

**TOBREX - tobramycin ointment**  
**STAT RX LLC USA**

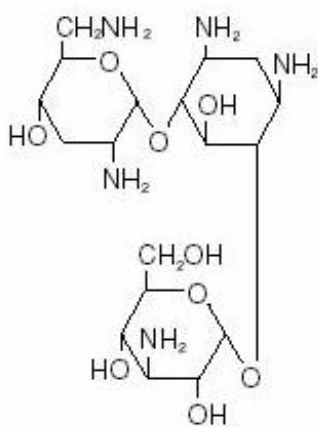
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**DESCRIPTION**

TOBREX<sup>®</sup> (tobramycin ophthalmic ointment) 0.3% is a sterile topical ophthalmic antibiotic formulation prepared specifically for topical therapy of external ophthalmic infections.

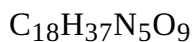
Each gram of TOBREX (tobramycin ophthalmic ointment) 0.3% contains: **Active:** tobramycin 0.3% (3 mg). **Preservative:** chlorobutanol 0.5%. **Inactives:** mineral oil, white petrolatum.

Tobramycin is a water-soluble aminoglycoside antibiotic active against a wide variety of gram-negative and gram-positive ophthalmic pathogens.

The chemical structure of tobramycin is :



Molecular formula:



Molecular weight:

467.52

Chemical name:

0- $\{3\text{-amino-3-deoxy-}\alpha\text{-D-glucopyranosyl-(1}\rightarrow\text{4)}\}$ -0- $\{2,6\text{-diamino-2,3,6-trideoxy-}\alpha\text{-D-ribohexopyranosyl-(1}\rightarrow\text{6)}\}$ -2-deoxystreptamine.

**CLINICAL PHARMACOLOGY**

*In Vitro Data:* *In vitro* studies have demonstrated tobramycin is active against susceptible strains of the following microorganisms: Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase- positive and coagulase-negative), including penicillin-resistant strains.

Streptococci, including some of the Group A–beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae*.

*Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Proteus mirabilis*, *Morganella morganii*, most *Proteus vulgaris* strains, *Haemophilus influenzae* and *H. aegyptius*, *Moraxella lacunata*, *Acinetobacter calcoaceticus* and some *Neisseria* species. Bacterial susceptibility studies demonstrate that in some cases, microorganisms resistant to gentamicin retain susceptibility to tobramycin.

## **INDICATIONS AND USAGE**

TOBREX (tobramycin ophthalmic ointment) 0.3 % is a topical antibiotic indicated in the treatment of external infections of the eye and its adnexa caused by susceptible bacteria. Appropriate monitoring of bacterial response to topical antibiotic therapy should accompany the use of TOBREX (tobramycin ophthalmic ointment) 0.3%. Clinical studies have shown tobramycin to be safe and effective for use in children.

## **CONTRAINDICATIONS**

TOBREX (tobramycin ophthalmic ointment) 0.3% is contraindicated in patients with known hypersensitivity to any of its components.

## **WARNINGS**

**NOT FOR INJECTION INTO THE EYE.** Sensitivity to topically applied aminoglycosides may occur in some patients. If a sensitivity reaction to TOBREX (tobramycin ophthalmic ointment) 0.3 % occurs, discontinue use.

## **PRECAUTIONS**

### **General**

As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated. Ophthalmic ointments may retard corneal wound healing.

Cross-sensitivity to other aminoglycoside antibiotics may occur; if hypersensitivity develops with this product, discontinue use and institute appropriate therapy.

Patients should be advised not to wear contact lenses if they have signs and symptoms of ocular infections.

### **Information For Patients**

Do not touch tube tip to any surface, as this may contaminate the ointment.

**Do not use the product if the imprinted carton seals have been damaged, or removed.**

### **Pregnancy Category B**

Reproduction studies in three types of animals at doses up to thirty-three times the normal human systemic dose have revealed no evidence of impaired fertility or harm to the fetus due to tobramycin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

### **Nursing Mothers**

Because of the potential for adverse reactions in nursing infants from TOBREX<sup>®</sup> (tobramycin ophthalmic ointment) 0.3 %, a decision should be made whether to discontinue nursing the infant or discontinue the drug, taking into account the importance of the drug to the mother.

### **Pediatric Use**

Safety and effectiveness in pediatric patients below the age of 2 months has 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**

The most frequent adverse reactions to TOBREX (tobramycin ophthalmic ointment) 0.3% are hypersensitivity and localized ocular toxicity, including lid itching and swelling, and conjunctival erythema. These reactions occur in less than three of 100 patients treated with TOBREX (tobramycin ophthalmic ointment) 0.3%. Similar reactions may occur with the topical use of other aminoglycoside antibiotics. Other adverse reactions have not been reported from TOBREX (tobramycin ophthalmic ointment) 0.3% therapy; however, if topical ocular tobramycin is administered concomitantly with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration. In clinical trials, TOBREX (tobramycin ophthalmic ointment) 0.3% produced significantly fewer adverse reactions (3.7%) than did GARAMYCIN<sup>®</sup> Ophthalmic Ointment (10.6%).

### **OVERDOSAGE**

Clinically apparent signs and symptoms of an overdose of TOBREX (tobramycin ophthalmic ointment) 0.3% (punctate keratitis, erythema, increased lacrimation, edema and lid itching) may be similar to adverse reaction effects seen in some patients.

### **DOSAGE AND ADMINISTRATION**

In mild to moderate disease, apply a half-inch ribbon into the affected eye(s) two or three times per day. In severe infections, instill a half-inch ribbon into the affected eye(s) every three to four hours until improvement, following which treatment should be reduced prior to discontinuation.

How to Apply TOBREX (tobramycin ophthalmic ointment) 0.3%:

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 TOBREX (tobramycin ophthalmic ointment) 0.3 % in the “V” pocket. Do not let the tip of the tube touch your eye.
4. Look downward before closing your eye.

### **HOW SUPPLIED**

3.5g STERILE ointment supplied in an aluminum tube with a white polyethylene tip and white polyethylene cap (NDC 0065-0644-35), containing tobramycin 0.3% (3 mg/g).

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

**Rx Only**

The Alcon logo consists of the word "Alcon" in a bold, black, sans-serif font. A registered trademark symbol (®) is located at the top right of the letter "n".

Manufactured for:

**ALCON LABORATORIES, INC.**

Fort Worth, Texas 76134 USA

Manufactured by:

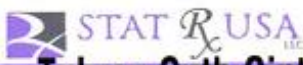
**S.A. ALCON-COUVREUR N.V.**

Puurs, Belgium

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Revised: October 2003

TOBREX OPHTHALMIC OINTMENT PACKAGE LABEL - 0.3% 3.5GM

Packaged and distributed by:  **STAT RX USA** LLC Gainesville, GA 30501

**Tobrex Opth Oint**  
0.3% 3.5 gm

Generic For:

**NDC 16590-225-35** Prod# 225-35  
Lot# SAMPLE

Each Gram Contains: Tobramycin 0.3%


Mfg By: Alcon Labs Inc. NDC 0065-0644-35  
Fl. Worth, TX 76134

Mfg Lot: 262821M Discard After: 07/11 BW 10/5/2010 SAMPLE

**RX ONLY-KEEP OUT OF REACH OF CHILDREN**

**For EYES**

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.



**TOBREX**

tobramycin ointment

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:16590-225(NDC:0065-0644)
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
TOBRAMYCIN (UNII: VZ8RRZ51VK) (TOBRAMYCIN - UNII:VZ8RRZ51VK)	TOBRAMYCIN	3 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>chlorobutanol</b> (UNII: HM4YQM8WRC)	
<b>mineral oil</b> (UNII: T5L8T28FGP)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16590-225-35	3.5 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050555	11/25/1981	

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

Name	Address	ID/FEI	Business Operations
STAT RX LLC USA		786036330	repack, relabel

Revised: 11/2010

STAT RX LLC USA