

GENTAMICIN SULFATE- gentamicin sulfate ointment
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.

GENTAMICIN SULFATE
OINTMENT USP, 0.1%

Rx only

For Dermatologic Use Only
Not For Ophthalmic Use

DESCRIPTION:

Gentamicin Sulfate Ointment is a wide spectrum antibiotic preparation for topical administration. Each gram contains 1.0 mg of Gentamicin in a base of White Petrolatum with Methylparaben and Propylparaben as preservatives.

CLINICAL PHARMACOLOGY:

Gentamicin sulfate is a wide spectrum antibiotic that provides highly effective topical treatment in primary and secondary bacterial infections of the skin. Gentamicin Sulfate Ointment may clear infections that have not responded to treatment with other topical antibiotic agents. In primary skin infections such as impetigo contagiosa, treatment 3 or 4 times daily with Gentamicin Sulfate Ointment usually clears the lesions promptly. In secondary infections, Gentamicin Sulfate Ointment aids in the treatment of the underlying dermatoses by controlling the infection. Bacteria susceptible to the action of gentamicin sulfate 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 aerogenes*, *Escherichia coli*, *Proteus vulgaris*, and *Kiebsiella pneumoniae*.

INDICATIONS AND USAGE:

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 (including poison ivy), infected excoriations, and bacterial super-infections of fungal or viral infections. Please Note: Gentamicin sulfate is a bactericidal agent that is not effective against viruses or fungi in skin infections. Gentamicin sulfate 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. Good results have been obtained 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. Gentamicin Sulfate Ointment helps retain moisture and has been useful in infection on dry eczematous or psoriatic skin. Gentamicin Sulfate Ointment may be used in children over one year of age as well as in adults.

CONTRAINDICATIONS:

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

PRECAUTIONS:

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

ADVERSE REACTIONS:

In patients with dermatoses treated with gentamicin sulfate, irritation (erythema and pruritis) that did not usually require discontinuance of treatment has been reported in a small percentage of cases. There was no evidence of irritation or sensitization, however, in any of these patients patch-tested subsequently with gentamicin sulfate on normal skin. Possible photosensitization has been reported in several patients but could not be elicited in these patients by reapplication of gentamicin sulfate followed by exposure to ultraviolet radiation.

DOSAGE AND ADMINISTRATION:

A small amount of Gentamicin Sulfate Ointment should be applied gently to the lesions three or four times daily. 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 to permit maximum contact between the antibiotic and the infection. Care should be exercised to avoid further contamination of the infected skin. Infected stasis ulcers have responded well to treatment with gentamicin sulfate under gelatin packing.

HOW SUPPLIED:

Gentamicin Sulfate Ointment USP, 0.1% is supplied in 15 gram tubes NDC 0168-0078-15.

Store at controlled room temperature 15°-30°C (59°-86°F).

E. FOUGERA & CO.

A division of
Fougera
PHARMACEUTICALS INC.
Melville, New York 11747

I27815D
R12/11
#292

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15G CONTAINER

NDC 0168-0078-15

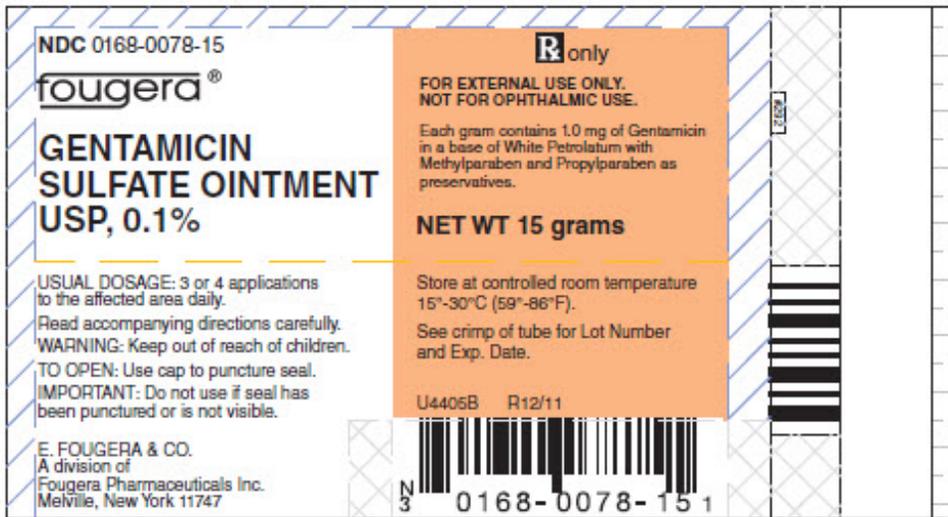
Fougera®

**GENTAMICIN
SULFATE OINTMENT
USP, 0.1%**

Rx only

**FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.**

NET WT 15 grams



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15G CARTON

NDC 0168-0078-15

Fougera®

**GENTAMICIN SULFATE
OINTMENT USP, 0.1%**

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NET WT 15 grams



GENTAMICIN SULFATE

gentamicin sulfate ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0168-0078
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GENTAMICIN (UNII: T6Z9V48IKG) (GENTAMICIN - UNII:T6Z9V48IKG)	GENTAMICIN	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0078-15	15 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062533	03/17/2010	

Labeler - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

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E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.