GENTAMICIN SULFATE- gentamicin sulfate solution/ drops
Bausch & Lomb Incorporated

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:

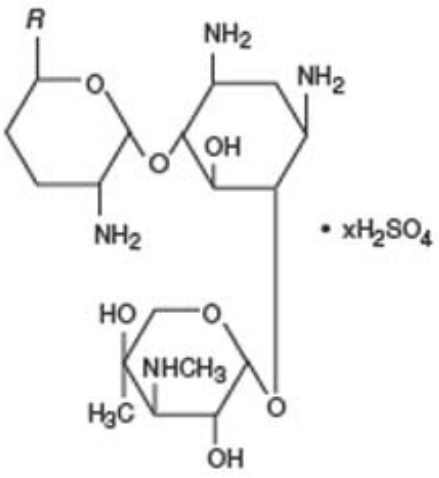
Active: gentamicin sulfate, USP (equivalent to 3 mg gentamicin).

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:



Gentamicin	R	Mol. Wt.
C_1	$H_3C—HN—C(CH_3)—H$	477.60
C_2	$H_2N—C(CH_3)—H$	463.58
C_{1a}	CH_2NH_2	449.55
C_{2a}	$H_2N—C(H)—CH_3$	463.58

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.

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 24208-580-60 - 5 mL

NOT FOR INJECTION INTO THE EYE

FOR OPHTHALMIC USE ONLY

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

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

Revised: September 2022

9116006 **(Folded)**

9116106 **(Flat)**

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 24208-580-60

Gentamicin
Sulfate
Ophthalmic
Solution, USP
0.3%
(Sterile)

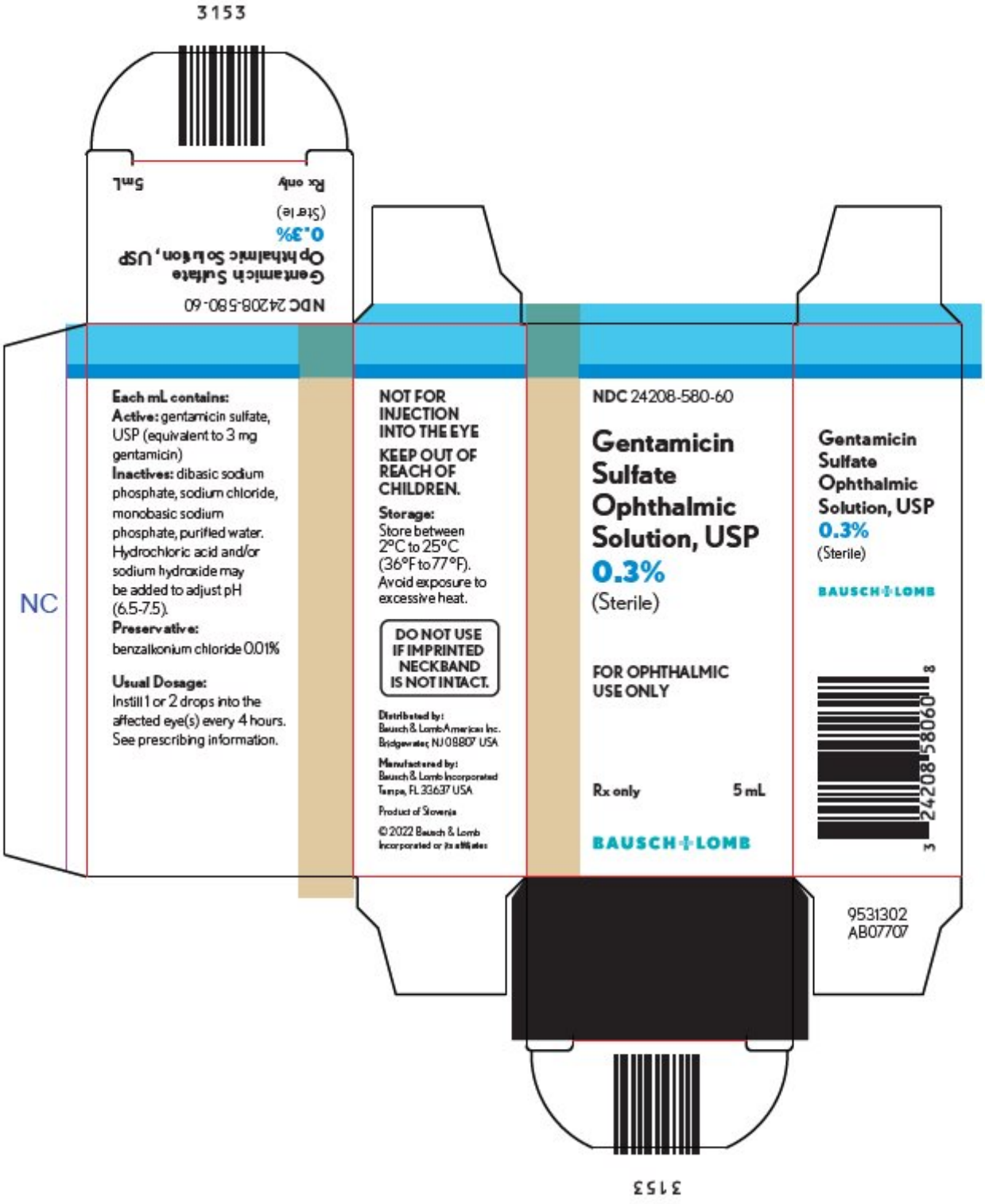
FOR OPHTHALMIC
USE ONLY

Rx only

5 mL

BAUSCH + LOMB

9531302
AB07707



GENTAMICIN SULFATE

gentamicin sulfate solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24208-580
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 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24208-580-60	1 in 1 CARTON	05/11/1994	
1		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:24208-580-64	1 in 1 CARTON	05/11/1994	06/30/2018
2		15 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 - Bausch & Lomb Incorporated (196603781)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(24208-580)

Revised: 9/2022 Bausch & Lomb Incorporated