Scheduling status: S2

Proprietary Name and Dosage Form:

SUPIROBAN OINTMENT

Glenmark

COMPOSITION
Mupirocin ointment 20 mg/g

PHARMACOLOGICAL CLASSIFICATION
A. 20.1.6 Topical Antibiotics

PHARMACOLOGICAL ACTION
Pharmacological Properties

Mupirocin 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.

PHARMACOKINETICS:

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.

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, folliculitis, 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 Ointment 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
Supiroban Ointment 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.

Supiroban Ointment 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.

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 AND SPECIAL PRECAUTIONS
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.

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.

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, 30 g or 50 g ointment.

STORAGE INSTRUCTIONS
Store at or below 25 ^{o}C.

Do not refrigerate

KEEP OUT OF THE REACH OF CHILDREN.

Registration Number
A 43/20.1.6/0680

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