INDICATIONS AND USAGE

GARASONE Ophthalmic/Otic Solution is indicated in the treatment of ocular inflammation when concurrent use of an antimicrobial agent is judged necessary.

GARASONE Ophthalmic/Otic Solution may also be used for the treatment of lesions in the external ear canal, such as acute and chronic otitis externa, eczematoid-dermatitis, seborrhoeic dermatitis and contact dermatitis secondarily infected with susceptible microorganisms.

DOSAGE AND ADMINISTRATION:

Ophthalmic: Dosage should be adjusted to specific needs of the patient. The usual dose is one to two drops instilled into the conjunctival sac of the affected eye three to four times daily. In the acute stage, frequency of administration may be increased to two drops every one to two hours; thereafter, frequency of administration may be reduced as the disorder is brought under control. The duration of topical treatment will vary with type and severity of disease. While GARASONE Ophthalmic/Otic Solution is used during the day, GARASONE Ophthalmic ointment may be applied at bedtime.

Otic: Thoroughly clean the ear canal of cerumen and debris. The suggested initial dosage of GARASONE Ophthalmic/Otic Solution is three or four drops two to four times a day. The patient should lie with the affected ear turned upward; instill the solution and let the patient remain in this position for several minutes to ensure penetration of the medication into the ear canal. After a favorable response is obtained, reduce dosage gradually and discontinue once cure is achieved.

If preferred, a cotton wick may be inserted into the canal and then saturated with the suspension. This wick should be kept moist by adding further suspension every four hours. The wick should be replaced at least once every 24 hours.
In chronic ophthalmic or otic conditions, withdrawal of treatment should be accomplished by gradually decreasing the frequency of application.

**ADVERSE REACTIONS**

Ophthalmic/Otic preparations may sting briefly upon application.

Adverse effects due to ophthalmic corticosteroids include increased intraocular pressure; glaucoma; infrequent optic nerve damage; defects in visual acuity and visual fields; posterior subcapsular cataract formation; delayed wound healing; filtering blebs following cataract surgery; secondary ocular infection from pathogens including herpes simplex.

Corticosteroid-containing ophthalmic preparations can also cause acute anterior uveitis or perforation of the globe. Mydriasis, loss of accommodation and ptosis have occasionally been reported following topical corticosteroid therapy.

Allergic sensitization may occur with ophthalmic antibiotics. Transient eye irritation has been reported with ophthalmic gentamicin sulfate.

**CONTRAINDICATIONS**

Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and viral diseases of the cornea and conjunctiva, mycobacterial or fungal infections of the eye or ear, trachoma, or hypersensitivity to any component of this preparation contraindicates its use. Use of corticosteroid/ antibiotic combinations is contra indicated after removal of a corneal foreign body and in patients with absent or perforated tympanic membranes.

As with at ophthalmic products containing benzalkonium chloride, patients are advised not to wear soft contact lenses during treatment with GARASONE Ophthalmic/Otic Solution.

**PRECAUTIONS**

GARASONE Ophthalmic/Otic Solution is for topical use only. It should never be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

If prompt clinical response is not obtained with the use of GARASONE Ophthalmic/ Otic Solution, further evaluation is advised.

Eyelid Colin ‘as and tests to determine the susceptibility of infecting organisms may be indicated if signs/symptoms persist or recur in spite of the recommended course of treatment with this product.

When GARASONE Ophthalmic/Otic Solution is applied to the eye for ten or more days, intraocular pressure should be monitored. Tonometry and slit lamp examination are advisable. Patients susceptible to increased intraocular pressure from treatment with topical corticosteroids include patients with a family history of open-angle glaucoma, a high degree of myopia and diabetes.

In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with the use of topical corticosteroids. Accordingly, it is not advisable to treat bacterial corneal ulcers, which may be due to *Pseudomonas aeruginosa*, with a combination antibiotic/anti-inflammatory product as initial therapy. It is prudent to use an anti-infective agent alone initially. For ulcers caused by *Pseudomonas*, GARAMYCIN* Ophthalmic Ointment would be indicated. If the infection responds to the anti-infective treatment, then the addition of an anti-inflammatory agent to minimize the fibrous reaction and scarring of the cornea is suggested.

In acute purulent conditions, corticosteroids may mask infection or enhance existing infection. Use corticosteroid preparations with extreme caution in the treatment of herpes simplex.

When an aminoglycoside antibiotic is used locally in the ear, potential eighth 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.

Prolonged use of topical antibiotics or corticosteroids may give rise to overgrowth of nonsusceptible microorganisms and fungi. Should this occur, or if irritation or hypersensitivity to GARASONE Ophthalmic/Otic Solution develops, discontinue use
of this preparation and institute appropriate therapy. Cross-allergenicity among aminoglycosides or corticosteroids has been demonstrated.

To avoid contamination and cross-infection, avoid the use of the same bottle of medication for the treatment of otic and ocular infections. Contamination of the solution may occur if the dropper tip touches any surface. The use of this dispenser by more than one person may spread infection.

**USAGE IN PREGNANCY**

GARASONE Ophthalmic/Otic Solution should not be given to pregnant women unless the potential benefit justifies the potential risk to the fetus.

**NURSING MOTHERS**

It is not known whether the components of GARASONE Ophthalmic/Otic Solution are excreted in human milk. Consideration should be given to discontinue nursing while the product is being used. Caution should be exercised when GARASONE Ophthalmic/Otic Solution is administered to a nursing woman.

**PEDIATRIC USAGE**

Safety and effectiveness of GARASONE Ophthalmic/Otic Solution in children below the age of eight years have not been established.

**OVERDOSAGE INFORMATION:**

**Symptoms:** Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency. A single overdosage of gentamicin would not be expected to produce symptoms.

**Treatment:** Appropriate symptomatic treatment of corticosteroid overdosage is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

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

Approximately 80% to 90% is removed from the circulatory system during twelve hours of hemodialysis. Peritoneal dialysis appears to be less effective.

**HOW SUPPLIED**

Dropper bottle of 5 ml.

**STORAGE**

Stored not above 25°C. Protect from light.

*Trademark
GARASONE Ophthalmic Ointment
Schering-Plough

Brand of gentamicin sulfate and betamethasone sodium phosphate
FOR OPHTHALMIC USE ONLY

DESCRIPTION
Each gram of GARASONE Ophthalmic Ointment contains gentamicin sulfate, equivalent to 3 mg of gentamicin, and 1 mg of betamethasone sodium phosphate in an ointment base.

Inactive ingredients
Mineral oil and white petrolatum.

ACTIONS
GARASONE Ophthalmic Ointment combines the potent anti-inflammatory and anti-allergic action of betamethasone sodium phosphate with the broad spectrum bactericidal activity of the aminoglycoside gentamicin sulfate. Betamethasone offers the advantage over other corticosteroids of enhanced anti-inflammatory effect with the use of lower dosages.

In vivo, staphylococcal species have responded favorably to gentamicin sulfate. In vitro, gentamicin sulfate is active against a wide variety of pathogenic Gram-negative and some Gram-positive bacteria: coagulase-positive and coagulase-negative staphylococci, Escherichia coli, Proteus species (indole-positive and indole-negative), Pseudomonas aeruginosa, species of the Klebsiella-Enterobacter-Serratia group, species of Citrobacter, Salmonella, Shigella, Moraxella, Serratia and Neisseria, particularly the gonococcus.

INDICATIONS AND USAGE
GARASONE Ophthalmic Ointment is indicated in the treatment of ocular inflammation when concurrent use of an anti-microbial agent is judged necessary, e.g., staphylococcal blepharoconjunctivitis, phlyctenular keratoconjunctivitis, microbial conjunctivitis and allergic conjunctivitis with secondary infection caused by pathogens sensitive to gentamicin.

GARASONE Ophthalmic Ointment is also recommended for the treatment of inflammatory and allergic disorders involving the superficial structures of the eye when bacterial infection, sensitive to gentamicin, is either present, suspected or anticipated. These ocular disorders include: conjunctivitis (non-purulent bacterial, catarrhal, vernal); blepharitis (non-purulent, allergic, associated with seborrheic dermatitis); keratitis (non-specific superficial, post-operative); episcleritis; dacryocystitis; hordeolum; meibomianitis; and injuries (penetrating and non-penetrating) involving the anterior segment of the eye caused by foreign bodies, radiation, thermal, chemical and post-operative factors.

In deep-seated ocular diseases, systemic therapy may be required. However, in these diseases, GARASONE Ophthalmic Ointment may be used as adjunctive therapy.

DOSAGE AND ADMINISTRATION
Apply a thin coating of GARASONE Ophthalmic Ointment into the conjunctival sac of the affected eye three to four times daily. In the acute stage, the frequency of administration may be increased: GARASONE Ophthalmic Ointment may be applied every two hours; thereafter, the frequency of administration may be reduced as the symptoms subside. Dosage should be adjusted to the specific needs of the patient. In chronic conditions, withdrawal of treatment should be accomplished by gradually decreasing the frequency of application.

ADVERSE REACTIONS
Ophthalmic preparations may sting briefly upon application.
Ocular hypersensitivity manifested by increased ocular hyperemia and edema and burning sensation were reported with use of GARASONE Ophthalmic Ointment. Adverse effects due to ophthalmic corticosteroids include increased intraocular pressure; glaucoma; infrequent optic nerve damage; defects
in visual acuity and visual fields; posterior subcapsular cataract formation; delayed wound healing; acute anterior uveitis; perforation of the globe; mydriasis; loss of accommodation; ptosis.

Allergic sensitization may occur with ophthalmic antibiotics.

Transient eye irritation has been reported with ophthalmic gentamicin sulfate.

**CONTRAINDICATIONS**

**GARASONE Ophthalmic Ointment** is contraindicated in epithelial herpes simplex, keratitis (dendritic keratitis), vaccinia, varicella, and viral diseases of the cornea and conjunctiva, mycobacterial or fungal infections of the eye, trachoma, or hypersensitivity to any component of this preparation. Use of corticosteroid/antibiotic combinations is contraindicated after removal of a corneal foreign body.

**PRECAUTIONS**

If prompt clinical response is not obtained with the use of **GARASONE Ophthalmic Ointment**, further evaluation is advised.

When **GARASONE Ophthalmic Ointment** is applied to the eye for 10 or more days, tonometry and slit lamp examination are advisable.

In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with the use of topical corticosteroids.

Accordingly, it is not advisable to treat bacterial corneal ulcers, which may be due to **Pseudomonas aeruginosa**, with a combination antibiotic-anti-inflammatory product as initial therapy. It is prudent to use an anti-infective agent alone initially. For ulcers caused by **Pseudomonas**, **GARAMYCIN** Ophthalmic Ointment would be indicated.

If the infection responds to the anti-infective treatment, then the addition of an anti-inflammatory agent to minimize the fibrous reaction and scarring of the cornea is suggested.

In acute purulent conditions of the eye, corticosteroids may mask infection or enhance existing infection. Use corticosteroid preparations with extreme caution in the treatment of **herpes simplex**.

Prolonged use of topical antibiotics or corticosteroids may give rise to overgrowth of nonsusceptible microorganisms and fungi. Should this occur, or if irritation or hypersensitivity to **GARASONE Ophthalmic Ointment** develops, discontinue use of this preparation and institute appropriate therapy.

Cross-allergenicity among aminoglycosides or corticosteroids has been demonstrated. Contamination of the ointment may occur if the dispenser tip touches any surface.

Safety and effectiveness of **GARASONE Ophthalmic Ointment** in children below the age of eight years have not been established.

**OVERDOSAGE**

**Symptoms**

Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushings disease.

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

**Treatment**

Appropriate symptomatic treatment is indicated. Acute hypercorticotoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

Although a single overdose is not expected to require treatment, gentamicin can be removed from
the blood by hemodialysis or peritoneal dialysis. Approximately 80% to 90% is removed from the circulatory system during twelve hours of hemodialysis. Peritoneal dialysis appears to be less effective.

HOW SUPPLIED
Tubes of 5 grams.
Store between 2° and 30°C.

* Trademark