

# **GENTAMICIN SULFATE CREAM USP, 0.1%- gentamicin sulfate cream**

## **McKesson Corporation**

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### **Gentamicin Sulfate Cream USP, 0.1%**

#### **DESCRIPTION**

Gentamicin Sulfate Cream 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 containing stearic acid, propylene glycol monostearate, isopropyl myristate, polysorbate 40, propylene glycol, sorbitol solution and purified water with methylparaben and butylparaben 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 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 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 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 Teligent Pharma, Inc. at 1-856-697-1441, 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 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 as follows:  
15 gram tube (NDC 63739-055-65)  
30 gram tube (NDC 63739-055-66)

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

Manufactured by:  
Teligent Pharma, Inc.  
Buena, NJ 08310

Distributed by:  
McKesson Corporation  
dba Sky Packaging  
4971 Southridge Blvd., Suite 101  
Memphis, TN 38141

C101643  
Rev 03/2021

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 63739-055-65  
Gentamicin Sulfate  
Cream USP, 0.1%\*

Net Wt. 15 grams  
Rx Only  
FOR EXTERNAL USE ONLY.  
NOT FOR OPHTHALMIC USE.

The image shows a simulated principal display panel for a tube of Gentamicin Sulfate Cream USP, 0.1%\*. The panel is enclosed in a dashed blue border. At the top left, the NDC number 'NDC 63739-055-65' is printed in red. Below this, a dark red horizontal bar contains the product name 'Gentamicin Sulfate' in white. Underneath the bar, the text 'Cream USP, 0.1%\*' is printed in red. A teal horizontal bar below that contains 'Net Wt. 15 grams' on the left and 'Rx Only' on the right. Below the teal bar, the text 'FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.' is printed in blue. The lower section of the panel contains detailed information in small black text: '\* Each gram contains: Gentamicin Sulfate USP equivalent to 1 mg gentamicin base in a cream base containing stearic acid, propylene glycol monostearate, isopropyl myristate, polysorbate 40, propylene glycol, sorbitol solution and purified water. Preserved with butylparaben and methylparaben. Usual Dosage: 3 or 4 applications to the affected area daily. WARNING: Keep this and all drugs out of the reach of children. Store at controlled room temperature 15° to 30°C (59° to 86°F). To Open: use pointed end on cap to puncture seal. Important: Do not use if seal has been punctured or is not visible. See crimp of tube for lot no. and expiration date.' To the right of this text is a barcode with the numbers '3 63739 05565 0' printed below it. At the bottom left is the 'SKY' logo. To the right of the logo, the manufacturer information is listed: 'Manufactured by: Teigen Pharma, Inc. Evans, NJ 08310'. To the right of that, the distributor information is listed: 'Distributed by: McKesson Corporation dba Sky Packaging 4971 Southridge Blvd., Suite 101 Memphis, TN 38141 C101643 Rev 03/2021'.

NDC 63739-055-65  
Gentamicin Sulfate  
Cream USP, 0.1%\*

Net Wt. 15 grams  
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NDC 63739-055-65

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Net Wt. 15 grams

Rx Only

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Usual Dosage: 3 or 4 applications to the affected area daily. See package insert for full prescribing information.

WARNING: Keep this and all drugs out of the reach of children.

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See crimp of tube for lot no. and expiration date.

NDC 63739-055-65

# Gentamicin Sulfate Cream USP, 0.1%\*

Net Wt. 15 grams

Rx Only

FOR EXTERNAL USE ONLY.  
NOT FOR OPHTHALMIC USE.

Important: Do not use if seal has been punctured or is not visible.

Directions for puncturing tube seal: Remove cap. Turn cap upside down and place puncture tip onto tube seal; push down until seal is punctured. Screw cap back on to close.



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C101642

Manufactured by:  
Teligent Pharma, Inc.  
Buena, NJ 08310  
CB-085-15-00  
Rev 03/2021



NDC 63739-055-66  
Gentamicin Sulfate  
Cream USP, 0.1%\*

Net Wt. 30 grams

R<sub>x</sub> Only

FOR EXTERNAL USE ONLY.  
NOT FOR OPHTHALMIC USE.

NDC 63739-055-66

# Gentamicin Sulfate Cream USP, 0.1%\*

Net Wt. 30 grams

Rx Only

FOR EXTERNAL USE ONLY.  
NOT FOR OPHTHALMIC USE.

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Usual Dosage: 3 or 4 applications to the affected area daily.

See package insert for full prescribing information.

WARNING: Keep this and all drugs out of the reach of children.

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

To Open: use pointed end on cap to puncture seal.

Important: Do not use if seal has been punctured or is not visible.  
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C101644 Rev 03/2021



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 Gentamicin Sulfate  
 Cream USP, 0.1%\*

Net Wt. 30 grams  
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NDC 63739-055-66

**Gentamicin Sulfate**  
**Cream USP, 0.1%\***

**Net Wt. 30 grams** **Rx Only**

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NDC 63739-055-66

**Gentamicin Sulfate**  
**Cream USP, 0.1%\***

**Net Wt. 30 grams** **Rx Only**

FOR EXTERNAL USE ONLY.  
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 C101645 Rev 03/2021

Manufactured by:  
 Teligent Pharma, Inc.  
 Buena, NJ 08310



3 63739 05566 7

## GENTAMICIN SULFATE CREAM USP, 0.1%

gentamicin sulfate cream

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:63739-055
<b>Route of Administration</b>	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>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Propylene Glycol Monopalmitostearate</b> (UNII: F76354LMGR)	
<b>Isopropyl Myristate</b> (UNII: 0RE8K4LNJS)	
<b>Polysorbate 40</b> (UNII: ST111B5A2X)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Methylparaben</b> (UNII: A218C7HI9T)	
<b>Butylparaben</b> (UNII: 3QPI1U3FV8)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63739-055-66	1 in 1 CARTON	05/25/2021	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:63739-055-65	1 in 1 CARTON	05/25/2021	
2		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	ANDA209304	10/18/2019	

**Labeler** - McKesson Corporation (140529962)

**Registrant** - Teligent, Inc. (011036910)

## Establishment

Name	Address	ID/FEI	Business Operations
Teligent, Inc.		011036910	manufacture(63739-055) , label(63739-055) , pack(63739-055)

Revised: 5/2021

McKesson Corporation