TOBREX® Alcon Tobramycin Topical Antibiotic

Action and Clinical

Like other aminoglycosides, the bactericidal activity of tobramycin is accomplished by specific inhibition of normal protein synthesis in susceptible bacteria, but at the present time, very little is known about this action. It is thought that inhibition of synthesis is due to an action on ribosomes that, in turn, causes bacterial misreading of messenger RNA.

Because the ocular concentrations of tobramycin achieved after topical application are higher than those which can be safely used in systemic therapy, standardized susceptibility tests may not be appropriate to predict its effectiveness.

The gram-positive bacteria against which tobramycin solution is clinically effective include the coagulase-positive and coagulase-negative staphylococci, including penicillin-resistant strains, S. pneumoniae, other alpha-hemolytic streptococci, Group A beta-hemolytic and non-hemolytic streptococci. The gram-negative bacteria against which tobramycin ophthalmic solution has been shown to have clinical effectiveness includes most strains of P. aeruginosa, E. coli, K. pneumoniae, E. aerogenes, P. mirabilis (indole-negative) and indole-positive Proteus species, as well as Haemophilus, Moraxella, and A. calcoacetius. Bacterial susceptibility studies show that many microorganisms resistant to gentamicin retain susceptibility to tobramycin. A significant bacterial population resistant to tobramycin has not yet emerged; however, bacterial resistance may develop upon prolonged use.

Indications And Clinical Uses:

For 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 its use.

Contra-Indications:

Patients with known hypersensitivity to any of its components. Partial cross-allergenicity to other aminoglycosides has been established.

Warnings:

Warnings in Clinical States:

Not for injection into the eye. Sensitivity to topically applied
aminoglycosides may occur in some patients. If a sensitivity reaction to tobramycin occurs, discontinue use.

Pregnancy: Reproduction studies in 3 types of animals at doses up to 33 times the normal 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.

Lactation: Because of the potential for adverse reactions in nursing infants from tobramycin, 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.

Precautions:

As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection or drug resistance occurs, or irritation or sensitization to any of the components of this preparation develops, treatment should be discontinued and appropriate therapy should be initiated. The patient should be advised to consult a physician if improvement fails to occur, or if signs of superinfection should occur. The patient should also be advised to avoid contamination of the dropper tip by the eye, or other objects.

If tobramycin is administered concomitantly with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration.

Adverse Reactions:

The most frequent adverse reactions to tobramycin are localized ocular toxicity and hypersensitivity, including lid itching and swelling and conjunctival erythema. These reactions occur in less than 3% of patients treated. Other adverse reactions have not been reported.

Symptoms And Treatment Of Overdose:

Clinically apparent signs and symptoms of an overdose e.g., punctate keratitis, erythema, increased lacrimation, edema and lid itching, may be similar to adverse reaction effects in some patients. In case of dramatic systemic overdose, serum concentrations should be monitored and prolonged levels above 12 µg/mL avoided.
Hemodialysis will help remove tobramycin from the blood. Such reactions and the necessity for counter measures are not expected from the use of Tobrex.

**Dosage And Administration:**

Ointment: For mild to moderate disease instill a 1.25 cm ribbon into the conjunctival sac of the affected eye(s) 2 to 3 times per day. For severe infections instill a 1.25 cm ribbon into the conjunctival sac of the affected eye(s) every 3 to 4 hours until improvement is detected. Following improvement, treatment should be reduced prior to discontinuation.

Solution: In mild to moderate disease, instil 1 or 2 drops into the affected eye(s) every 4 hours. In severe infections, instill 2 drops into the eye(s) hourly until improvement, following which treatment should be reduced prior to discontinuation.

Children: Clinical studies have shown tobramycin to be safe and effective for use in children.

**Availability And Storage:**

Ointment: Each g of sterile, ophthalmic ointment contains: tobramycin 3 mg and chlorobutanol 0.5% as preservative, in a mineral oil and petrolatum base. Tubes of 3.5 g. Keep tightly closed.

Solution: Each mL of sterile solution contains: tobramycin 0.3% (3 mg) and benzalkonium chloride 0.01% as preservative. Nonmedicinal ingredients: boric acid, purified water, sodium chloride, sodium hydroxide and/or sulfuric acid (to adjust pH), sodium sulfate and tyloxapol. Drop-Tainer dispensers of 5 mL. Keep tightly closed.