



**Gentak® (gentamicin sulfate ophthalmic ointment, USP) 0.3%**

**Gentamicin Sulfate Ophthalmic Solution, USP 0.3%**

- ▶ Gentamicin Sulfate Sterile Ophthalmic Solution 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.*

- ▶ Gentamicin Sulfate Sterile Ophthalmic Solution is contraindicated in patients with known hypersensitivity to any of the components.

- ▶ 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:

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- ▶ Gentamicin sulfate ophthalmic ointment is contraindicated in patients with known hypersensitivity to any of the components.



**Gentak® (gentamicin sulfate ophthalmic ointment, USP) 0.3%**



NDC #	DESCRIPTION	SIZE	UNIT OF SALE	BRAND COMPARE	ORANGE BOOK CODE
17478-284-35	0.3% Sterile Ophthalmic Ointment	3.5 g	1	Genoptic® by Allergan	AT

**EACH mL CONTAINS:**

<b>ACTIVE:</b>	Gentamicin Sulfate equivalent to 3 mg Gentamicin;
<b>PRESERVATIVE:</b>	Methylparaben and Propylparaben;
<b>INACTIVES:</b>	White Petrolatum and Mineral Oil.
<b>STORAGE:</b>	Store at 2° to 30°C (36° to 86°F).

NDC #	CARDINAL	AMERISOURCEBERGEN	MCKESSON	MORRIS DICKSON
17478-284-35	1465277	832-956	1185859	084558

**Gentamicin Sulfate Ophthalmic Solution, USP 0.3%**



NDC #	DESCRIPTION	SIZE	UNIT OF SALE	BRAND COMPARE	ORANGE BOOK CODE
17478-283-10	0.3% Sterile Ophthalmic Solution	5 mL	1	Genoptic® by Allergan	AT

**EACH mL CONTAINS:**

<b>ACTIVE:</b>	Gentamicin Sulfate USP (equivalent to 3 mg Gentamicin base);
<b>PRESERVATIVE:</b>	Benzalkonium Chloride;
<b>INACTIVES:</b>	Disodium Phosphate, Monosodium Phosphate, and Sodium Chloride. The pH range is from 6.8 to 7.3.
<b>STORAGE:</b>	Store at 2° to 30°C (36° to 86°F).

NDC #	CARDINAL	AMERISOURCEBERGEN	MCKESSON	MORRIS DICKSON
17478-283-10	1465285	862-037	1185842	084590



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**NOT FOR PRESCRIBING PURPOSES. PLEASE REFER TO PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.**

# Gentak® Gentamicin Sulfate Ophthalmic Ointment, USP, 0.3%

STERILE

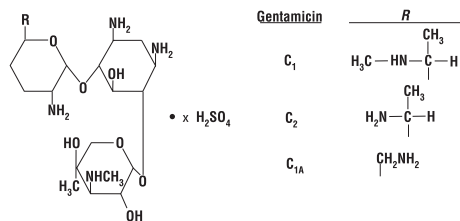
**R**only

## 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<sub>1</sub>, C<sub>2</sub>, and C<sub>1A</sub>. 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*.

# Gentamicin Sulfate Ophthalmic Solution, USP, 0.3%

STERILE

**R**only

## DESCRIPTION

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

Gentamicin Sulfate Ophthalmic Solution is a sterile, aqueous solution for ophthalmic use.

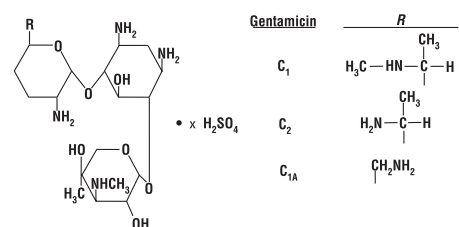
**Each mL contains:**

**Active:** Gentamicin Sulfate USP (equivalent to 3 mg gentamicin base)

**Preservative:** Benzalkonium Chloride

**Inactives:** Disodium Phosphate, Monosodium Phosphate, and Sodium Chloride. The pH range is from 6.8 to 7.3.

Gentamicin is obtained from cultures of *Micromonospora purpurea*. It is a mixture of the sulfate salts of gentamicin C<sub>1</sub>, C<sub>2</sub>, and C<sub>1A</sub>. All three components appear to have similar antimicrobial activities. Gentamicin sulfate occurs as a white 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*

## INDICATIONS AND USAGE

Gentamicin sulfate ophthalmic ointment is indicated in the topical treatment of ocular bacterial infections including conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharocconjunctivitis, 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.

*aerogenes*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Neisseria gonorrhoeae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*.

**INDICATIONS AND USAGE** Gentamicin Sulfate Sterile Ophthalmic Solution is indicated in the topical treatment of ocular bacterial infections, including conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharocconjunctivitis, 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 Sterile Ophthalmic Solution is contraindicated in patients with known hypersensitivity to any of the 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:** 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

GK000N

Rev. 09/08

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

**DOSAGE AND ADMINISTRATION** Gentamicin Sulfate sterile ophthalmic solution; 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 once every hour.

**HOW SUPPLIED** GENTAK® Gentamicin Sulfate ophthalmic solution - Sterile, 5-mL plastic dropper bottle, box of one. (NDC 17478-283-10)

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

Avoid exposure to excessive heat.

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