

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mupirocin 20 mg/g Nasal Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g of nasal ointment contains 2.00 g of mupirocin, as mupirocin calcium.

1 g of nasal ointment contains 20 mg of mupirocin, as mupirocin calcium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White soft paraffin based nasal ointment containing a glycerin ester.

Off-white smooth nasal ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Mupirocin 20 mg/g Nasal Ointment is indicated for the elimination of nasal carriage of staphylococci, including methicillin resistant *Staphylococcus aureus* (MRSA) in adults, adolescents and children aged one year and older.

4.2 Posology and method of administration

Posology

Adults (including the elderly) and children from one year of age:

Mupirocin 20 mg/g Nasal Ointment should be applied to the anterior nares two to three times a day.

Paediatric population:

Children < 1 year:

The safety and efficacy of Mupirocin 20 mg/g Nasal Ointment in children under one year of age has not been established. No data are available.

Renal impairment:

No dosage adjustment is necessary.

Hepatic impairment:

No dosage adjustment is necessary.

Method of administration

Topical.

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 cotton bud may be used instead of the little finger for the application in particular to infants or patients who are very ill.

Nasal carriage should normally clear within 5–7 days of commencing treatment and be verified by microbiological testing.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Infants should not be treated with Mupirocin 20 mg/g Nasal Ointment to avoid aspiration in the trachea.

4.4 Special warnings and precautions for use

Should a possible sensitisation reaction or severe local irritation occur with the use of Mupirocin 20 mg/g Nasal Ointment, treatment should be discontinued, the product should be wiped away and appropriate therapy instituted.

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

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.

This mupirocin 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.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

The nasal ointment should not be administered concomitantly with other nasal ointments or active substances to avoid dilution of the ointment which could alter mucosal penetration and thereby efficacy and product stability.

4.6 Fertility, pregnancy and lactation

Pregnancy

Reproduction studies on mupirocin in animals have revealed no evidence of harm to the fetus (see section 5.3). As there is no clinical experience on its use during pregnancy, Mupirocin 20 mg/g Nasal Ointment should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment.

Breast-feeding

There is insufficient information on the excretion of mupirocin/metabolites in human milk.

As with other topical treatments, only low systemic exposition would be expected for lactating woman. Mupirocin 20 mg/g Nasal Ointment should only be used during breast-feeding when the potential benefit of the mother outweigh the possible risk of the child.

Fertility

There are no data on the effects of mupirocin on human fertility. Studies in rats showed no effects on fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

Mupirocin 20 mg/g Nasal Ointment has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ to $<1/10$), uncommon ($\geq 1/1,000$ to $<1/100$), rare ($\geq 1/10,000$ to $<1/1,000$), very rare ($<1/10,000$), including isolated reports.

Uncommon adverse reactions were determined from pooled safety data from a clinical trial population of 422 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: Cutaneous hypersensitivity reactions. Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema.

Respiratory, thoracic and mediastinal disorders

Uncommon: Nasal mucosa reactions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms and signs

There is currently limited experience with overdosage of Mupirocin 20 mg/g Nasal Ointment.

Treatment

There is no specific treatment for an overdose of Mupirocin 20 mg/g Nasal Ointment. 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 national poisons centre, where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other nasal preparations.

ATC code: R01AX06

Mechanism of action

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

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

Mechanism of resistance

Low-level resistance in staphylococci is thought to result from point mutations within the usual staphylococcal chromosomal gene (*ileS*) for the target isoleucyl tRNA synthetase enzyme. High-level resistance in staphylococci 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 of the outer membrane of the Gram-negative bacterial cell wall.

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

Microbiological susceptibility

The prevalence of acquired resistance may vary geographically and with time for selected species, and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infection is questionable.

<i>Commonly susceptible species:</i>
<i>Staphylococcus aureus</i> *
<i>Streptococcus</i> spp.
<i>Species for which acquired resistance may be a problem:</i>
Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)
Methicillin-resistant coagulase-negative <i>Staphylococci</i> (MRCoNS)

<i>Inherently resistant organisms:</i>
<i>Corynebacterium</i> spp.
<i>Micrococcus</i> spp.

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

Mupirocin susceptibility (MIC) breakpoints for *Staphylococcus aureus*:

Susceptible: less than or equal to 1 mg/L
Resistant: greater than 256 mg/L

5.2 Pharmacokinetic properties

Studies have shown that following topical application of mupirocin there is very little systemic absorption of drug-related material. To mimic possible enhanced systemic penetration of mupirocin by application to damaged skin or a vascular site such as the mucous membrane, intravenous studies have been performed. Mupirocin was rapidly eliminated from the plasma by metabolism to monic acid, which in turn was excreted mainly in the urine.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use and development. Mutagenicity studies revealed no risks to man.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, white soft
Bis-Diglyceryl Polyacyladipate-2

6.2 Incompatibilities

In the absence of compatibility studies, this product must not be mixed with other medicinal products.

6.3 Shelf life

3 years
After first opening contents can be used up to 7 days.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Aluminium tube with epoxy-phenolic inner lacquer, fitted with a HDPE nozzle and HDPE screw cap containing 3 g or 5 g ointment.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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.

7 MARKETING AUTHORISATION HOLDER

INFECTOPHARM Arzneimittel und Consilium GmbH

Von-Humboldt-Straße 1

64646 Heppenheim

Germany

Tel. +49 (0) 6252 / 95 70 00

Fax +49 (0) 6252 / 95 88 44

Email: info@infectopharm.com

Internet: www.infectopharm.com

8 MARKETING AUTHORISATION NUMBER(S)

PL 15011/0023

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/02/2019

10 DATE OF REVISION OF THE TEXT

14/02/2019