STATROL- neomycin sulfate and polymyxin b sulfate ointment
ALCON LABORATORIES, INC.

Statrol®
neomycin and polymyxin B
sulfates ophthalmic ointment, USP

DESCRIPTION

STATROL® (Neomycin and Polymyxin B Sulfates Ophthalmic Ointment, USP) is a sterile ophthalmic drug combining two antibacterials in ointment form.

Each gram of ointment contains: **Active**: Neomycin Sulfate equivalent to 3.5 mg Neomycin base, Polymyxin B Sulfate equal to 10,000 polymyxin B units.

Preservatives: Methylparaben 0.05%, Propylparaben 0.01%. **Inactive:** White Petrolatum, Anhydrous Liquid Lanolin. DM-01

CLINICAL PHARMACOLOGY

The anti-infective components in STATROL Ophthalmic Ointment provide action against specific organisms susceptible to them. Polymyxin B Sulfate and Neomycin Sulfate are active *in vitro* against *Staphylococcus aureus, Escherichia coli, Klebsiella/Enterobacter* species, *Neisseria* species, *Pseudomonas aeruginosa*. This product does not provide adequate coverage against: *Serratia marcescens,* Streptococci, including *Streptococcus pneumoniae.*

INDICATIONS AND USAGE

STRATOL Ophthalmic Ointment is indicated in the topical treatment of infections of the external eye and its adnexa caused by susceptible bacteria. Such infections encompass conjunctivitis, keratitis, and keratoconjunctivitis, blepharitis and blepharoconjunctivitis, acute meibomianitis and dacryocystitis.

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.

WARNINGS

NOT FOR INJECTION INTO THE EYE. Should a sensitivity reaction occur, discontinue use. Ophthalmic ointments may retard corneal wound healing. Neomycin Sulfate may cause cutaneous sensitization. Remove contact lenses before using.

PRECAUTIONS

General

As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms including fungi. If superinfection occurs, appropriate measures should be initiated. Whenever clinical judgment dictates; the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, corneal staining.

Information for Patients

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. Keep out of the reach of children.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate carcinogenic or mutagenic potential have not been conducted with Polymyxin B Sulfate. Treatment of cultured human lymphocytes *in-vitro* with neomycin increased the frequency of chromosome aberrations at the highest concentrations (80 µg/mL) tested; however, the effects of neomycin on carcinogenesis and mutagenesis in humans are unknown.

Polymyxin B Sulfate has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown.

Pregnancy

Teratogenic Enects

Pregnancy Category C.

Animal reproduction studies have not been conducted with STATROL® (Neomycin and Polymyxin B Sulfates Ophthalmic Ointment, USP). It is also not known whether Neomycin Sulfate and/or Polymyxin B Sulfate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. STATROL Ophthalmic Ointment should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether these drugs are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when STATROL Ophthalmic Ointment is administered to a nursing mother.

ADVERSE REACTIONS

Adverse reactions have occurred with the anti-infective components. 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 ingredients are allergic sensitizations. (SEE WARNINGS.)

DOSAGE AND ADMINISTRATION

Instill about a half-inch ribbon into the conjunctival sac(s) up to three or four times daily, or may be used adjunctively with the solution at bedtime.

HOW SUPPLIED

STATROL (Neomycin and Polymyxin B Sulfates Ophthalmic Ointment, USP) in 3.5 g ophthalmic tube: **NDC** 0065-0624-36.

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

Federal (USA) law prohibits dispensing without prescription.

Alcon®

OPHTHALMIC

ALCON LABORATORIES, INC.

Fort Worth, Texas; 76134; USA

Revised: June 1995

Printed in USA

298392

STATROL

neomycin sulfate and polymyxin b sulfate ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0065-0624
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
neomycin sulfate (UNII: 057Y626693) (neomycin - UNII:I16QD7X297)		3.5 mg in 1 g
polymyxin B sulfate (UNII: 19371312D4) (polymyxin B - UNII:J2VZ07J96K)		10000 in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
white petrolatum (UNII: 4T6H12BN9U)	
anhydrous liquid lanolin ()	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0065-0624-36	3.5 g in 1 TUBE		

Labeler - ALCON LABORATORIES, INC.

Revised: 5/2006 ALCON LABORATORIES, INC.