Bactroban™ *CREAM*

Mupirocin

QUALITATIVE AND QUANTITATIVE COMPOSITION

Mupirocin calcium equivalent to 2% w/w mupirocin free acid.

PHARMACEUTICAL FORM

White cream for topical administration in a multi-use tube.

CLINICAL PARTICULARS

Indications

BACTROBAN cream is indicated for the topical treatment of secondarily infected traumatic lesions such as small lacerations, sutured wounds or abrasions.

Dosage and Administration

Dosage

Adults/children elderly
Three times a day for up to 10 days, depending on the response.
Hepatic impairment : No dosage adjustment is necessary
Renal impairment : No dosage adjustment is necessary

Method of administration

A small quantity 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 reduction in the antibacterial activity and potential loss of stability of the mupirocin in the cream.

Contraindications

BACTROBAN cream should not be given to patients with a history of hypersensitivity to any of its constituents.

Warnings and Precautions

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.

Interactions.

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.

Adverse Reactions
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
Not applicable

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 shows little risk of selection of bacterial resistance if used as prescribed.
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:

<u>Aerobic Gram-positive:</u>
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

Pharmacokinetics
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 metabolized to the microbiologically inactive metabolite monic acid and rapidly excreted. Mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is rapidly excreted by the kidney.

Pre-clinical Safety Data
No further information of relevance.

PHARMACEUTICAL PARTICULARS

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
BACTROBAN cream may be stored at room temperature (below 25^0C) up to the expiry date. Do not freeze.

Nature and Contents of Container
Squeezable aluminium tubes with a screw cap containing 5 g and 10g.

Instructions fo Use/Handling
No special instructions.
Any product remaining at the end of treatment should be discarded.

HARUS DENGAN RESEP DOKTER

Bactroban Cream, Tube@5g Reg.No DKIxxxxxxxxx
Bactroban Cream, Tube@10g Reg.No DKIxxxxxxxxx

Manufactured by
PT.Glaxo Wellcome Indonesia
For PT. SmithKline Beecham Pharmaceuticals
Bogor, Indonesia

BACTROBAN™ CREAM is a product of research from SmithKline Beecham Pharmaceuticals. BACTROBAN is a trademark.

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