment 2% is supplied in 3 g tubes.

Storage Conditions

Store below 25°C.

NAME AND ADDRESS OF THE SPONSOR

GlaxoSmithKline Australia Pty Ltd
Level 4
436 Johnston Street
Abbotsford Victoria 3067

POISON SCHEDULE OF THE MEDICINE

Schedule 4 – Prescription Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

29 March 1996

DATE OF MOST RECENT AMENDMENT

23 April 2015

Version 5.0