

# MAXITROL™

## Sterile Ophthalmic Suspension and Ointment

### Presentation

MAXITROL (Dexamethasone 0.1%, Neomycin Sulfate, Polymyxin B Sulfate) is a multiple dose anti-infective steroid combination in sterile suspension and sterile ointment forms for topical application.

The ophthalmic preparation of MAXITROL combines two antibiotics offering broad spectrum antibacterial activity with the anti-inflammatory activity of a corticosteroid, dexamethasone, for combating certain microbial infections of the anterior segment of the eye(s). The suspension is formulated in an isotonic menstium containing hydroxypropyl methylcellulose for maximum effectiveness and comfort.

Each mL of suspension contains:

Active: Dexamethasone 0.1%, Neomycin Sulfate 3,500 I.U./mL, Polymyxin B Sulfate 6,000 I.U./mL

Preservative: Benzalkonium Chloride 0.004%

Vehicle: Hydroxypropyl Methylcellulose 0.5%

Inactives and Purified Water

Each gram of ointment contains:

Active: Dexamethasone 0.1%, Neomycin Sulfate 3,500 I.U./g, Polymyxin B Sulfate 6,000 I.U./g.

Preservatives: Methyl Paraben 0.05%, Propyl Paraben 0.01%.

Inactives: White Petrolatum, Anhydrous Liquid Lanolin.

### Uses

#### Actions

Corticoids suppress the inflammatory response to a variety of agents and they probably delay or slow healing. Since corticoids may inhibit the body's defence mechanism against infection, a concomitant antimicrobial drug may be used when this inhibition is considered to be clinically significant in a particular case.

The anti-infective component in the combination is included to provide action against specific organisms susceptible to it. Neomycin Sulfate is considered active against the following microorganisms: *Staphylococcus aureus*, *Corynebacterium diphtheriae*, *Streptococcus viridans*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus vulgaris*, *Aerobacter aerogenes*, and *Haemophilus influenzae*.

Polymyxin B Sulfate is considered active against the following microorganisms: *Pseudomonas aeruginosa*, *Aerobacter aerogenes*, *Escherichia coli*, *Klebsiella pneumoniae* and Koch-Weeks bacillus.

When a decision to administer both a corticoid and an antimicrobial is made, the administration of such drugs in combination has the advantage of greater patient compliance and convenience, with the added assurance that the appropriate dosage of both drugs is administered, plus assured compatibility of ingredients when both types of drugs are in the same formulation and, particularly, that the correct volume of drug is delivered and retained.

The relative potency of corticosteroids depends on the molecular structure, concentration and release from the vehicle.

#### Pharmacokinetics

Unknown.

#### Indications

MAXITROL is indicated in ocular inflammation when concurrent use of an antimicrobial is judged necessary.

## **Dosage and Administration**

Keep out of reach of children.

### **MAXITROL Suspension**

One to two drops topically in the conjunctival sac(s). In severe disease, drops may be used hourly, being tapered to discontinuation as the inflammation subsides. In mild disease, drops may be used up to four to six times daily.

### **MAXITROL Ointment**

Apply a small amount into the conjunctival sac(s) up to three or four times daily or, may be used adjunctively with drops at bedtime.

## **Contraindications**

Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and many other viral diseases of the cornea and conjunctiva (except herpes zoster keratitis). Mycobacterial infection of the eye. Fungal diseases of ocular structures. Hypersensitivity to a component of the medication. (Hypersensitivity to the antibiotic component occurs at a higher rate than for other components).

The use of these combinations is always contraindicated after uncomplicated removal of a corneal foreign body.

## **Warnings and Precautions**

For topical use only. Not for injection.

Prolonged use may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in the visual acuity and fields of vision, and posterior subcapsular cataract formation. Prolonged use may suppress the host response and thus increase the hazard of secondary bacterial, fungal or viral ocular infections and mask the clinical signs of infection. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Employment of steroid medication in the treatment of herpes simplex requires great caution.

Sensitivity to topically administered aminoglycosides, such as neomycin, may occur in some patients. If hypersensitivity develops during use of this medicine, treatment should be discontinued.

Products containing neomycin sulfate may cause cutaneous sensitization.

Cross-hypersensitivity to other aminoglycosides can occur, and the possibility that patients who become sensitized to topical neomycin may also be sensitive to other topical and/or systemic aminoglycosides should be considered.

Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic neomycin or when applied topically to open wounds or damaged skin. Nephrotoxic and neurotoxic reactions have also occurred with systemic polymyxin B. Although these effects have not been reported following topical ocular use of this product, caution is advised when used concomitantly with systemic aminoglycoside or polymyxin B therapy.

The initial prescription and renewal of the medication order beyond 20 mL or 8 g should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

The possibility of persistent fungal infections of the cornea should be considered after prolonged steroid dosing. If fungal infection occurs, corticosteroids therapy should be discontinued.

As with other anti-infectives, prolonged use of antibiotics such as neomycin and polymyxin may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy.

In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids.

### **Effects on Fertility**

There are no available data on the use of this medicine affecting male or female fertility.

### **Pregnancy**

There are no adequate or well-controlled studies in pregnant women. Studies in animals have shown reproductive toxicity. MAXITROL should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or foetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

### **Nursing Mothers**

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, use only when considered essential by the physician.

### **Paediatric Use**

Safety and effectiveness in paediatric patients have not been established.

### **Effects on Ability to Drive and Use Machines**

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after instillation, the patient must wait until the vision clears before driving or using machinery.

### **Contact Lenses**

Contact lens wear is not recommended during treatment of an ocular inflammation or infection. Additionally, MAXITROL Eye drops suspension contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses.

### **Adverse Effects**

Adverse reactions have occurred with steroid/anti-infective combination drugs which can be attributed to the steroid component, the anti-infective component, or the combination. Exact incidence figures are not available since no denominator of treated patients is available.

Reactions occurring most often from the presence of the anti-infective ingredient are allergic sensitizations. The reactions due to the steroid components in decreasing order of frequency are: elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage, posterior sub-capsular cataract formation and delayed wound healing.

### **Secondary infection**

The development of secondary infection has occurred after use of combinations containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroid. The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used.

Secondary bacterial ocular infection following suppression of host responses also occurs.

### **Post Marketing Experience**

The following adverse reactions are classified according to the following convention: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $<1/10$ ), uncommon ( $\geq 1/1,000$  to  $<1/100$ ), rare ( $\geq 1/10,000$  to  $<1/1,000$ ), very rare ( $<1/10,000$ ), or not known (cannot be estimated from the available data). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. The adverse reactions have been observed during clinical trials and post-marketing experience for MAXITROL Eye drops suspension or Ointment.

#### Eye Disorders

Uncommon ( $\geq 0.1\%$  to  $< 1\%$ ): keratitis, intraocular pressure increased, vision blurred, photophobia, mydriasis, eyelid ptosis, eye pain, eye swelling, eye pruritus, ocular discomfort, foreign body sensation in eyes, eye irritation, ocular hyperaemia, lacrimation increased

#### Immune Disorders

Uncommon ( $\geq 0.1\%$  to  $< 1\%$ ): hypersensitivity

#### Interactions

No clinically relevant interactions have been described with MAXITROL Eye drops suspension or Ointment.

#### Overdosage

Due to the characteristics of this preparation, intended for topical use, no toxic effects are expected when administered to the eye neither at the recommended doses nor in the event of accidental ingestion of the contents of a bottle. In case of overdose, treatment should be supportive.

In New Zealand call 0800 POISON or 0800 764 766 for advice on management.

#### Pharmaceutical Precautions

Store below 25°C.

Discard 4 weeks after opening.

#### Medicine Classification

Prescription Medicine.

#### Package Quantities

MAXITROL Suspension supplied in 5 mL sterile DROP-TAINER<sup>®</sup> dispensers.

MAXITROL Ointment in 3.5 g ophthalmic tubes.

#### Further Information

Nil.

#### Name and Address

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