

**GENTAMICIN SULFATE- gentamicin sulfate solution/ drops**  
**NuCare Pharmaceuticals, Inc.**

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**Gentamicin Sulfate**  
**Ophthalmic Solution, USP**  
**0.3%**  
**(Sterile)**  
**Rx only**

**DESCRIPTION**

Gentamicin sulfate ophthalmic solution, USP is a sterile, aqueous solution buffered to approximately pH 7.0 and formulated for ophthalmic use.

**Each mL contains:**

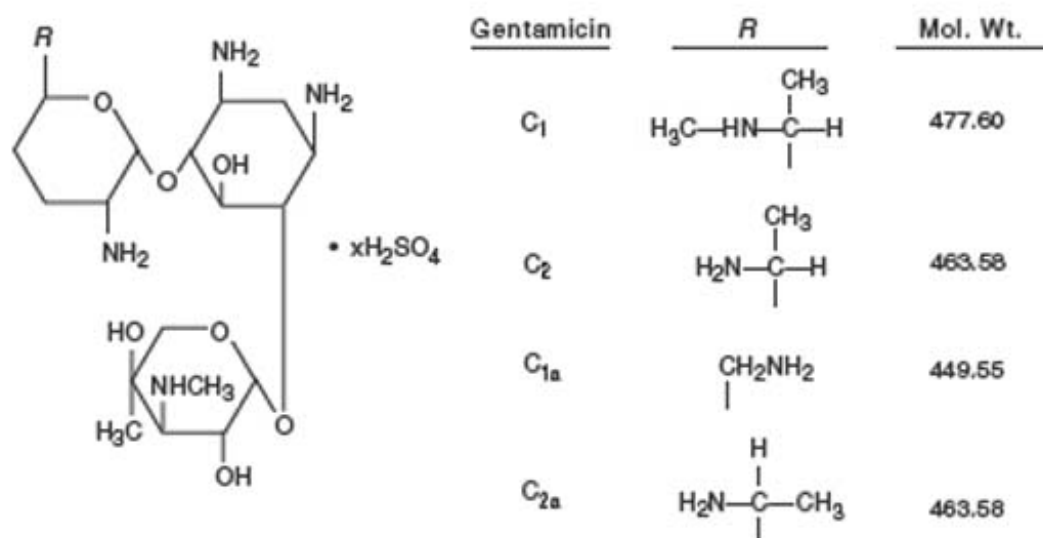
**Active:** gentamicin sulfate, USP (equivalent to 3 mg gentamicin).

**Inactives:** dibasic sodium phosphate, sodium chloride, monobasic sodium phosphate, purified water. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH (6.5 - 7.5).

**Preservative:** benzalkonium chloride 0.01%.

Gentamicin is an aminoglycoside antibiotic obtained from cultures of *Micromonospora purpurea*. It is a mixture of the sulfate salts of gentamicin C1, C2, C1a and C2a. All three components appear to have similar antimicrobial activity. Gentamicin sulfate occurs as a white to buff powder and is soluble in water and insoluble in alcohol.

The structural formula is as follows:



**CLINICAL PHARMACOLOGY**

## **Microbiology**

Gentamicin sulfate is active *in vitro* against many strains of the following microorganisms:

*Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Enterobacter aerogenes*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Neisseria gonorrhoeae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*.

## **INDICATIONS AND USAGE**

Gentamicin sulfate ophthalmic solution is indicated in the topical treatment of ocular bacterial infections including conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharoconjunctivitis, acute meibomianitis, and dacryocystitis, caused by susceptible strains of the following microorganisms:

*Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Enterobacter aerogenes*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Neisseria gonorrhoeae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*.

## **CONTRAINDICATIONS**

Gentamicin sulfate ophthalmic solution is contraindicated in patients with known hypersensitivity to any of its components.

## **WARNINGS**

### **NOT FOR INJECTION INTO THE EYE**

Gentamicin sulfate ophthalmic solution is not for injection. It should never be injected subconjunctivally, nor should it be directly introduced into the anterior chamber of the eye.

## **PRECAUTIONS**

### **General**

Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms including fungi. Bacterial resistance to gentamicin may also develop. If purulent discharge, inflammation or pain becomes aggravated, the patient should discontinue use of the medication and consult a physician. If irritation or hypersensitivity to any component of the drug develops, the patient should discontinue use of this preparation and appropriate therapy should be instituted.

### **Information for Patients**

To avoid contamination, do not touch tip of container to the eye, eyelid or any surface.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

There are no published carcinogenicity or impairment of fertility studies on gentamicin. Aminoglycoside antibiotics have been found to be non-mutagenic.

## **Pregnancy**

Gentamicin has been shown to depress body weights, kidney weights and median glomerular counts in newborn rats when administered systemically to pregnant rats in daily doses approximately 500 times the maximum recommended ophthalmic human dose. There are no adequate and well-controlled studies in pregnant women. Gentamicin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

## **ADVERSE REACTIONS**

Bacterial and fungal corneal ulcers have developed during treatment with gentamicin ophthalmic preparations.

The most frequently reported adverse reactions are ocular burning and irritation upon drug instillation, non-specific conjunctivitis, conjunctival epithelial defects and conjunctival hyperemia.

Other adverse reactions which have occurred rarely are allergic reactions, thrombocytopenic purpura and hallucinations.

**To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-553-5340 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **DOSAGE AND ADMINISTRATION**

Instill one or two drops into the affected eye(s) every four hours. In severe infections dosage may be increased to as much as two drops every hour.

## **HOW SUPPLIED**

Gentamicin sulfate ophthalmic solution USP, 0.3% is supplied sterile in a white LDPE plastic bottle, with a white LLDPE extended controlled drop tip and white polypropylene cap in the following size:

NDC 68071-3554-5 5 mL

**NOT FOR INJECTION INTO THE EYE**

**FOR OPHTHALMIC USE ONLY**

<b>DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.</b>
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**Storage:** Store between 2°C to 25°C (36°F to 77°F). Avoid exposure to excessive heat.

**KEEP OUT OF REACH OF CHILDREN.**

**Distributed by:**

Bausch & Lomb Americas Inc.  
Bridgewater, NJ 08807 USA

**Manufactured by:**

Bausch & Lomb Incorporated  
Tampa, FL 33637 USA

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Revised: September 2022

9116006 (**Folded**)

9116106 (**Flat**)

**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL**

 **NuCare Pharmaceuticals, Inc.**

**NDC: 68071-3554-5**  
**Gentamicin Sulfate 0.3%**  
**5mL Ophth. Soln.**

Each mL contains: Active: Gentamicin Sulfate, USP (equivalent to 3mg Gentamicin)  
See manufacturer's label for full list of ingredients

**Product #: R0270005**  
**Rx Only**

**Gentamicin Sulfate 0.3%**  
Lot: 00000 NDC: 68071-3554-05  
MFR NDC: 24208-580-60 Exp.: 00-00  
Serial# 0000000002

**Gentamicin Sulfate 0.3%**  
Lot: 00000 NDC: 68071-3554-05  
MFR NDC: 24208-580-60 Exp.: 00-00  
Serial# 0000000002

GTIN 00368071355451  
Serial# 0000000002  
Exp. Date 00-00  
LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**WARNING: KEEP OUT OF REACH OF CHILDREN** **STORE AT CONTROLLED TEMPERATURE 36-77°F.**

Manufactured by: **Bausch & Lomb Incorporated**  
Tampa, FL 33637  
Packaged by: **NuCare Pharmaceuticals, Inc.**  
Orange, CA 92867

Patent Instructions:  
Place \_\_\_\_\_ drop(s) into the affected eye(s) every \_\_\_\_\_ hours.

Rev 01/01/19

68071355405-5-00000-00000

**GENTAMICIN SULFATE**

gentamicin sulfate solution/ drops

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68071-3554(NDC:24208-580)
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>GENTAMICIN SULFATE</b> (UNII: 8X7386QLRV) (GENTAMICIN - UNII:T6Z9V48IKG)	GENTAMICIN	3 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM</b> (UNII: GR686LBA74)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-3554-5	1 in 1 CARTON	12/07/2023	
1		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064048	05/11/1994	

**Labeler** - NuCare Pharmaceuticals,Inc. (010632300)

## Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-3554)

Revised: 12/2023

NuCare Pharmaceuticals,Inc.