STATROL- neomycin sulfate and polymyxin b sulfate solution
Alcon

Statrol®
neomycin and polymyxin B
sulfates ophthalmic solution, USP

DESCRIPTION

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

Each mL of solution contains: **Active**: Neomycin Sulfate equivalent to 3.5 mg Neomycin base, Polymyxin B Sulfate equal to 16,250 polymyxin B units.

Preservative: Benzalkonium Chloride .004%. **Vehicle:** 0.5% Hydroxypropyl Methylcellulose 2910. **Inactive:** Boric Acid, Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH), Purified Water. DM-02

CLINICAL PHARMACOLOGY

The anti-infective components in STATROL Ophthalmic Solution 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 Solution 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. 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 bottle tip to eyelids or to any other surface. The use of this bottle by more than one person may spread infection. Keep bottle 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 Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with STATROL® (Neomycin and Polymyxin B Sulfates Ophthalmic Solution, 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 Solution 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 Solution 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 one or two drops in the lower conjunctival sac(s) three or more times daily as required.

HOW SUPPLIED

STATROL (Neomycin and Polymyxin B Sulfates Ophthalmic Solution, USP) in 5 mL plastic DROP-TAINER® dispenser: **NDC** 0998-0623-05.

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

Federal (USA) law prohibits dispensing without prescription.

Alcon®
OPHTHALMIC
ALCON (Puerto Rico) INC.
Humacao, Puerto Rico 00791 USA

Revised: June 1995
Printed in USA

238382

STATROL

neomycin sulfate and polymyxin b sulfate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0998-0623
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 mL
polymyxin B sulfate (UNII: 19371312D4) (polymyxin B - UNII:J2VZ07J96K)		16250 in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
benzalkonium chloride ()	
hydroxypropyl methylcellulose 2910 ()	
boric acid (UNII: R57ZHV85D4)	
sodium chloride (UNII: 451W47IQ8X)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	
water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0998-0623-05	5 mL in 1 BOTTLE, PLASTIC		

STATROL

neomycin sulfate and polymyxin b sulfate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0065-0623
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 mL
polymyxin B sulfate (UNII: 19371312D4) (polymyxin B - UNII:J2VZ07J96K)		16250 in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
benzalkonium chloride ()	
hydroxypropyl methylcellulose 2910 ()	
boric acid (UNII: R57ZHV85D4)	
sodium chloride (UNII: 451W47IQ8X)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	
water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0065-0623-05	5 mL in 1 BOTTLE, PLASTIC		

Labeler - Alcon

Revised: 5/2006 Alcon