APPROVED
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Instruction for medical use

BACTOPIC®

Composition:
active substance: mupirocin;
1 gram of ointment contains 20 mg of mupirocin;
excipients: polyethylene glycol 3350, polyethylene glycol 400.

Pharmaceutical form. Ointment.
Main physical and chemical properties: white or almost white ointment.

Pharmacotherapeutic group. Antibiotics for local use. Mupirocin.
ATC Code: D06A X09.

Pharmacological properties.
Pharmacodynamics.
Mupirocin, an antibacterial agent for topical use, is active against microorganisms that cause the majority of infectious skin diseases, including *Staphylococcus aureus*, methicillin-resistant strains, other staphylococci and streptococci. The drug is also active against gram-negative microorganisms such as *Escherichia coli* and *Haemophilus influenzae*.
Mupirocin is an antibiotic that is produced by fermentation of *Pseudomonas fluorescens*.
Mupirocin is a strong inhibitor of bacterial protein and RNA synthesis by inhibiting isoleucyl-transfer-RNA synthetase.
Pharmacokinetic properties.
Following topical application of Bactopic® ointment, mupirocin is minimally absorbed systemically, and the absorbed amount is rapidly metabolized to a microbiologically inactive metabolite – monoic acid. The penetration of mupirocin into deeper epidermal and dermal layers of the skin increases in damaged areas of the skin and under occlusion patches.

Clinical characteristics.
Indications.
Local treatment of bacterial skin infections, such as impetigo, folliculitis, and furunculosis, caused by mupirocin-susceptible microorganisms.

Contraindications.
Hypersensitivity to mupirocin or to any other component of the drug.
This pharmaceutical form is not intended for ophthalmic and intranasal use.

Interaction with other medicinal products and other forms of interaction.
No drug interactions have been identified.

Special warnings and precautions for use.

Hypersensitivity reactions

In the event of hypersensitivity reactions or severe local reactions from the skin while applying ointment, treatment should be stopped; the skin should be washed with water to remove ointment residues, and appropriate therapy should be administrated.

Pseudomembranous colitis

As with other antibacterials, prolonged use of mupirocin may result in excessive growth of insensitive microorganisms.

Following use of antibiotics, pseudomembranous colitis may develop, the severity of which may vary from mild to condition, dangerous to life. Therefore, it is important to consider the possibility of such diagnosis in patients who develop diarrhea during or after the administration of antibiotics. Although the likelihood of developing this phenomenon in the local use of mupirocin is lower, in the event of prolonged or severe diarrhea or abdominal cramping, treatment should be stopped immediately, and an additional patient examination should be performed.

Renal insufficiency

Polyethylene glycol can be absorbed from open wounds and damaged skin and is excreted by the kidneys. In common with other polyethylene glycol-based ointments, Bactopic® ointment should not be used in conditions where absorption of large quantities of polyethylene glycol is possible, especially if there is evidence of moderate or severe renal impairment.

Bactopic® ointment cannot be used:

- for the treatment of eye diseases;
- intranasal;
- in combination with catheters;
- in the area of catheterization of central veins.

Accidental contact of the drug with the eyes

Avoid contact with the eyes. If this happens, the eyes should be thoroughly rinsed with water until the remnants of the ointment are completely removed.

Fertility, pregnancy and lactation.

Pregnancy. The study of mupirocin in animals did not reveal signs of harmful effects on the fetus. Clinical data on the use of ointment with mupirocin during pregnancy are absent. Bactopic® ointment should be used during pregnancy only when the potential benefit to the mother will outweigh the potential risk to the fetus.

Lactation. There are no data on the excretion of mupirocin in breast milk in its local application. If necessary, cracked nipples of the mammary glands may be treated with ointment, but they should be rinsed thoroughly before feeding the baby.

Fertility. No data are available on the effect of mupirocin on fertility in humans. Animal studies have shown no effect on fertility.

Effects on ability to drive and use machines.

Adverse reactions that have had a negative impact on the ability to drive or operate other mechanisms have not been identified.

Posology and method of administration.

Adults, children and elderly patients

A small amount of ointment should be applied to the affected skin 2–3 times per day for up to 10 days, depending on the response to treatment.

The treated area may be covered by a dressing.

Hepatic insufficiency
Dose adjustment is not required.
Renal insufficiency
See section "Special warnings and precautions for use".
Elderly patients
There are no restrictions on the use in the elderly unless there is evidence of the absorption of polyethylene glycol, which is part of Bactopic® ointment, and signs of moderate or severe renal impairment.
The drug is for external use.
After applying the drug to the skin, wash hands thoroughly.
Do not mix with other preparations as there is a risk of dilution, resulting in a reduction of the antibacterial activity, along with potential loss of mupirocin stability in the ointment.
Any product amount remaining at the end of treatment should be discarded.

Children.
It is used to treat children aged 2 months and above.

Overdose.
Symptoms. The toxicity of mupirocin is very low. There is currently limited experience with symptoms of mupirocin overdose.
Therapeutic measures. In the event of overdose with local application of the ointment or its accidental ingestion, there is no specific treatment. In the event of overdose, the patient should be treated supportively with appropriate monitoring as necessary.
In case of erroneous oral intake of large quantities of the ointment, renal function should be closely monitored in patients with renal insufficiency because of the possible side effects of polyethylene glycol.

Undesirable effects.
Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (>1/10), common (>1/100, <1/10), uncommon (>1/1,000,<1/100), rare (>1/10,000, <1/1,000), very rare (<1/10,000), including isolated reports.
Immune system
Very rare: systemic allergic reactions including anaphylaxis, generalized rash, urticaria, and angioedema.
Skin and subcutaneous tissues
Common: burning localized to the area of application, eczema.
Uncommon: itching, erythema, pain and dry skin at the application site. Hypersensitivity skin reactions: rash, increased exudation, swelling at the site of application of the ointment, contact dermatitis.
Nervous system: headache, dizziness.
Digestive tract: nausea, abdominal pain, ulcerative stomatitis.
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. Medical and pharmaceutical workers, as well as patients or their legal representatives are asked to report any suspected adverse reactions and lack of effectiveness of the medicinal product through the Pharmacovigilance Automated Information System at: https://aisf.dec.gov.ua.

Shelf life.
2 years.

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

Package.
15 g of ointment in aluminium tube. Each tube in carton box.

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.