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INSTRUCTION
for medical use

BACTOPIC®

Composition:
active substance: mupirocin calcium;
1 gram of ointment contains mupirocin calcium equivalent to mupirocin 20 mg;

excipients: white soft paraffin, softisan 649.

Pharmaceutical form. Nasal ointment.
Main physical and chemical properties: white to off white homogeneous ointment.

Pharmacotherapeutic group. Antibiotics and chemotherapeutics for dermatological use.
ATC code: D06AX09.
Pharmacodynamics.
Mupirocin is the main antibacterial component of a group of structurally dependent metabolites formed by fermentation of *Pseudomonas fluorescens*. The mechanism of action of mupirocin is inhibition of bacterial isoleucyl-transfer-RNA synthetase, so cross-resistance with other antibiotics is not expected.
Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bactericidal properties at the higher concentrations reached when applied topically.

Commonly susceptible species:
*Staphylococcus aureus**
Streptococcus spp.
Species for which acquired resistance may be a problem:
Methicillin-resistant-*Staphylococcus aureus* (MRSA)
Methicillin-resistant coagulase-negative *Staphylococci* (MRCoNS)
Resistant organisms:
Corynebacterium spp.
Micrococcus 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.

Pharmacokinetic properties.

Studies have shown that following topical application of mupirocin there is very little systemic absorption of drug. 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.

Clinical characteristics.

Indications.

Local treatment of nasal infections caused by *Staphylococcus aureus*, including methicillin-resistant strains.

Contraindications.

Hypersensitivity to mupirocin or to any other component of the drug.

Interaction with other medicinal products and other forms of interaction.

No drug interactions have been identified.

Special warnings and precautions for use.

Hypersensitivity reactions.

Should a possible hypersensitivity reaction or severe local irritation occur with the use of ointment, treatment should be discontinued, the product should be washed off and appropriate therapy instituted.

Pseudomembranous colitis.

As with other antibacterial products, prolonged use of mupirocin 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.

Accidental contact with the eyes.

This mupirocin nasal ointment 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.

Pregnancy and lactation.

Pregnancy.

Studies on mupirocin in animals have revealed no evidence of harm to the fetus. There is no clinical experience on mupirocin ointment use during pregnancy. Bactopic® ointment should only be used in pregnancy when the potential benefits to the mother outweigh the possible risks of treatment to the fetus.

Lactation.

It is unknown whether mupirocin is excreted in human milk when applied topically.

Fertility.

There are no data on the effects of mupirocin on human fertility. Studies in animals showed no effects on fertility.

Effects on ability to drive and use machines.

No adverse effects on the ability to drive or operate machinery have been identified.

Posology and method of administration.
Adults, children and elderly patients
Use your little finger or a cotton wool bud to apply a small amount of ointment (about the size of a match head) to the nasal mucosa of each nostril 2–3 times a day. After applying the ointment, press the sides of your nose together several times to allow the ointment to spread around the nasal mucosa. Clearance of the nasal cavity from pathogens usually occurs 3–5 days after treatment. Treatment should not exceed 10 days.
The drug is for topical use only.
Wash your hands thoroughly after applying the drug to the mucous membranes.
Do not mix with other preparations as there is a risk of dilution, resulting in a reduction of the antibacterial activity and potential loss of stability of the active ingredient in the ointment.
No dose adjustment is required for hepatic or renal insufficiency.

Children.
Use for the treatment of children over 12 years of age. The safety of the drug in children under 12 years of age has not been established.

Overdose.
Symptoms. There is currently limited experience with symptoms of mupirocin overdosage.
Treatment. There is no specific treatment. Symptomatic treatment and appropriate monitoring of the patient's condition are indicated.

Adverse reactions.
Adverse reactions listed below include those reported in clinical trials and postmarketing experience. The following terms and frequencies are applied: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10000 to <1/1000), very rare (<1/10000), including isolated cases, and not known (frequency cannot be estimated from available data).
Immune system disorders: very rare – skin hypersensitivity reactions, systemic allergic reactions including anaphylaxis, generalized rash, urticaria and angioedema.
Respiratory, thoracic and mediastinal disorders: uncommon – nasal mucosa reactions: itching, burning sensation, redness, as well as runny nose, sneezing, nasal congestion, cough, pharyngitis.
Nervous system disorders: not known – headache, change in taste sensations.
Reporting of adverse reactions.
Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system, and to the applicant via the website feedback form: https://kusum.ua/pharmacovigilance/.

Shelf life.
2 years.

Storage conditions.
Store in original packing at temperature below 25°C.
Keep out of reach of children.

Package.
3 g ointment packed in aluminium tube fitted with a nozzle and screw cap. One such tube in a carton packing along with pack insert containing instructions for medical use.

Conditions of supply.
By prescription.

Manufacturer.
KUSUM HEALTHCARE PVT LTD.

Location of manufacturer and its address of business activity.
SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

Date of last revision.