Active Ingredients: Dexamethasone 0.1%, Neomycin (present as Sulfate) 3,500 units/ml and Polymyxin B Sulfate 6,000 units/ml.

Vehicle: Hydroxypropylmethyl cellulose 3550 mPa.s. 0.5%.

Preservative: Benzalkonium Chloride 0.004%

The Eye preparation of ISOPTO MAXITROL® combines two antibiotics offering broad spectrum anti-bacterial activity with the anti-inflammatory activity of a new corticosteroid, dexamethasone for combating certain microbial infections of the anterior segment of the eye(s) and the external ear canal. The formulation is formulated in an isotonic menstrum containing hydroxypropylmethyl cellulose for maximum effectiveness and comfort.

ACTION:

Polymyxin B Sulfate is a highly selective antimicrobial agent having greater activity against gram-negative than gram-positive organisms. Polymyxin is one of the most active antibiotics known against Pseudomonas aeruginosa. Most strains of this organism are inhibited by 10 mcg/ml or less. The following organisms have been demonstrated in vitro to be highly susceptible: A. aerogenes, E. coli, K. pneumoniae, Koch-Weeks bacillus, Pseudomonas aeruginosa.

The nature of the anti-bacterial action of Polymyxin B Sulfate is remarkable. It is almost uniquely bactericidal, resembling the action of chemical disinfectants rather than antibiotics. Neomycin Sulfate is a broad spectrum antibiotic, highly active against various gram-positive and negative bacteria. Some organisms which are sensitive to this antibiotic are: Staphylococcus aureus, C. diphtheriae, E. coli, A. aerogenes, K. pneumoniae, Proteus vulgaris, and Pseudomonas aeruginosa.

The action of Neomycin against sensitive organisms is both bacteriostatic and bactericidal. The mechanism of action is unknown. Dexamethasone has been shown to be demonstrated only at a low rate in vitro. Barr. et al. (6) reported that the combination of Polymyxin B Sulfate and Neomycin Sulfate had a definite synergistic action when tested in vitro against Staphylococcus aureus, E. coli, Pseudomonas aeruginosa, and Proteus vulgaris. Streptococcus fecalis, Proteus vulgaris, Streptococcus agalactiae, and Pseudomonas aeruginosa. Other investigators have corroborated these results.

Dexamethasone, the most active of a series of recently synthesized, 16-methyl substituted hydrocortisone analogs, is one of the most potent and effective corticosteroids presently available. The anti-inflammatory action and high degree of corneal penetration makes it ideal for combining with these antibiotics in controlling the undesirable phases of inflammation associated with bacterial infections.

INDICATIONS:

Eye: In the management of infectious ocular inflammations produced by organisms which are sensitive to the antibiotics, Neomycin Sulfate and Polymyxin B Sulfate. Acute or chronic nonpurulent conjunctivitis, blepharoconjunctivitis and keratoconjunctivitis: nosophic superficial keratitis; deep keratitis; acute rosacea keratitis; indocyclits mild acute acute; recurrent marginal ulceration and corneal ulcer (use with care in those diseases causing thinning of the cornea because of the danger of perforation); nonpurulent blepharitis, scleritis; episcleritis; scleroconjunctivitis; herpes zoster ophthalmicus (do not use in Herpes simplex); and post-

CONTRAINDICATIONS:

This drug is contraindicated tuberculous, fungal and most viral lesions of eye (Herpes simplex/dendritic keratitis); vaccinia; varicella; acute purulent conjunctivitis of acute purulent blepharitis, aural fungal infection.

PRECAUTIONS:

Extended use of topical steroid therapy may cause increased intraocular pressure in certain individuals. It is advisable that intraocular pressure be checked frequently. In those diseases causing thinning of the cornea, perforation has been known to occur with the use of topical steroids. Prolonged use may result in overgrowth of non-susceptible organisms, including fungi. Appropriate measures should be taken when this occurs in individuals may be sensitive to one or more components of this product. If any reactions indicating sensitivity are observed, discontinue use.

Although topical steroids have not been reported to have an adverse effect on pregnancy, the safety of their use in pregnancy has not absolutely been established. Therefore it is advisable not to use this product for long-term treatments of pregnant patients.

DOSAGE AND ADMINISTRATION:

Eye: One or two drops topically in the conjunctival sac(s) 4 to 6 times daily. Dosage may be reduced after 3 to 4 days when satisfactory improvement has been obtained.

Treatment should be repeated as long as necessary following physician's advice.

STORAGE CONDITION:

Do not store above 30°C, and discard bottle after 28 days of its opening.

AVAILABLE DOSAGE FORMS:

ISOPTO MAXITROL® is supplied in 5 ml sterile DROPTAINER® Dispensers. (Rx)

Also available: ISOPTO MAXITROL® eyeear Ointment 3.5 g (Rx): ISOPTO MAXIDE® (dexamethasone) 5 and 15 ml (Rx).

REFERENCES:


WARNING FOR BENZALKONIUM CHLORIDE:

May cause eye irritation
- Avoid contact with soft contact lenses.
- Remove contact lenses prior to application and wait at least 15 Minutes before reinsertion contact lens.
- Known to discolor soft contact lenses.