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SCHEDULING STATUS **S2**

PROPRIETARY NAME AND DOSAGE FORM

SUPIROBAN OINTMENT

COMPOSITION

Mupirocin ointment 20 mg/g

PHARMACOLOGICAL CLASSIFICATION

A. 20.1.6 Topical Antibiotics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

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

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

Following intravenous or oral administration, mupirocin is rapidly metabolised to the inactive monic acid.

Activity:

Mupirocin shows in vivo activity against Staphylococcus aureus (including methicillin resistant strains), S. epidermidis and beta haemolytic Streptococcus species.

Pharmacokinetic properties:

Absorption:

Mupurocin is poorly absorbed (less than 0.24 %) through intact human skin. However, if it is absorbed

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(e.g. through broken / diseased skin) or it is given systemically, it is metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted.

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

Supiroban Ointment is indicated for the topical treatment of primary and secondary bacterial skin infections caused by Staphylococcus aureus and other susceptible organisms.

Primary Skin Infection:

Impetigo, follicullitis, furunculosis and ecthyma

Secondary Infections:

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

Prophylaxis:

Supiroban 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

Supiroban Ointment is not indicated for the treatment of skin lesions infected with Pseudomonas aeruginosa.

Supiroban Ointment should not be used by patients with a history of hypersensitivity to any of its constituents.

WARNINGS AND SPECIAL PRECAUTIONS

Supiroban ointment is not suitable for:

λ Ophthalmic use

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- λ Intranasal use
- λ Use in conjunction with cannulae.
- λ 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.

Supiroban should be used with caution in patients with extensive burns or wounds because of the possibility of macrogol toxicity.

Care is required in patients with renal impairment.

In the event of a possible hypersensitivity reaction or severe local irritation occurring with use of Supiroban Ointment, treatment should be discontinued, the product should be rinsed off and appropriate alternative therapy for the infection instituted.

DOSAGE AND DIRECTIONS FOR USE

Adults, children, elderly:

Two to three times a day for up to 10 days, depending on the response.

Renal impairment:

See "Warnings".

Method of administration:

A small quantity of Supiroban 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.

SIDE EFFECTS

Local reactions such as burning, stinging and itching may occur after application to the skin.

Erythema, dryness and itching have been reported less frequently.

Systemic allergic reactions with Supiroban Ointment may occur.

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

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See Side Effects.

Treatment is symptomatic and supportive

IDENTIFICATION

A white, translucent water miscible ointment

PRESENTATION

Supiroban Ointment is available in a latex, aluminium (not lacquered), collapsible tube with cap. The tube contains 14 g, 15 g and 50 g Ointment.

STORAGE INSTRUCTIONS

Store at or below 25^{O}C.

Do not refrigerate

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER

43/20.1.6/0680

Namibia Reg. No. 11/20.1.6/0213

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