BACTROBAN® TOPICAL

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

BACTROBAN® TOPICAL Ointment

COMPOSITION:

BACTROBAN TOPICAL ointment contains 2 % *m/m* mupirocin.

Excipients: polyethylene glycol. (Refer to WARNINGS AND SPECIAL PRECAUTIONS – Patients with renal impairment).

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.6 Topical Antibiotics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties

Mupirocin is an antibiotic produced through fermentation of *Pseudomonas fluorescens* and inhibits bacterial protein synthesis by binding to bacterial isoleucyl t-RNA synthetase.

Mupirocin shows little risk of selection of resistant bacteria if used as prescribed.

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

Pharmacokinetic properties:

1. Absorption: Mupirocin is poorly absorbed (less than 0,24 %) through intact human skin. However, if it is absorbed (e.g. through broken/diseased skin) or it is

given systemically, it is metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted.

2. Excretion: Mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is excreted mainly by the kidney (90 %).

INDICATIONS:

BACTROBAN TOPICAL ointment is indicated for the topical treatment of primary and secondary bacterial skin infections caused by *Staphylococcus aureus* and other susceptible organisms.

Primary skin infections:

Impetigo, folliculitis, furunculosis and ecthyma.

Secondary infections:

Infected dermatoses e.g., infected eczema. Infected traumatic lesions e.g., abrasions, insect bites, minor (not requiring hospitalisation) wounds and burns.

Prophylaxis: Mupirocin may be used to avoid bacterial contamination of small wounds, incisions and other clean lesions, and to prevent infection of abrasions and small cuts and wounds.

CONTRA-INDICATIONS:

BACTROBAN TOPICAL ointment is not indicated for the treatment of skin lesions infected with *Pseudomonas aeruginosa*.

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

WARNINGS AND SPECIAL PRECAUTIONS:

This mupirocin ointment formulation is not suitable for:

- ophthalmic use
- intranasal use

- use in conjunction with cannulae
- at the site of central venous cannulation.

Avoid contact with eyes. If contaminated, the eyes should be thoroughly irrigated with water until the ointment residues have been removed.

Patients with renal impairment:

No restrictions, unless the condition being treated could lead to absorption of polyethylene glycol and there is evidence of moderate to severe renal impairment.

Polyethylene glycol can be absorbed from open wounds, burns and damaged skin and is excreted by the kidneys. BACTROBAN TOPICAL 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. The excretion of polyethylene glycol may be impaired and could lead to nephrotoxicity and severe metabolic disturbances.

In the rare event of a possible sensitisation reaction or severe local irritation occurring with the use of BACTROBAN TOPICAL ointment, treatment should be discontinued, the product should be rinsed off and appropriate alternative therapy for the infection instituted.

Prolonged or irregular use may result in overgrowth of non-susceptible strains of *S. aureus* and other organisms.

PREGNANCY AND LACTATION:

The safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults, children, elderly:

2-3 times a day for up to 10 days, depending on the response.

Hepatic impairment: As above.

Renal impairment: See WARNINGS AND SPECIAL PRECAUTIONS.

Method of Administration:

A small quantity of BACTROBAN ointment should be applied to cover the affected area.

The treated area may be covered by a dressing.

Any product remaining at the end of treatment should be discarded.

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 ointment.

SIDE EFFECTS:

Side effects 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.

Common and uncommon side effects were determined from pooled safety data from a clinical trial population of 1 573 treated patients encompassing 12 clinical studies. Very rare side effects were primarily determined from post-marketing experience data and therefore refer to reporting rate rather than true frequency.

Immune system disorders:

Very rare: Systemic allergic reactions have been reported with BACTROBAN TOPICAL.

Skin and subcutaneous tissue disorders:

Common: Burning localised to the area of application.

Uncommon: Itching, erythema, stinging and dryness localised to the area of application.

Cutaneous sensitisation reactions to mupirocin or the ointment base.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See SIDE EFFECTS.

IDENTIFICATION:

BACTROBAN TOPICAL ointment is an off-white coloured ointment packed in tubes.

PRESENTATION:

BACTROBAN TOPICAL ointment is available in 15 g and 100 g tubes each packed in an outer carton.

STORAGE INSTRUCTIONS:

Store below 25 °C.

Keep out of reach of children.

REGISTRATION NUMBER:

T/20.1.6/75

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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