

GENTAMICIN SULFATE - gentamicin sulfate cream
Physicians Total Care, Inc.

Rx Only

DESCRIPTION

Each gram of GENTAMICIN CREAM contains gentamicin sulfate equivalent to 1 mg of gentamicin base in a cream base of: methylparaben, butylparaben, stearic acid, cerasynt PA (propylene glycol monostearate), isopropyl myristate, propylene glycol, polysorbate 40, sorbitol solution and water. Each gram of GENTAMICIN OINTMENT contains gentamicin sulfate 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, a wide spectrum antibiotic 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 OINTMENT AND CREAM 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 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 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 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, although regular observation of patients sensitive to topical antibiotics is advisable when such patients are treated with any topical antibiotic. GENTAMICIN CREAM is recommended for wet, oozing primary infections, and greasy, secondary infections, such as pustular acne or infected seborrheic dermatitis, and where a water washable cream preparation is desired. GENTAMICIN OINTMENT helps retain moisture and has been useful in infection on dry eczematous or psoriatic skin. GENTAMICIN CREAM and OINTMENT have been used successfully in infants over one year of age as well as in adults and children.

CONTRAINDICATIONS

This product, GENTAMICIN OINTMENT AND CREAM 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 should be discontinued and appropriate therapy instituted.

ADVERSE REACTIONS

In patients with dermatoses treated with GENTAMICIN, 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.

DOSAGE AND ADMINISTRATION

A small amount of GENTAMICIN 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 OINTMENT or CREAM 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 under gelatin packing.

HOW SUPPLIED

GENTAMICIN CREAM is supplied in

15 gram tube	NDC 54868- 3524-0
30 gram tube	NDC 54868- 3524-1

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

MANUFACTURED

BY PERRIGO

BRONX, NY 10457

1C800 RC J2

Relabeling of "Additional" barcode label by:

Physicians Total Care, Inc.

Tulsa, OK 74146

PRINCIPAL DISPLAY PANEL

GENTAMICIN CREAM

30 gram

DIST. BY: PHYSICIANS TOTAL CARE
TULSA, OK 74146

NDC 54868-3524-1 30 GM

GENTAMICIN CRM 0.1%

LOT # 0000 EXP. DATE 01/60

REG. BY: PERMIT NO. 10457



35240300000

GENTAMICIN SULFATE

gentamicin sulfate cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:54868-3524(NDC:45802-056)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLPARABEN (UNII: 3QPIIU3FV8)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL MONOSTEARATE (UNII: F76354LMGR)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 40 (UNII: STI1B5A2X)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-3524-0	1 in 1 CARTON		
1		15 g in 1 TUBE		
2	NDC:54868-3524-1	1 in 1 CARTON		
2		30 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062307	05/12/1995	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 3/2011

Physicians Total Care, Inc.