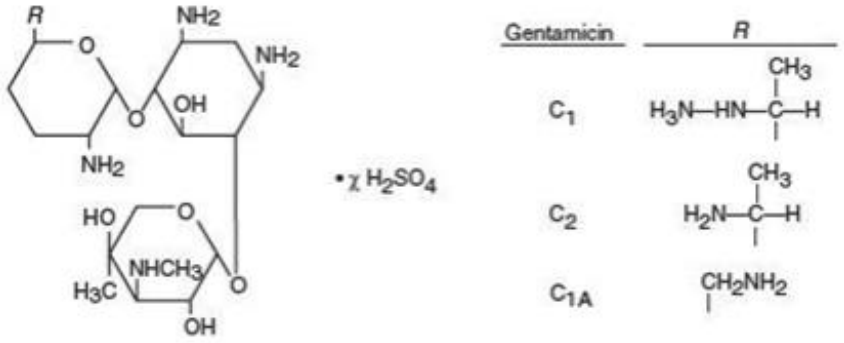
GENTAMICIN SULFATE- gentamicin sulfate solution/ drops
Pacific Pharma, Inc.

GENTAMICIN SULFATE
ophthalmic solution, USP 0.3%
sterile

DESCRIPTION

Gentamicin sulfate ophthalmic solution, USP is a sterile, topical anti-infective agent for ophthalmic use.

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 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:



Each mL contains: Active: gentamicin sulfate equivalent to 3 mg (0.3%) gentamicin base. **Preservative:** benzalkonium chloride. **Inactives:** edetate disodium; polyvinyl alcohol 1.4%; purified water; sodium chloride; sodium phosphate, dibasic; and hydrochloric acid and/or sodium hydroxide may be added to adjust pH. The solution is an aqueous, buffered solution with a shelf life pH range of 6.5 to 7.5.

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, USP 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, USP is contraindicated in patients with known hypersensitivity to any of its components.

WARNINGS

NOT FOR INJECTION INTO THE EYE.

Gentamicin sulfate ophthalmic solution, USP 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 microorganisms, 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.

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

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 white opaque LDPE plastic bottles and tips with beige high impact polystyrene (HIPS) caps as follows:

5 mL in 10 mL bottle – NDC 60758-188-05

Storage:

Store at or below 25°C (77°F). Avoid exposure to excessive heat (40°C/104°F or above).

Revised: 10/2017

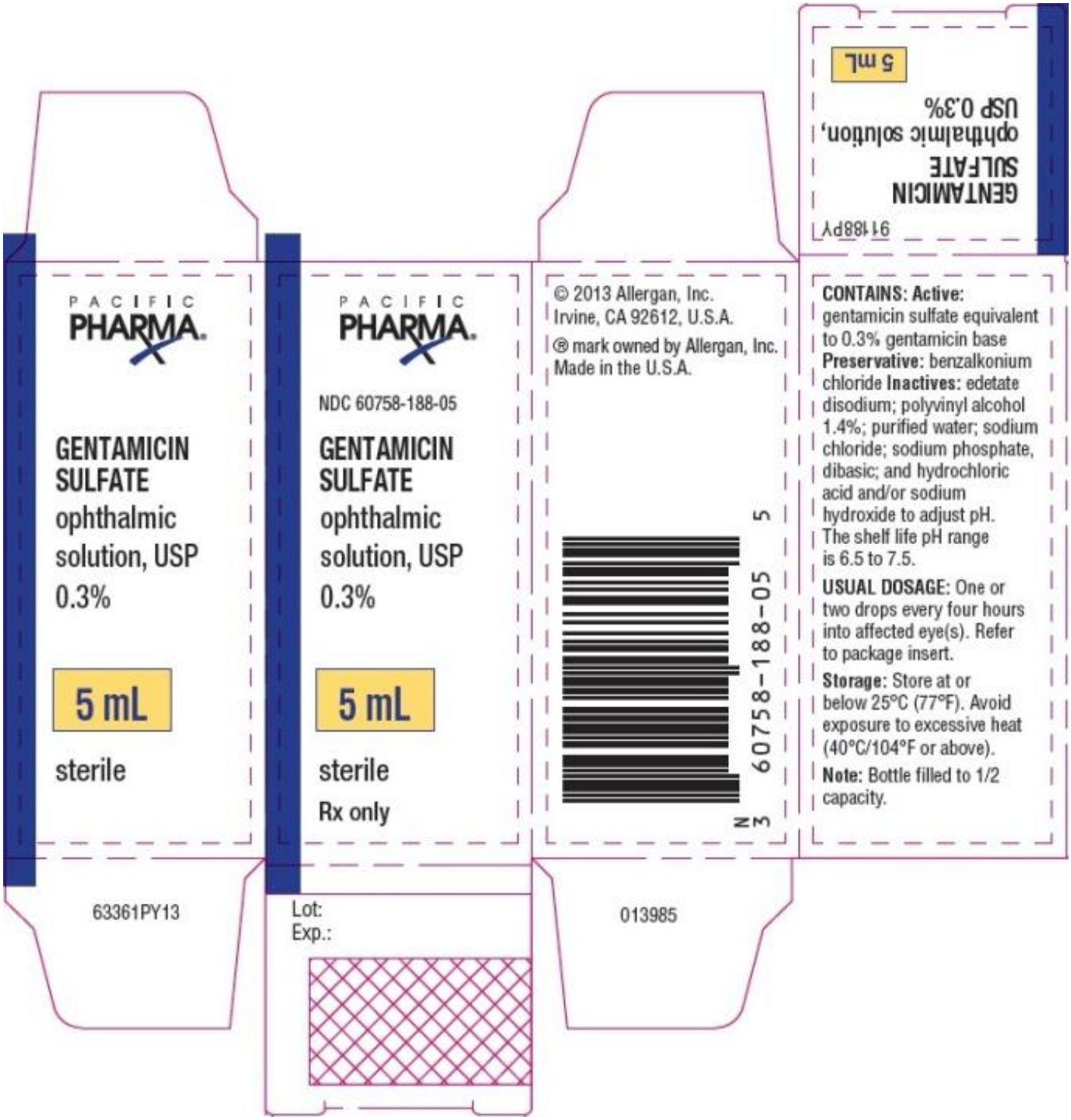
Distributed for: Allergan USA, Inc.
Madison, NJ 07940

Made in the U.S.A.

v1.0USPI188

PRINCIPAL DISPLAY PANEL

NDC 60758-188-05
GENTAMICIN
SULFATE
ophthalmic
solution, USP
0.3%
5 mL
sterile
Rx Only



GENTAMICIN SULFATE

gentamicin sulfate solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60758-188
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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60758-188-05	1 in 1 CARTON	01/05/1998	
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	ANDA062452	01/05/1998	

Labeler - Pacific Pharma, Inc. (877645267)

Revised: 7/2018 Pacific Pharma, Inc.