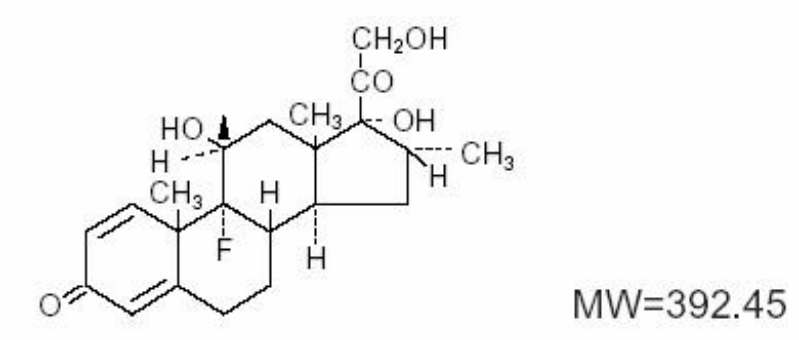
**NEOMYCIN SULFATE, POLYMYXIN B SULFATE AND DEXAMETHASONE - neomycin, polymyxin b and dexamethasone suspension**
**STAT RX LLC USA**

---

## DESCRIPTION
## DESCRIPTION

Neomycin and polymyxin B sulfates and dexamethasone ophthalmic suspension is a multiple dose anti-infective steroid combination in sterile suspension form for topical application. The chemical structure for the active ingredient, dexamethasone, is:
DEX STRUCTURE IMAGE




Established Name:

dexamethasone

Chemical Name:

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

The other active ingredients are neomycin sulfate and polymyxin B sulfate.

**Each mL contains: Actives:** neomycin sulfate equivalent to neomycin 3.5 mg, polymyxin B sulfate 10,000 units, dexamethasone 0.1%. **Preservative:** benzalkonium chloride 0.004%. **Vehicle:** hypromellose 2910 0.5%. **Inactives:** sodium chloride, polysorbate 20, hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water.

## CLINICAL PHARMACOLOGY
## 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
## 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 corticosteroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of corticosteroids 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

## 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

## WARNINGS

NOT FOR INJECTION. Do not touch dropper tip to any surface, as this may contaminate the contents. 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 corticosteroids. In acute purulent conditions of the eye, corticosteroids 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.

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

## PRECAUTIONS
## PRECAUTIONS

The initial prescription and renewal of the medication order beyond 20 mL 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

corticosteroid dosing.

**Pregnancy**

Pregnancy Category C. 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. Neomycin and polymyxin B sulfates and dexamethasone ophthalmic suspension 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 neomycin and polymyxin B sulfates and dexamethasone ophthalmic suspension is administered to a nursing woman.

**Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

## ADVERSE REACTIONS

**ADVERSE REACTIONS**

Adverse reactions have occurred with corticosteroid/anti-infective combination drugs which can be attributed to the corticosteroid 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 corticosteroid 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 corticosteroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of corticosteroids. The possibility of fungal invasion must be considered in any persistent corneal ulceration where corticosteroid treatment has been used.

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

## DOSAGE AND ADMINISTRATION

**DOSAGE AND ADMINISTRATION**

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.

Not more than 20 mL should be prescribed initially and the prescription should not be refilled without

further evaluation as outlined in PRECAUTIONS above.

**FOR TOPICAL OPHTHALMIC USE ONLY.**

## HOW SUPPLIED

**HOW SUPPLIED**

Sterile ophthalmic suspension in 5 mL plastic DROP-TAINER* dispenser (**NDC** 61314-630-06).

**STORAGE:** Store at 8°-27°C (46°-80°F).

**Rx Only**

*DROP-TAINER is a registered trademark of Alcon Manufacturing, Ltd.

FALCON LOGO IMAGE

Dist. by:

**FALCON Pharmaceuticals, Ltd.**
Fort Worth, Texas 76134 USA

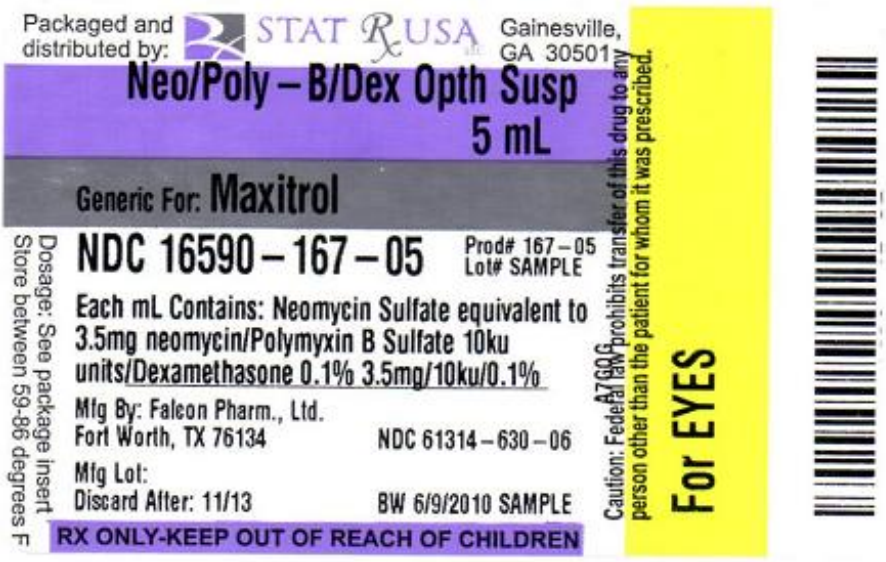
Mfd by:
**ALCON LABORATORIES, INC.**
Fort Worth, Texas 76134 USA

Printed in USA

**340905-0803**

## PACKAGE LABEL

NEO POLYB DEX LABEL IMAGE




## NEOMYCIN SULFATE, POLYMYXIN B SULFATE AND DEXAMETHASONE

neomycin, polymyxin b and dexamethasone suspension

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:16590-167(NDC:61314-630) |
| **Route of Administration** | OPHTHALMIC | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **NEOMYCIN SULFATE** (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297) | NEOMYCIN SULFATE | 3.5 mg in 1 mL |
| **POLYMYXIN B SULFATE** (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K) | POLYMYXIN B SULFATE | 10000 U in 1 mL |
| **DEXAMETHASONE** (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL) | DEXAMETHASONE | 1 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **BENZALKONIUM** (UNII: 7N6JUD5X6Y) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **HYDROCHLORIC ACID** (UNII: QTT17582CB) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:16590-167-05 | 5 mL in 1 BOTTLE | | |

| Marketing Information | | | |
|---|---|---|---|
| **Marketing Category** | **Application Number or Monograph Citation** | **Marketing Start Date** | **Marketing End Date** |
| ANDA | ANDA062341 | 05/22/1984 | |

**Labeler -** STAT RX LLC USA (786036330)

| Establishment | | | |
|---|---|---|---|
| **Name** | **Address** | **ID/FEI** | **Business Operations** |
| STAT RX LLC USA | | 786036330 | repack, relabel |

Revised: 6/2010 STAT RX LLC USA