

Dermasoft[®] Ointment

Mupirocin 2%

COMPOSITION:

Dermasoft[®] ointment: Each gram ointment contains Mupirocin USP 20 mg.

PHARMACOLOGY:

Mupirocin is a naturally occurring antibiotic. It is an antibacterial agent produced by fermentation using the organism *Pseudomonas fluorescens*. It is active against a wide range of bacteria those responsible for the majority of skin infections, e.g. *Staphylococcus aureus* including methicillin-resistant *Staphylococcus aureus* (MRSA) other *staphylococci* and *streptococci*. It is also active against certain gram-negative pathogens, like *Escherichia coli* and *Haemophilus influenzae*. Mupirocin inhibits bacterial protein synthesis by reversibly and specifically binding to bacterial isoleucyl transfer-RNA synthetase. Due to this unique mode of action, Mupirocin demonstrates no in vitro cross-resistance with other classes of antimicrobial agents. Mupirocin is bactericidal at concentrations achieved by topical administration. However, the minimum bactericidal concentration (MBC) against relevant pathogens is generally eight-fold to thirty-fold higher than the minimum inhibitory concentration (MIC).

INDICATION:

Dermasoft[®] ointment is indicated for the topical treatment of impetigo due to: *Staphylococcus aureus* and *Streptococcus pyogenes*. It is also indicated in folliculitis and furunculosis.

DOSE & ADMINISTRATION:

For children and adult: A small amount of Dermasoft[®] ointment should be applied to the affected area three times daily for 10 days. The area treated may be covered with gauze dressing if desired. If Patients not showing a clinical response within 3 to 5 days, treatment should be re-evaluated.

CONTRA-INDICATIONS:

This drug is contraindicated in individuals with a history of sensitivity reactions to any of its components.

WARNING AND PRECAUTION:

Dermasoft[®] ointment is not for ophthalmic or intra-nasal use. If a reaction suggesting sensitivity or chemical irritation should occur with the use of Dermasoft[®] ointment, treatment should be discontinued and appropriate alternative therapy for the infection instituted. As with other antibacterial products, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. When Dermasoft[®] ointment is used on the face care should be taken to avoid the eyes. Polyethylene Glycol can be absorbed from open wounds and damaged skin and is Excreted by the kidneys. In common with other polyethylene glycol-based ointments, Dermasoft[®] 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.

SIDE EFFECTS:

The following local adverse reactions have been reported in connection with the use of Dermasoft[®] ointment: burning, stinging, or pain in 1.5% of patients itching in 1% of patients, rash, nausea, erythema, dry skin, tenderness, swelling, contact dermatitis and increased exudate in less than 1% of patients.

USE IN PREGNANCY & LACTATION:

The drug is classified in Pregnancy Category B. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Mupirocin is used to a nursing woman.

USE IN CHILDREN & ADOLESCENTS:

The safety and effectiveness of Dermasoft[®] ointment have been established in the age range of 2 months to 16 years. Use of the Dermasoft[®] ointment in these age groups is supported by evidence from adequate and well-controlled studies of Mupirocin in impetigo in pediatric patients.

DRUG INTERACTION:

The effect of the concurrent application of Mupirocin and other drug products has not been studied.

OVERDOSE:

An overdose of Mupirocin topical is not expected to be dangerous. Seek emergency medical attention if anyone has accidentally swallowed.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Dermasoft[®] ointment: Each box contains 10 gm ointment in a tube.



Manufactured by

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