Mupirocin Nasal Ointment MEDSURGE

mupirocin (as calcium) 20 mg/g (2 % w/w) nasal ointment tube

1 PRODUCT NAME

Mupirocin Nasal Ointment Medsurge contains mupirocin 2 % w/w, as calcium salt, as the active ingredient.

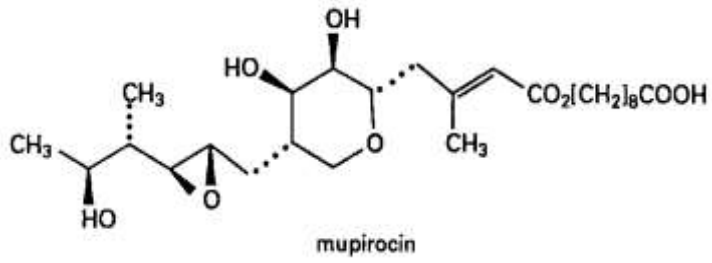
2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mupirocin 20 mg/g (2 % w/w), as mupirocin calcium

Mupirocin is a naturally occurring antibiotic, produced by fermentation of the organism *Pseudomonas fluorescens.*

The chemical name is: 9-[4-[5*S*-[2*S*,3*S*-epoxy-5*S*-hydroxy-4*S*-methylhexyl]-3*R*,4*R*-dihydroxytetrahydropyran-2*S*-yl]-3-methylbut-2-(*E*)-enoyloxy]-nonanoic acid.

Chemical structure



mupirocin

Molecular Formula: $C_{26}H_{44}O_9$ (mupirocin) and $\underline{C_{52}H_{90}CaO_{20}}$ (mupirocin calcium dihydrate)
Molecular Mass: 500.63 (mupirocin) and 1075.35 g/mol (mupirocin calcium dihydrate)

CAS number

12650-69-0 (mupirocin) and 115074-43-6 (mupirocin calcium dihydrate)

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

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Nasal Ointment.
Mupirocin Nasal Ointment is an off-white smooth nasal ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Mupirocin 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 sides 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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Wash your hands after application.

4.3 Contraindications

Mupirocin 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 Mupirocin Nasal Ointment, treatment should be discontinued, the product should be wiped off and appropriate alternative therapy for the infection instituted.

Mupirocin Nasal Ointment is not suitable for ophthalmic use.

Avoid contact with 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 non-susceptible 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 Mupirocin 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

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.

Effects on laboratory tests

No data available.

4.5 Interaction with other medicines and other forms of interaction

Mupirocin 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

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.

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 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 Mupirocin 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 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 anaphylaxis, generalised rash, urticaria and angioedema have been reported very rarely.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions at https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

There is currently limited experience with overdosage of mupirocin.

There is no specific treatment for an overdose of mupirocin. In the event of overdose, the patient should be treated supportively with appropriate monitoring as necessary.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

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

Comparability of Mupirocin Nasal Ointment and Bactroban® Nasal Ointment 2 %

The efficacy and safety of intranasal treatment with Mupirocin Nasal Ointment in the eradication of *Staphylococcus aureus* were assessed in a monocentric, randomised, double-blind, three-armed, vehicle-controlled clinical trial with the originator (Bactroban® Nasal Ointment 2 %) as the active comparator and a vehicle arm to demonstrate sufficient study sensitivity. All ointments were administered intranasally three times a day for 5 days. Healthy volunteers of either gender, aged ≥ 18 years, with stable nasal colonisation with *Staphylococcus aureus* were eligible for study participation. Stable colonisation was ensured by ≥ 2 positive baseline nasal cultures (at least 24 hours apart) for *Staphylococcus aureus* within 5 days before starting treatment. Treatment success was assessed as the primary efficacy parameter on day 8 ± 1, i.e. 48-96 hours after the end of treatment, and was defined as complete eradication of *Staphylococcus aureus*, i.e. a negative nasal culture for all *Staphylococcus aureus* strains.

A total of 245 subjects with stable nasal colonisation with *Staphylococcus aureus* were treated in this study (104 with Mupirocin Nasal Ointment, 105 with Bactroban® Nasal Ointment 2 %, 36 with vehicle ointment). The FA (full-analysis) population consisted of all 245 subjects, the PP (per-protocol) population consisted of 238 subjects (101/103/34). The treatment success rates in the PP population were 81.2 % for Mupirocin Nasal Ointment, 81.6 % for Bactroban® Nasal Ointment 2 %, and 8.8 % for vehicle. The difference in treatment success between Mupirocin Nasal Ointment and Bactroban® Nasal Ointment 2 % was -0.004 with a 95 % CI of -0.120 to +0.113, which was entirely within the predefined equivalence margin (δ) of -0.20 to +0.20, indicating a statistical equivalence of both medications. Corresponding results were found in the FA population (95 % CI of -0.116 to +0.112). Study sensitivity with regard to the chosen δ of 0.20 was proven because the δ did not exceed the predefined limit of 50 % of the difference (0.5 * 0.727 = 0.3635) between the treatment success rate in the Bactroban® Nasal Ointment 2 % group (comparator) and in the vehicle group for the PP population.

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.

5.2 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 (see also section 4.4, subsection “Paediatric use”).

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

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Glycerin ester (bis-diglyceryl polyacyladipate-2)

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Mupirocin Nasal Ointment is supplied in lacquered aluminium tubes fitted with a nozzle and screw cap in the following presentations.

Presentation	Pack size
3 g	Single
5 g	Single

Not all pack sizes may be distributed in New Zealand.

6.6 Special precautions for disposal <and other handling>

No special requirements for disposal.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

Medsurge Pharma Limited
PO Box 331054
Takapuna
Auckland 0622

Marketed and distributed by Medsurge Healthcare Pty Ltd.
Telephone: 0800 788 261
Website: www.medsurgehc.com

9 DATE OF FIRST APPROVAL

16 January 2020

10 DATE OF REVISION OF THE TEXT

25 March 2026

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
6.3	Removed in-use statement.

Bactroban® is a registered trademark of the GlaxoSmithKline group of companies.