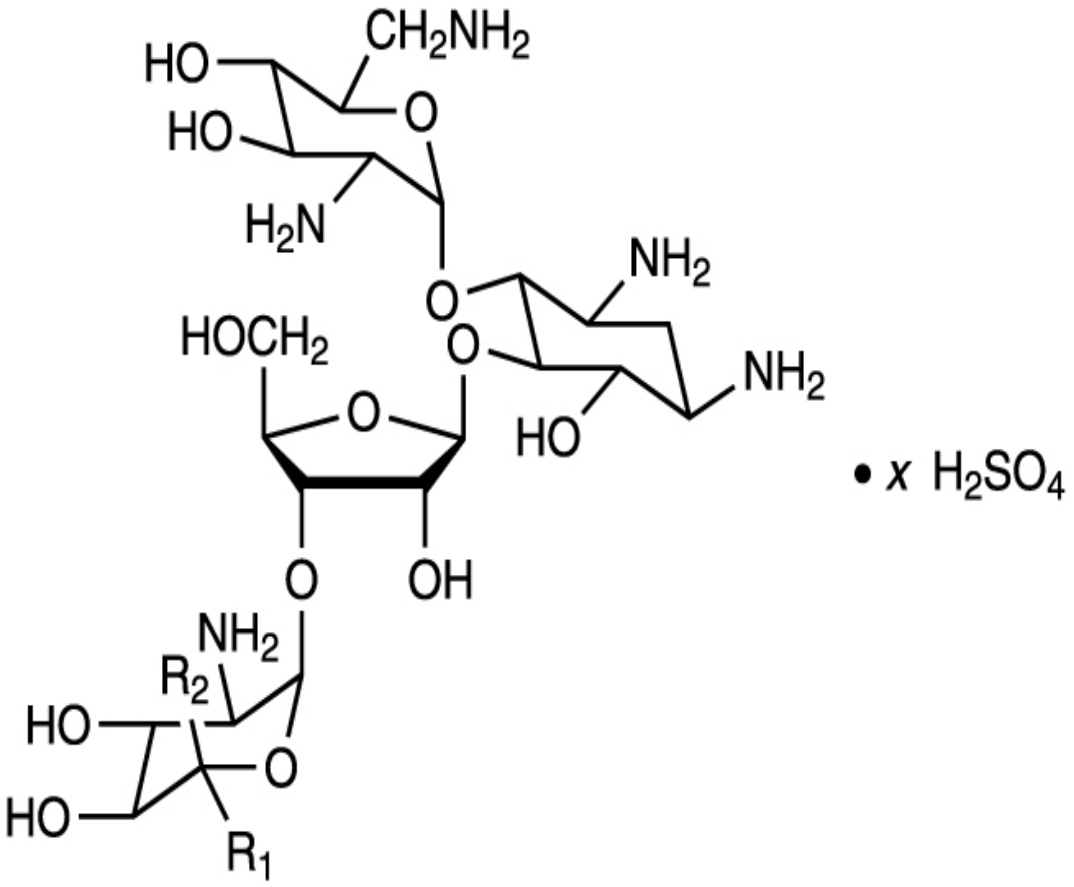
Maxitrol®
(neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment)
Sterile

DESCRIPTION: MAXITROL® (neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment) is a multiple dose anti-infective steroid combination in sterile ointment form for topical application.

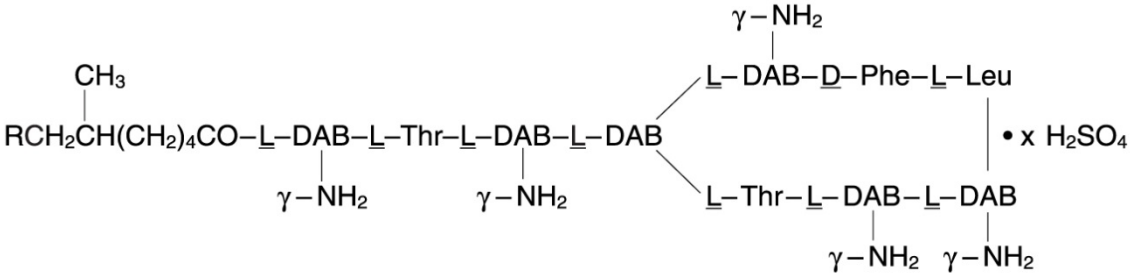
The chemical structure for the active ingredient Neomycin Sulfate is:



Neomycin B (R_1=H, R_2=CH_2NH_2)

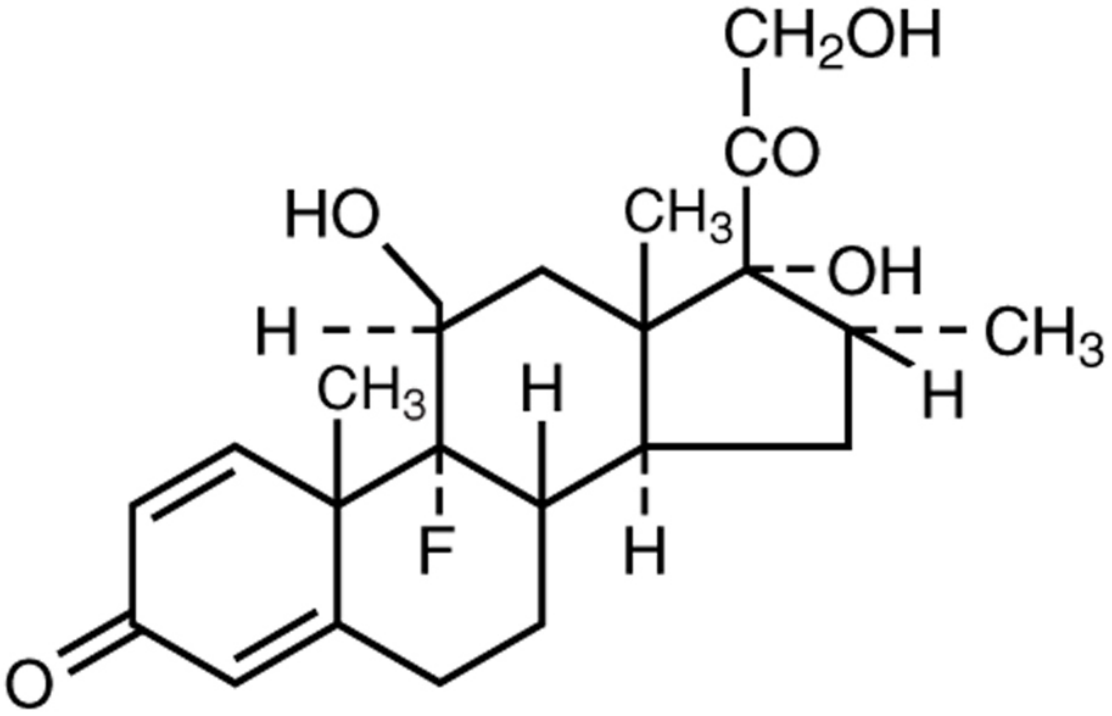
Neomycin C (R_1=CH_2NH_2, R_2=H)

The chemical structure for the active ingredient Polymyxin B Sulfate is:



Polymyxin B_1 (R=CH_3)
Polymyxin B_2 (R=H)
DAB=α,γ-diaminobutyric acid

The chemical structure for the active ingredient Dexamethasone is:



$C_{22}H_{29}FO_5$

MW = 392.47

Established Name: Dexamethasone

Chemical Name: Pregna-1, 4-diene-3, 20-dione,9-fluoro-11,17, 21-trihydroxy-16-methyl-, (11β, 16α)-.

Each gram contains: Active: neomycin sulfate equivalent to neomycin 3.5 mg, polymyxin B sulfate 10,000 units, dexamethasone 0.1%. **Preservatives:** methylparaben 0.05%, propylparaben 0.01%. **Inactives:** white petrolatum, anhydrous liquid lanolin.

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

When a decision to administer both a corticosteroid 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.

INDICATIONS AND USAGE: For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns; or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

The particular anti-infective drug in this product is active against the following common bacterial eye pathogens: *Staphylococcus aureus, Escherichia coli, Haemophilus influenzae, Klebsiella/Enterobacter* species, *Neisseria* species, and *Pseudomonas aeruginosa.*
This product does not provide adequate coverage against: *Serratia marcescens* and Streptococci, including *Streptococcus pneumoniae.*

CONTRAINDICATIONS: Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and many other viral diseases of the cornea and conjunctiva. 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.)

WARNINGS: NOT FOR INJECTION.
Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of steroid medication in the treatment of herpes simplex requires great caution.

Prolonged use may result in glaucoma, with damage to the optic nerve, defects in 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 ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection. If this product is used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Products containing neomycin sulfate may cause cutaneous sensitization. Sensitivity to topically administered aminoglycosides, such as neomycin, may occur in some patients. If hypersensitivity develops during use of the product, treatment should be discontinued. 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.

PRECAUTIONS: The initial prescription and renewal of the medication order beyond 8 g should be made by a physician only after examination of the patient with the aid of magnification, such as a slit lamp biomicroscopy and, where appropriate, fluorescein staining. The possibility of persistent fungal infections of the cornea should be considered after prolonged steroid dosing. Fungal infection should be suspected in patients with persistent corneal ulceration.

Information for Patients: If inflammation or pain persists longer than 48 hours or becomes aggravated, the patient should be advised to discontinue use of the medication and consult a physician.

This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the tube tip to eyelids or to any other surface. The use of this tube by more than one person may spread infection. Keep tube tightly closed when not in use.

Patients should be advised that their vision may be temporarily blurred following dosing with MAXITROL® (neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment). Care should be exercised in operating machinery or driving a motor vehicle.

Pregnancy. Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ophthalmic application in multiples of the therapeutic dose.
In the mouse, corticosteroids produce fetal resorptions and a specific abnormality, cleft palate. In the rabbit, corticosteroids have produced fetal resorptions and multiple abnormalities involving the head, ears, limbs, palate, etc.

There are no adequate or well-controlled studies in pregnant women. MAXITROL (neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment) should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus. 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, caution should be exercised when MAXITROL (neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment) is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: No overall clinical differences in safety or effectiveness have been observed between the elderly and other adult patients.

ADVERSE REACTIONS: 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 component are: elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular 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.

DOSAGE AND ADMINISTRATION: Apply a small amount into the conjunctival sac(s) up to three or four times daily.

How to Apply MAXITROL (neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment):

1. Tilt your head back.
2. Place a finger on your cheek just under your eye and gently pull down until a "V" pocket is formed between your eyeball and your lower lid.
3. Place a small amount (about 1/2 inch) of MAXITROL (neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment) in the "V" pocket. Do not let the tip of the tube touch your eye.
4. Look downward before closing your eye.

Not more than 8 g should be prescribed initially and the prescription should not be refilled without further evaluation as outlined in PRECAUTIONS above.

HOW SUPPLIED:

3.5 g STERILE ointment supplied in an aluminum tube with a white polyethylene tip and white polyethylene cap. (**NDC** 0065-0631-36).

STORAGE: Store at 2°-25°C (36°- 77°F).

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Distributed by:

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