

GENTAMICIN SULFATE- gentamicin sulfate ointment
Cosette Pharmaceuticals, Inc.

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, alpha-hemolytic), *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.

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 0713-**0682**-15)
30 g tube (NDC 0713-**0682**-31)

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

Manufactured by:

Cosette Pharmaceuticals, Inc.
111 Coolidge Street
South Plainfield, NJ 07080

Iss. 08/2019
8-0682CP1

PRINCIPAL DISPLAY PANEL

NDC 0713-0682-15

Gentamicin Sulfate Ointment, USP 0.1%

15 g

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NDC 0713-0682-15

Rx only

Gentamicin Sulfate Ointment, USP

0.1%

15 g

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

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

Usual Dosage: Apply a small amount gently to lesions 3 to 4 times per day; see insert.

KEEP OUT OF THE REACH OF CHILDREN.

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

For lot number and expiration date, see crimp of tube or carton.



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0713-0682-15

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Manufactured by: Cosette Pharmaceuticals, Inc.
111 Coolidge Street, South Plainfield, NJ 07080
11-68215CP2 Rev. 04/2020



Gentamicin Sulfate Ointment, USP 0.1%

30 g

Rx only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Cosette Pharmaceuticals, Inc.



Gentamicin Sulfate Ointment, USP

NDC 0713-0682-31

Rx only

0.1%

30 g

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

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

Usual Dosage: Apply a small amount gently to lesions 3 to 4 times per day; see insert.

KEEP OUT OF THE REACH OF CHILDREN.

Store at 20-25°C (68°-77°F)

[see USP Controlled Room Temperature].

For lot number and expiration date,
see crimp of tube or carton.

Manufactured by: Cosette Pharmaceuticals, Inc.
111 Coolidge Street, South Plainfield, NJ 07080
11-68231CP1 Iss. 08/2019





GENTAMICIN SULFATE

gentamicin sulfate ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0713-0682
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
Light Mineral Oil (UNII: N6K5787QVP)	
Petrolatum (UNII: 4T6H12BN9U)	

Methylparaben (UNII: A2I8C7HI9T)

Propylparaben (UNII: Z8IX2SC1OH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0682-15	1 in 1 CARTON	12/21/2017	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0713-0682-31	1 in 1 CARTON	12/21/2017	
2		30 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 - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals, Inc.		116918230	analysis(0713-0682) , label(0713-0682) , manufacture(0713-0682) , pack(0713-0682)

Revised: 11/2020

Cosette Pharmaceuticals, Inc.