

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 65-024

APPROVED LABELING



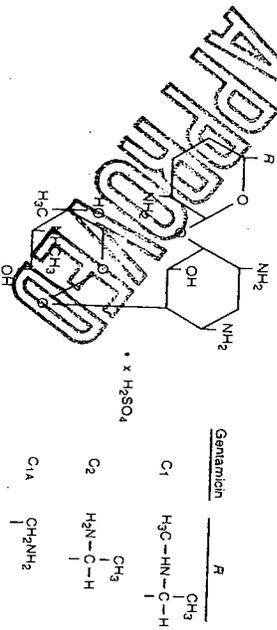
fougera®

GENTAMICIN SULFATE OPHTHALMIC OINTMENT USP STERILE

DESCRIPTION: Gentamicin sulfate is a water soluble antibiotic of the aminoglycoside group.

Gentamicin Sulfate Ophthalmic Ointment USP is a sterile ointment for topical ophthalmic use. Each gram contains gentamicin sulfate (equivalent to 3 mg gentamicin) in a base of white petrolatum and mineral oil.

Gentamicin is obtained from cultures of *Micromonospora purpurea*. 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 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, blepharocconjunctivitis, acute melibromitis, 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*.

(over)

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BY FOIA STAFF

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 non-susceptible 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 and 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: Teratogenic effects - Pregnancy Category C. Gentamicin has been shown to depress body weights, kidney weights, and red blood cell counts in newborn rats when administered systemically. Pregnant rats in daily doses approximately 500 times the maximum recommended human dose. There are no adequate and well-controlled studies in pregnant women. Gentamicin should be used during pregnancy only if the potential benefits 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 been reported during treatment with gentamicin ophthalmic preparations. The most frequently reported adverse reactions are ocular burning and stinging upon drug instillation, non-specific conjunctivitis, conjunctival epithelial desquamation and conjunctival hyperemia.

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

DOSE AND ADMINISTRATION: Apply a small amount (about 1/2 inch) to the affected eye(s) two to three times a day.

HOW SUPPLIED: Gentamicin Sulfate Ophthalmic Ointment USP (equivalent to 3 mg gentamicin) is supplied as follows:

- 3.5 gram tubes
- NDC 0168-0044-38

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

E. FOUGERA & CO.

a division of Atlanta Inc.
MELVILLE, NEW YORK 11747

124438A
R4/03
#82



1 17/32

CIRCUMFERENCE

SHOULDER

TUBE LENGTH
2 5/8"

B.M.
11/16"

OPEN END

NDC 0168-0044-38

fougera®

**GENTAMICIN
SULFATE
OPHTHALMIC
OINTMENT
USP**

STERILE
Usual Dosage: Apply a small amount (about 1/2 inch) to the affected eye(s). Use two to three times a day. Read accompanying directions carefully.

E. FOUGERA & CO.
a division of Allerga Inc.
MELVILLE, NEW YORK 11747

Gentamicin Sulfate, USP equivalent to 3 mg gentamicin per gram. Each gram contains Gentamicin Sulfate, USP equivalent to 3 mg gentamicin base, in a base of white petrolatum and mineral oil.

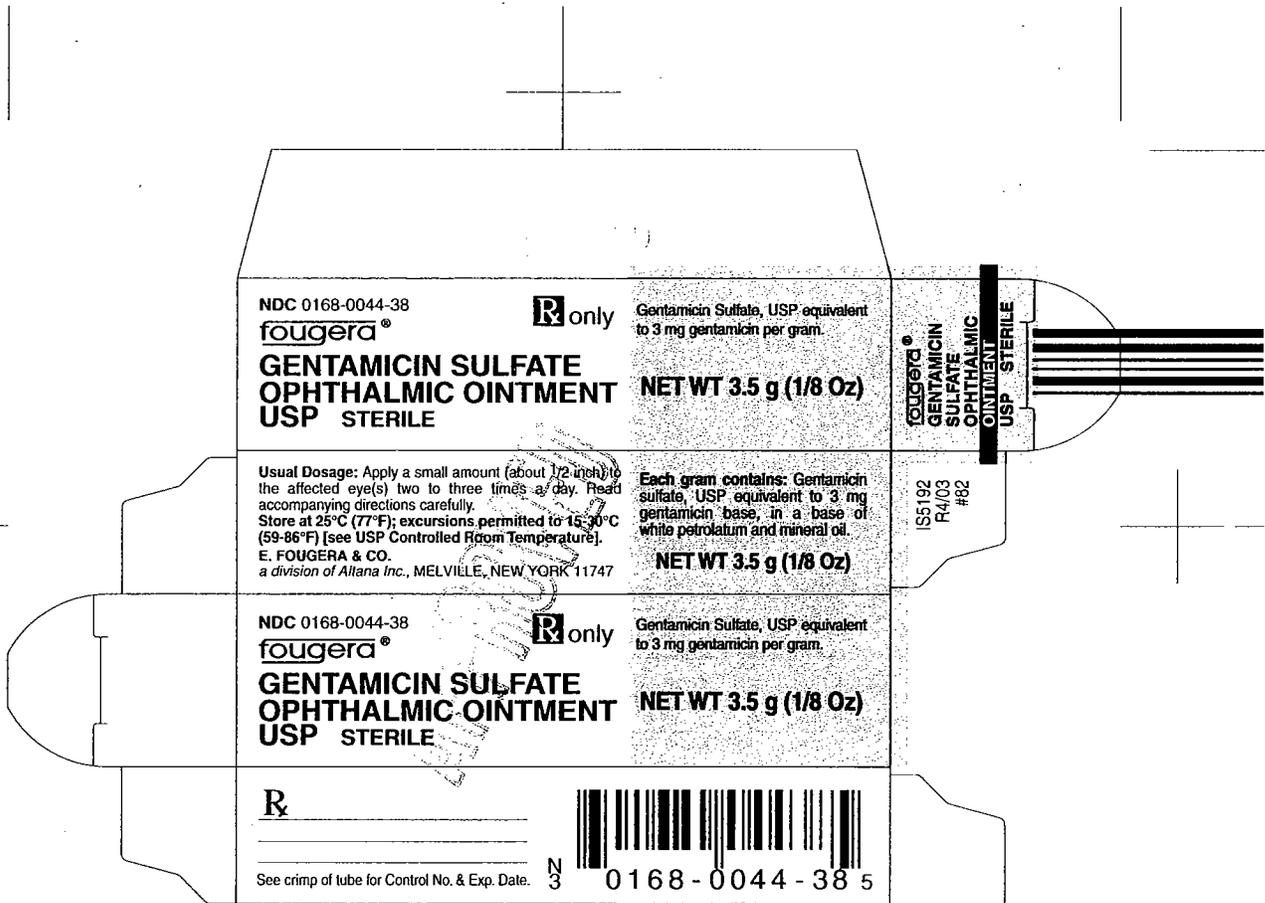
NET WT 3.5 g (1/8 Oz)

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) (see USP Controlled Room Temperature). See crimp of tube for Control No. and Exp. Date.

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COPY START
1/8"

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NDC 0168-0044-38

fougera®

R only

Gentamicin Sulfate, USP equivalent to 3 mg gentamicin per gram.

**GENTAMICIN SULFATE
OPHTHALMIC OINTMENT
USP STERILE**

NET WT 3.5 g (1/8 Oz)

Usual Dosage: Apply a small amount (about 1/2 inch) to the affected eye(s) two to three times a day. Read accompanying directions carefully.
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].
E. FOUGERA & CO.
a division of Altana Inc., MELVILLE, NEW YORK 11747

Each gram contains: Gentamicin sulfate, USP equivalent to 3 mg gentamicin base, in a base of white petrolatum and mineral oil.

NET WT 3.5 g (1/8 Oz)

fougera®
GENTAMICIN
SULFATE
OPHTHALMIC
OINTMENT
USP STERILE

IS5192
R4/03
#82

NDC 0168-0044-38

fougera®

R only

Gentamicin Sulfate, USP equivalent to 3 mg gentamicin per gram.

**GENTAMICIN SULFATE
OPHTHALMIC OINTMENT
USP STERILE**

NET WT 3.5 g (1/8 Oz)

R

See crimp of tube for Control No. & Exp. Date.



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