

GENTAK- gentamicin sulfate ointment
NuCare Pharmaceuticals, Inc.

GENTAK[®]

Gentamicin Sulfate

Ophthalmic Ointment USP, 0.3%

Sterile

Rx only

DESCRIPTION

GENTAK[®] Gentamicin sulfate is a water soluble antibiotic of the aminoglycoside group.

Gentamicin sulfate ophthalmic ointment is a sterile ointment for ophthalmic use. Each gram contains gentamicin sulfate equivalent to 3 mg gentamicin in a base of white petrolatum and mineral oil, with methylparaben and propylparaben as preservatives.

Gentamicin is obtained from cultures of *Micromonospora purpurea*. It is a mixture of the sulfate salts of gentamicin C₁, C₂, and C_{1A}. All three components appear to have similar antimicrobial activities. 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 ointment is indicated in the topical treatment of ocular bacterial infections including conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharconjunctivitis; 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 ointment is contraindicated in patients with known hypersensitivity to any of the components.

WARNINGS

NOT FOR INJECTION INTO THE EYE.

Gentamicin sulfate ophthalmic ointment 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.

Ophthalmic ointments may retard corneal healing.

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: Pregnancy Category C. 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.

Pediatric Use: Safety and effectiveness in neonates have not been established.

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.

DOSAGE AND ADMINISTRATION

Apply a small amount (approximately 1/2 inch ribbon) of ointment to the affected eye(s) two or three times a day.

HOW SUPPLIED

GENTAK[®] Gentamicin sulfate ophthalmic ointment USP, 0.3% is supplied in 3.5 g , box of one.
(NDC 68071-1513-5)

STORAGE: Store at 2° to 30°C (36° to 86°F).

Akorn

Manufactured by: Akorn, Inc.
Lake Forest, IL 60045
GKO00N Rev. 06/16

NuCare Pharmaceuticals, Inc.

NDC 68071-1513-5
Lot #: 000000 Exp. Date: 00-00

Gentak 0.3%
3.5g Ophth. Oint.

See manufacturer's label
for full list of ingredients

Product #: R1469035
Rx Only

Apply every _____ hours
_____ times a day.

Manufactured by:
Akorn, Inc. Lake Forest, IL 60045
R1469035

Package by:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

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

Rev. 01/10

WARNING: KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED TEMPERATURE 36-86 °F.

Gentak 0.3%
3.5g Ophth. Oint. Exp Date: 00-00
NDC 68071-1513-05 AWP: \$20.99
Mfg NDC 17478-284-35
Lot #: 000000 Rx # 22651109

Gentak 0.3%
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Barcode: 68071151306*3.5*000000*000000

GENTAK

gentamicin sulfate ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68071-1513(NDC:17478-284)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GENTAMICIN SULFATE (UNII: 8X7386QRLV) (GENTAMICIN - UNII:T6Z9V48IKG)	GENTAMICIN	3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	0.5 mg in 1 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.1 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-1513-5	3.5 g in 1 BOX; Type 0: Not a Combination Product	02/05/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064093	05/08/2006	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-1513)

Revised: 2/2021

NuCare Pharmaceuticals,Inc.