

BACTROBAN NASAL 2% OINTMENT
(mupirocin calcium)
For Intranasal Use

DESCRIPTION

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. 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)-enoxyloxy- nonanoic acid.

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).

Bactroban Nasal Ointment Product Information2(3)

CONTRAINDICATIONS

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

WARNINGS

Avoid contact with eyes.

PRECAUTIONS

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

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.

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.

There are, however, no adequate and well controlled studies in pregnant women. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing mothers: There is no information about the excretion of mupirocin in milk. Caution should be exercised when BACTROBAN Nasal Ointment is administered to a nursing woman.

DRUG INTERACTIONS

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 REACTIONS

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.

Bactroban Nasal Ointment Product Information3(3)

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.

PRESENTATION

BACTROBAN (mupirocin) Nasal Ointment 2% is supplied in 3 gram tubes. Store below 25°C.

MANUFACTURER

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia Vic 3155
Australia
Telephone: (03) 9721 6000

Date of Preparation: February 3 1996

Date of TGA approval: 29 March 1996

Date of Safety Related Update (1) 2 October, 1997
(2) 22 October 1998

Date of Last Amendment: 23 June 2003