Bactroban™ *CREAM*

Mupirocin

QUALITATIVE AND QUANTITATIVE COMPOSITION (active ingredient only)
Mupirocin calcium equivalent to 2% w/w mupirocin free acid.
PHARMACEUTICAL FORM
White cream of homogeneous appearance.
CLINICAL PARTICULARS
Therapeutic indications
Bactroban CREAM is indicated for the topical treatment of secondarily infected traumatic lesions such as small lacerations, sutured wounds or abrasions (up to 10cm in length or 100cm^2 in area), due to susceptible strains of Staphylococcus aureus and Streptococcus pyogenes.
Posology and method of administration
Dosage
Adults/children/elderly
Three times a day for up to 10 days, depending on the response.
Patients not showing a clinical response within 3 to 5 days should be re-evaluated.
The duration of treatment should not exceed 10 days.
Hepatic impairment: No dosage adjustment is necessary.
Renal impairment. No dosage adjustment is necessary.
Method of administration
A thin layer of cream should be applied to the affected area with a piece of clean cotton wool or gauze swab.
The treated area may be covered by a dressing.
Do not mix 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 cream.
Contra-indications
Bactroban CREAM should not be given to patients with a history of hypersensitivity to any of its constituents.
Special warnings and special precautions for use
For intranasal use, a separate presentation, **Bactroban Nasal Ointment,** is available.
Avoid contact with the eyes.
In the rare event of a possible sensitisation reaction or severe local irritation occurring with the use of **Bactroban CREAM,** treatment should be discontinued, the product should be washed off and appropriate alternative therapy for the infection instituted.
As with other antibacterial products, prolonged use may result in overgrowth of non-susceptible organisms.
Bactroban Cream has not been studied in infants under 1 year old and therefore it should not be used in these patients until further data become available.
Bactroban Cream contains cetyl alcohol and stearyl alcohol. These inactive ingredients may cause local skin reactions (e.g. contact dermatitis).
Interaction with other medicaments and other forms of interaction
No drug interactions have been identified.
Pregnancy and Lactation
Use in pregnancy:
Adequate human data on use during pregnancy are not available. However, animal studies have not identified any risk to pregnancy or embryo-foetal development.
Mupirocin should only be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.
Use in lactation:
Adequate human and animal data on use during lactation are not available. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast feeding.
Effects on ability to drive and use machines
No adverse effects on the ability to drive or operate machinery have been identified.
Undesirable effects
The following convention has been used for the classification of frequency: common ≥ 1/100 and < 1/10
Skin and subcutaneous tissue disorders:
Common: Cutaneous hypersensitivity reactions
Overdose
The toxicity of mupirocin is very low. In the event of accidental ingestion of the cream symptomatic treatment should be given.
PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Mupirocin is a novel antibiotic produced through fermentation by *Pseudomonas fluorescens.* Mupirocin inhibits isoleucyl transfer-RNA synthetase, thereby arresting bacterial protein synthesis. Due to this particular mode of action and its unique chemical structure, Mupirocin does not show any cross-resistance with other clinically available antibiotics.
Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bactericidal properties at the higher concentrations reached when applied locally.
Mupirocin is a topical antibacterial agent showing *in vivo* activity against *Staphylococcus aureus* (including methicillin-resistant strains), *S. epidermidis* and beta-haemolytic *Streptococcus* species.
The *in vitro* spectrum of activity includes the following bacteria:
Aerobic Gram-positive:
- *Staphylococcus aureus* (including beta-lactamase-producing strains and methicillin resistant strains).
- *Staphylococcus epidermidis* (including beta-lactamase-producing and methicillin-resistant strains)
- Other coagulase-negative staphylococci (including methicillin-resistant strains).
- *Streptococcus* species

Aerobic Gram-negative:
- *Haemophilus influenzae*
- *Neisseria gonorrhoeae*
- *Neisseria meningitidis*
- *Moraxella catarrhalis*
- *Pasteurella multocida*

Pharmacokinetic properties
Systemic absorption of Mupirocin through intact human skin is low although it may occur through broken/diseased skin. However, clinical trials have shown that when given systemically, it is metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted by the kidney.
Preclinical safety data
No further information of relevance.

List of Excipients

- Xanthan gum
- Liquid paraffin
- Cetomacrogol 1000
- Stearyl alcohol
- Cetyl alcohol
- Phenoxyethanol
- Benzyl alcohol
- Purified water

Incompatibilities
None identified.
Shelf-life
The expiry date is indicated on the packaging.
Special precautions for storage
Do not store above 25°C.
Do not freeze.
Nature and contents of container
Squeezable aluminium tubes with a screw cap containing 15 g.
Instructions for use/handling
Any product remaining at the end of treatment should be discarded.

Manufactured by:
Glaxo Operations UK Limited*
Barnard Castle,
UK

*Member of the GlaxoSmithKline group of companies.

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THIS IS A MEDICAMENT
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- **Keep all medicaments out of the reach of children.**

Council of Arab Health Ministers,
Union of Arab Pharmacists.

GlaxoSmithKline