GENTAK- gentamicin sulfate ointment
Akorn

GENTAK®
Gentamicin Sulfate
Ophthalmic Ointment USP,0.3%

Sterile

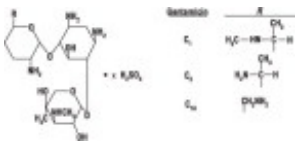
Rx only

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 C_1 C_2, 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, blepharonconjunctivitis: 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 con-traindicated 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 tube, box of one.

(NDC 17478-284-35)

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

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

Principal Display Panel Text for Container Label:

NDC 17478-284-35 Akorn Logo

Gentak®

brand of Gentamicin Sulfate

Ophthalmic Ointment USP, 0.3%

(equivalent to 3 mg gentamicin per gram)

Net Wt 3.5 g (1/8 oz) Sterile

Rx only

NDC 17478-284-35

AKORN

GENTAK®

brand of Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%

(equivalent to 3 mg gentamicin per gram)

Net Wt 3.5 g (1/8 oz)

Sterile

Rx only

Each Gram Contains: Gentamicin sulfate USP, equivalent to 3 mg gentamicin base, methylparaben 0.5 mg and propylparaben 0.1 mg as preservatives in a base of white petrolatum and mineral oil.

Usual Dosage: See package insert for dosage information.

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

LT-2659-5

Mfg by:
Akorn, Inc., Lake Forest, IL 60045

GKOAAL Rev. 06/16

(01) 00317478284352

Principal Display Panel Text for Carton Label:

3.5 g NDC 17478-284-35

Gentak®

Brand of Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%

(equivalent to 3 mg gentamicin per gram)

Net Wt 3.5 g (1/8 oz.) Sterile Rx only Akorn Logo

GENTAK

gentamicin sulfate ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	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:17478-284-35	1 in 1 CARTON	05/08/2006	
1		3.5 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	ANDA064093	05/08/2006	

Labeler - Akorn (117693100)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(17478-284) , ANALYSIS(17478-284) , STERILIZE(17478-284) , PACK(17478-284) , LABEL(17478-284)

Revised: 1/2022 Akorn