

GENTAMICIN SULFATE- gentamicin sulfate cream
Cosette Pharmaceuticals, Inc.

GENTAMICIN SULFATE CREAM, USP 0.1%

For Dermatologic Use Only

Not For Ophthalmic Use

Rx Only

DESCRIPTION

Gentamicin Sulfate Cream, USP 0.1% is a wide spectrum antibiotic preparation for topical administration. Each gram contains Gentamicin Sulfate USP equivalent to 1 mg gentamicin base in a cream base of isopropyl myristate, propylene glycol, propylene glycol monostearate, polysorbate 40, purified water, sorbitol solution and stearic acid. Preserved with butylparaben and methylparaben.

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 Cream 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 Cream usually clears the lesions promptly. In secondary skin infections, Gentamicin Sulfate Cream 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 Klebsiella 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 Cream, USP 0.1% is 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. Gentamicin Sulfate Cream, USP 0.1% has been used successfully in infants over one year of age, as well as in adults and children.

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.

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 cream 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 Cream, USP 0.1% is supplied in 15 gram tubes (0713-0683-15) and 30 gram tubes (0713-0683-31).

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

Distributed by:

Cosette Pharmaceuticals, Inc.
South Plainfield, NJ 07080

Rev. 05/2022
8-0683CPLNC2

VC7632

PRINCIPAL DISPLAY PANEL

NDC 0713-0683-15

Gentamicin Sulfate Cream, USP 0.1%

15 g

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FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Cosette Pharmaceuticals, Inc.



NDC 0713-0683-31

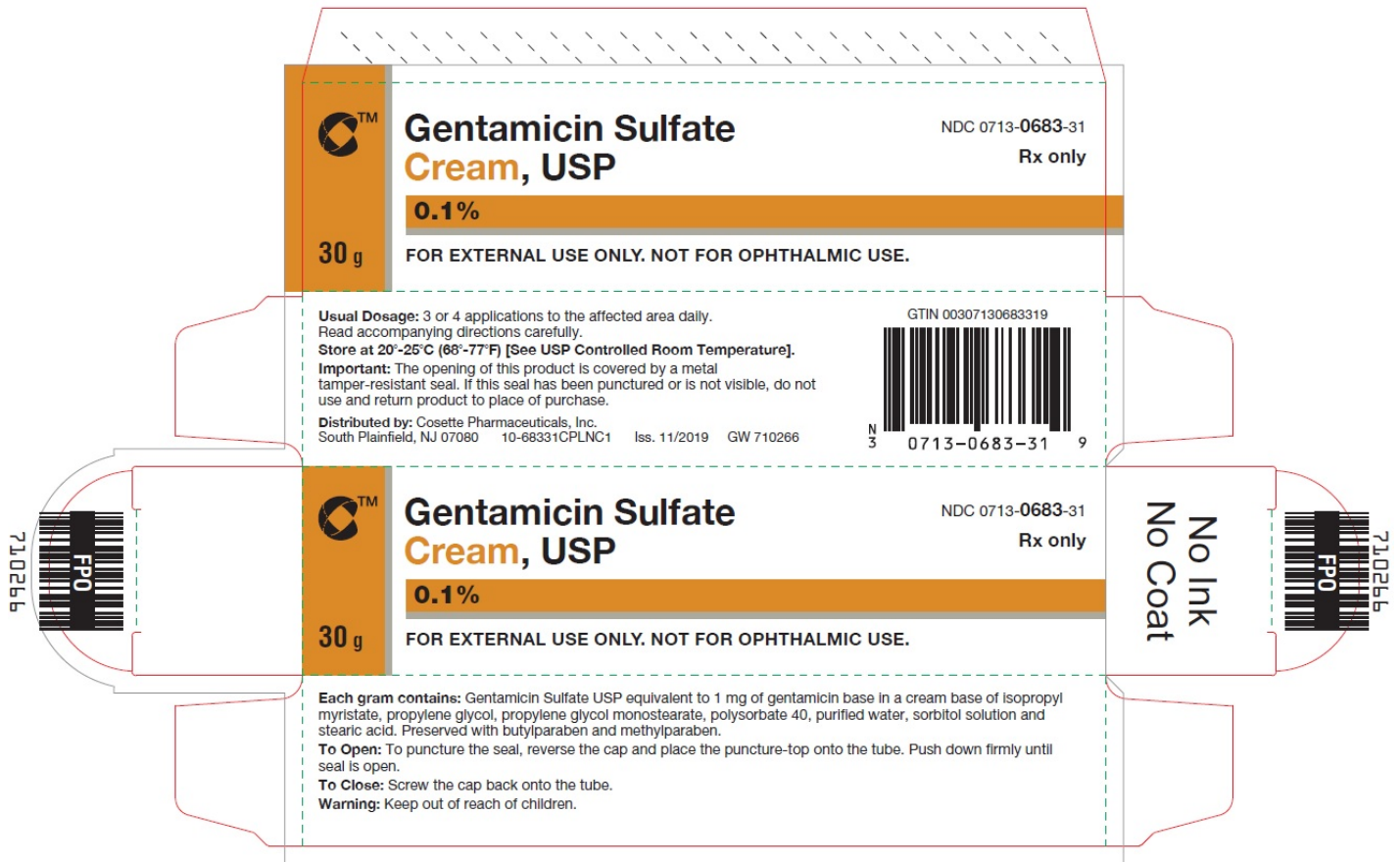
Gentamicin Sulfate Cream, USP 0.1%

30 g

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GENTAMICIN SULFATE

gentamicin sulfate cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0713-0683
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
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLENE GLYCOL MONOSTEARATE (UNII: MZM1I680W0)	
POLYSORBATE 40 (UNII: ST111B5A2X)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	

METHYLPARABEN (UNII: A2I8C7HI9T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0683-15	1 in 1 CARTON	11/11/2016	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0713-0683-31	1 in 1 CARTON	11/11/2016	
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	ANDA064056	11/11/2016	

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals NC Laboratories, LLC		079419931	analysis(0713-0683) , label(0713-0683) , manufacture(0713-0683) , pack(0713-0683)

Revised: 11/2023

Cosette Pharmaceuticals, Inc.