Prescribing Information

GARAMYCIN® OPHTHALMIC DROPS 0.3%
GARAMYCIN® OTIC DROPS 0.3%
GARAMYCIN® OPHTHALMIC OINTMENT 0.3%

(Gentamicin sulfate)

Topical antibiotic

Merck Canada Inc.
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Kirkland, Quebec H9H 4M7

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ACTION AND PHARMACOLOGY

GARAMYCIN, an aminoglycoside antibiotic, is active against the gram-positive bacteria commonly found in eye-ear infections: coagulase-positive and coagulase-negative Staphylococci, Group A beta-hemolytic and non-hemolytic Streptococci; and Diplococcus pneumoniae. GARAMYCIN is also active against gram-negative bacteria including P. aeruginosa, indole-positive and indole-negative Proteus species, E. coli, species of the Klebsiella-Enterobacter-Serratia group, Citrobacter species, Salmonella and Shigella, Moraxella species, Providencia species, H. vaginicola and Neisseria species, especially the gonococcus.

INDICATIONS

Ophthalmic: The treatment of superficial bacterial infections of the conjunctiva, cornea, eyelids, tear ducts and skin adjacent to the eye. Such infections include conjunctivitis, blepharitis, blepharoconjunctivitis, keratitis, keratoconjunctivitis, episcleritis, dacryocystitis, corneal ulcers and infected eye sockets. Also for the prevention of ocular infection if injury makes the eye or adjacent area vulnerable to infections: after removal of foreign bodies, after burns or laceration to the lids or conjunctivae or after damage from chemical or physical agents and before and after eye surgery.

Otic: May be used for the topical treatment of otitis externa caused by susceptible bacteria.

CONTRAINDICATIONS

Sensitivity to any of the components in GARAMYCIN.

Ophthalmic Use

As with all GARAMYCIN preparations containing benzalkonium chloride, patients are advised not to wear soft contact lenses during treatment.

Otic Use

GARAMYCIN Otic preparations are contraindicated in patients with absent or perforated tympanic membranes.

WARNINGS

Otic Use

When GARAMYCIN is used locally in the ear, potential eight cranial nerve toxicity should be considered. Animal studies have shown that gentamicin applied topically to the external ear canal may be absorbed since the drug has been detected in the serum and urine after this route of administration.

PRECAUTIONS

General:

Use of topical antibiotics occasionally allows overgrowth of nonsusceptible microorganisms such as fungi. If irritation, sensitization or superinfection develop, treatment with GARAMYCIN should be discontinued and appropriate therapy initiated.

To avoid possible contamination of the drops or ointment, do not touch the dropper tip or the ointment tube to any surface.

Clinical studies have shown that organisms previously sensitive to gentamicin have become resistant during therapy. Although this has occurred infrequently, the possibility should nevertheless be considered. There is evidence that cross-resistance between gentamicin and the aminoglycoside antibiotics may occur since bacteria made resistant

to aminoglycoside antibiotics artificially in the laboratory are also resistant to gentamicin; however, gentamicin may be active against clinical isolates of bacteria resistant to other aminoglycosides. Conversely, organisms resistant to gentamicin may be sensitive to other aminoglycoside antibiotics.

Otic Use

To minimize the risk of ototoxicity, the following precautions are suggested: the GARAMYCIN drops should be used for the shortest duration possible; the patient should be instructed precisely regarding the dosage and duration of therapy. Treatment should be discontinued if hearing loss, tinnitus, vertigo, or imbalance is noted. The use of GARAMYCIN eardrops should be reassessed, with respect to ototoxicity, 5-7 days after start of treatment and thereafter on a regular basis.

Pregnancy & Lactation

The safety of gentamicin for use during pregnancy has not been established. Since it is not known whether components of gentamicin Ophthalmic/Otic Solution are excreted in human milk, caution should be exercised when administered to a nursing woman.

Use in Children

Safety and effectiveness in children below the age of six years have not been established.

ADVERSE REACTIONS

Ophthalmic Use

Eye and ear medications may sting briefly on application and gentamicin ophthalmic and otic preparations are no exception. The most frequently reported adverse reactions at least possibly related to gentamicin are ocular burning and irritation upon drug instillation, non-specific conjunctivitis, conjunctival epithelial defects and conjunctival hyperemia.

Otic Use

The possibility of ototoxicity following otic application should be kept in mind, and the patient monitored accordingly on a regular basis (SEE CONTRAINDICATIONS, WARNINGS and PRECAUTIONS).

During the post-marketing of gentamicin containing otic preparations, rare cases of ototoxicity (hearing loss, tinnitus, vertigo, imbalance, ataxia or oscillopcia) in the presence of tympanic membrane perforation or tympanoplasty tubes have been reported. Ototoxicity was primarily vestibular and was generally associated with prolonged treatment duration. However, ototoxicity with treatment durations of 5 to 7 days has also been reported. In some instances, patients have not recovered from their symptoms (hearing loss, tinnitus, vertigo, imbalance, ataxia or oscillopcia).

OVERDOSE

Symptoms: A single overdose of gentamicin would not be expected to produce symptoms.

Treatment: Although a single overdose is not expected to require treatment, gentamicin can be removed from the blood by hemodialysis or peritoneal dialysis.

DOSAGE AND ADMINISTRATION

Ophthalmic Drops

Instil 2 drops into the conjunctival sac of the affected eye 3 to 4 times daily. Dosage may be increased in severe infections and reduced at the end of treatment. In the infections that may develop intermittently in the immature tear ducts of children (dacryocystitis), hot compresses and massage of the area over the tear duct may be useful as adjunct to the solution. In the treatment of acute pseudomonal corneal ulcer, 1 to 2 drops every 15 minutes in the daytime hours can be supplemented with the ophthalmic ointment at bedtime. For prophylaxis, such as after removal of a foreign body or following physical or chemical trauma, instil 1 to 2 drops 3 to 4 times daily until signs of inflammation have subsided. For prophylaxis before intraocular surgery, 1 to 2 drops should be instilled 4 to

5 times, preferably within 8 hours prior to surgery. GARAMYCIN Ophthalmic/Otic Solution may be administered as part of the routine post-operative daily dressing of the eye, until recovery from post-surgical inflammation is evident.

Ophthalmic Ointment

Apply ophthalmic ointment to the affected areas in or near the eye 3 to 4 times a day. If ophthalmic drops are used during the day, the ointment can be used at bedtime to continue treatment during the night.

Otic Drops

Thoroughly clean the ear canal of cerumen or debris. Instil 3 or 4 drops in the infected ear 3 times daily. The patient should lie with the affected ear upward; instil the solution and let the patient remain in this position for several minutes to insure penetration of the medication into the ear canal. If preferred, a cotton wick may be inserted into the ear canal and then saturated with the solution. The wick should be kept moist by adding further solution every four hours. The wick should be replaced once every 24 hours.

The need for GARAMYCIN eardrops should be reassessed 5 to 7 days after start of treatment and thereafter on a regular basis (SEE CONTRAINDICATIONS, WARNINGS and PRECAUTIONS).

AVAILABILITY

Ophthalmic Drops: Each mL of sterile aqueous solution buffered to approximately pH 7 contains: gentamicin 3 mg (as sulfate USP). Nonmedical ingredients: benzalkonium chloride, purified water, sodium chloride, sodium phosphate dibasic anhydrous and sodium phosphate monobasic monohydrate. Plastic dropper bottles of 5 mL.

Ophthalmic Ointment: Each gram of sterile ointment contains: gentamicin 3 mg (as sulfate USP). Nonmedical ingredients: methylparaben, mineral oil, propylparaben and white petrolatum. Tubes of 3.5 g with applicator tip.

Otic drops: Each mL of sterile aqueous solution buffered to approximately pH 7 contains: gentamicin 3 mg (as sulfate USP). Nonmedical ingredients: benzalkonium chloride, purified water, sodium chloride, sodium phosphate dibasic anhydrous and sodium phosphate monobasic monohydrate. Plastic dropper bottles of 7.5 mL.

Store between 15 to 30 °C.