

GENTAMED (Dermal Cream - Ointment)

Gentamicin Sulfate



COMPOSITION: Each 1 gr. of GENTAMED (cream, ointment) contains: Gentamicin sulfate equivalent to 3 mg of Gentamicin base.

Excipients:

Cream: Glycerol Monostearate, Cetostearyl Alcohol, Emulgin B2, Vaseline, Liquid Paraffin, Glycerin, Methyl Paraben Sodium, Propyl Paraben Sodium, Deionized Water.

Ointment: Liquid Paraffin, Vaseline.

PHARMACOLOGICAL PROPERTIES:

Gentamicin is a wide spectrum antibiotic that provides highly effective topical treatment in primary and secondary bacterial infections of the skin. This product may clear infections that have not responded to other topical antibiotic agents. Bacteria susceptible to the action of gentamicin include: sensitive strains of streptococci (group A beta-hemolytic, alpha-hemolytic), staphylococcus aureus (coagulase positive, coagulase negative, and some penicillinase-producing strains), and the gram-negative bacteria, pseudomonas aeruginosa, aerobacter aerogens, escherichia coli, proteus vulgaris and klebsiella pneumoniae.

INDICATIONS:

Primary skin infections: Impetigo contagiosa, superficial folliculitis, ecthyma, furunculosis, sycosis barbae, and pyoderma gangrenosum.

Secondary skin infections: Infectious eczematoid dermatitis, pustular acne, pustular psoriasis, infected seborrheic dermatitis, infected contact dermatitis, infected excoriations, and bacterial super-infections of fungal or viral infections.

It is useful in the treatment of infected skin cysts and certain other skin abscesses when preceded by incision and drainage to permit adequate contact between the antibiotic and the infecting bacteria.

GENTAMED is also used in the treatment of infected stasis and other skin ulcers, infected superficial burns, paronychia, infected insect bites and stings, infected lacerations and abrasions and wounds from minor surgery.

Patients sensitive to neomycin can be treated with gentamicin sulfate, although regular observation of patients sensitive to topical antibiotics is advisable when such patients are treated with any topical antibiotic. **GENTAMED** Cream, recommended for wet, oozing primary infections, and greasy, secondary infections, such as pustular acne or infected seborrheic dermatitis. If a water-washable preparation is desired, the cream is preferable.

GENTAMED Cream has been used successfully in infants over one year of age, as well as in adults and children.

CONTRAINDICATIONS:

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

PRECAUTIONS:

The Use of topical antibiotics occasionally allows overgrowth of nonsusceptible organisms, including fungi. If this occurs, or if irritation, sensitization, or superinfection develops, treatment with Gentamicin Sulfate should be discontinued and appropriate therapy instituted.

SIDE EFFECTS:

Irritation (erythema and pruritus) that did not usually require discontinuance of treatment.

There was no evidence of irritation or sensitization. Possible photosensitization has been reported in several patients but could not be elicited in these patients by reapplication of gentamicin followed by exposure to ultraviolet radiation.

DOSE AND ADMINISTRATION:

A small amount of **GENTAMED** ointment or cream should be applied gently to lesions three to four times a day. The area treated may be covered with a gauze dressing if desired.

In impetigo contagiosa, the crusts should be removed before application of Gentamicin Sulfate ointment to permit maximum contact between the antibiotic and the infection. Care should be exercised to avoid further contamination of the infected skin.

GENTAMED Ointment helps retain moisture and has been useful in infection on dry eczematous or psoriatic skin.

STORAGE CONDITIONS:

- Store at room temperature, between (15 - 30) °C.
- Keep out of reach of children.

PACKAGING:

Cream: Aluminum tube contains 20 gr. **GENTAMED** cream/carton box.

Ointment: Aluminum tube contains 20 gr. **GENTAMED** ointment/carton box.

* THIS IS A MEDICAMENT *

- Keep out of reach of children.
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly doctor's prescriptions, the method of use and instructions of the pharmacist who sold the medicament.
- The doctor and pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

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