AUSTRALIAN PRODUCT INFORMATION

BACTROBAN (mupirocin calcium) nasal ointment

1 NAME OF THE MEDICINE

Mupirocin calcium.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

BACTROBAN nasal ointment contains mupirocin calcium 2% w/w as the active ingredient.

Each gram of BACTROBAN nasal ointment 2% contains 20 mg mupirocin as the calcium salt.

List of excipients with known effect

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

Nasal ointment.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

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

4.2 DOSE AND METHOD OF 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.

4.3 CONTRAINDICATIONS

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

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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 the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF 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.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

(Pregnancy Category B1)Reproduction studies have been performed in rats and rabbits at systemic doses up to 160 mg/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.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE 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.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

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.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

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 trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

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.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Bis-disglyceryl polyacyladipate-2

White soft paraffin.

6.2 INCOMPATIBILITIES

See Section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

6.5 STORE BELOW 25°C.NATURE AND CONTENTS OF CONTAINER

BACTROBAN (mupirocin) nasal ointment 2% is supplied in 3 g tubes.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

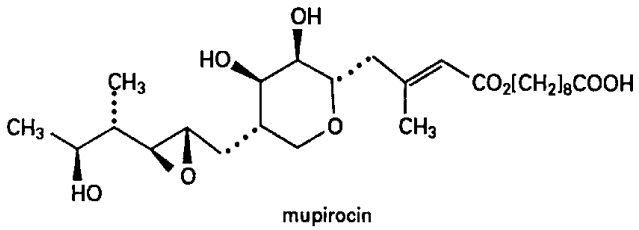
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

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.

Chemical structure



mupirocin

CAS number

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

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 – Prescription Only Medicine

8 SPONSOR

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

9 DATE OF FIRST APPROVAL

29 March 1996

10 DATE OF REVISION

18 January 2021

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	PI Reformat
4.6	Addition of pregnancy category
6.1	Update to excipient names in accordance with AAN
End of document	Update to trademark statement and addition of copyright statement

Version 6.0