

## **GENTAMICIN SULFATE- gentamicin sulfate ointment Proficient Rx LP**

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**Gentamicin Sulfate Ointment, USP 0.1%  
Rx Only  
For Dermatologic Use Only  
Not for Ophthalmic Use**

### **DESCRIPTION**

Gentamicin Sulfate Ointment, USP 0.1% is a wide spectrum antibiotic preparation for topical administration. Each gram of Gentamicin Sulfate Ointment, USP 0.1% contains Gentamicin Sulfate USP equivalent to 1 mg of gentamicin base in a base of light mineral oil and white petrolatum, with 0.5 mg methylparaben and 0.1 mg 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. This product may clear infections that have not responded to other topical antibiotic agents. In impetigo contagiosa and other primary skin infections, treatment with a small amount of Gentamicin Sulfate Ointment three to four times daily usually clears the lesions promptly. In secondary skin infections, the product facilitates the treatment of the underlying dermatosis by controlling the infection. Bacteria susceptible to the action of Gentamicin Sulfate include sensitive strains of *Streptococci* (group A beta-hemolytic, alphahemolytic), *Staphylococcus aureus* (coagulase positive, coagulase negative, and some penicillinase-producing strains), and the gram-negative bacteria, *Pseudomonas aeruginosa*, *Aerobacteraerogens*, *Escherichia coli*, *Proteus vulgaris* and *Klebsiellapneumoniae*.

### **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 superinfections of fungal or viral infections. NOTE: Gentamicin Sulfate is a bactericidal agent that is not effective against viruses or fungi in skin 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. 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 cream is recommended for wet,

oozing primary infections, and greasy, secondary infections, such as postular acne or infected seborrheic dermatitis. Gentamicin Sulfate Ointment, USP 0.1% helps retain moisture and has been useful in infection on dry eczematous or psoriatic skin. Gentamicin Sulfate Ointment, USP 0.1% has been used successfully in infants over one year of age as well as in adults and children.

## **CONTRAINDICATIONS**

Gentamicin Sulfate Ointment, USP 0.1% is contraindicated in individuals with a history of sensitivity reactions to any of its components.

## **PRECAUTIONS**

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 Ointment, USP 0.1% should be discontinued and appropriate therapy instituted.

## **ADVERSE REACTIONS**

In patients with dermatoses treated with Gentamicin Sulfate, irritation (erythema and pruritus) 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 on normal skin. 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.

**To report SUSPECTED ADVERSE REACTIONS, contact Cosette Pharmaceuticals, Inc. at 1-800-922-1038 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **DOSAGE AND ADMINISTRATION**

A small amount of Gentamicin Sulfate Ointment, USP 0.1% 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, USP 0.1% 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 Gentamicin Sulfate under gelatin packing.

## **HOW SUPPLIED**

Gentamicin Sulfate Ointment, USP 0.1% is available as follows:

15 g tube (NDC 71205-**560**-15)

**STORAGE** Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature].

**Distributed by:**

Cosette Pharmaceuticals, Inc.  
South Plainfield, NJ 07080

**Relabeled by:**

Proficient Rx LP  
Thousand Oaks, CA 91320

Iss. 08/2019  
8-0682CP1

**PRINCIPAL DISPLAY PANEL**

**NDC 71205-560-15**


**Gentamicin Sulfate Ointment, USP 0.1%**


**15 g**

**Rx only**

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

Scan Here





NDC 71205-560-15

**RX Only**

Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

Gentamicin Sulfate 0.1%

15 g Ointment

Each gram contains: Gentamicin Sulfate USP equivalent to 1 mg of gentamicin base in an ointment base of light mineral oil and white petrolatum.

*See package insert*

Product ID: SG056015

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

Dist. By: Cosette Pharmaceuticals, Inc. South Plainfield, NJ 07080


Store at 20°-25°C (68°-77°F) Keep medication out of the reach of children

Gentamicin Sulfate 0.1%  
15 g Ointment  
Lot #:00000 SN# MASTER  
NDC 71205-560-15 Exp:00/00/00

Gentamicin Sulfate 0.1%  
15 g Ointment  
Lot #:00000 SN# MASTER  
NDC 71205-560-15 Exp:00/00/00

Gentamicin Sulfate 0.1%  
15 g Ointment  
Lot #:00000 SN#MASTER  
NDC 71205-560-15 Exp:00/00/00

GTIN: 00371205560157  
SN# MASTER  
Exp. 00/00/00  
Lot #:00000



**GENTAMICIN SULFATE**

gentamicin sulfate ointment

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:71205-560(NDC:0713-0682)
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**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Gentamicin Sulfate</b> (UNII: 8X7386QRLV) (Gentamicin - UNII:T6Z9V48IKG)	Gentamicin	1 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Light Mineral Oil</b> (UNII: N6K5787QVP)	
<b>Petrolatum</b> (UNII: 4T6H12BN9U)	
<b>Methylparaben</b> (UNII: A2I8C7HI9T)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-560-15	1 in 1 CARTON	05/06/2021	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064054	11/28/2014	

**Labeler** - Proficient Rx LP (079196022)

### Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(71205-560)

Revised: 5/2021

Proficient Rx LP