OCUTACIN 0.3%

Eye Drops

Composition
Tobramycin 0.3% (3 mg)

Action
Tobramycin is a potent, broad-spectrum, rapidly bactericidal aminoglycoside antibiotic. It exerts its primary effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome. Tobramycin in this combination provides antibacterial protection against susceptible bacteria.

The following MIC breakpoints, separating susceptible from intermediate susceptible organisms, and intermediate susceptible from resistant organisms, are suggested: S (≤ 4 µg/ml, R (≥ 8 µg/ml). The prevalence of resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable. The following information gives only an approximate guidance on probabilities whether bacteria will be susceptible to Tobramycin.

The breakpoint definitions classifying isolates as susceptible or resistant are useful in predicting clinical efficacy of antibiotics that are administered systemically. However, when the antibiotic is administered in very high concentrations topically directly on the site of infection, these breakpoint definitions may not be applicable. Most isolates that would be classified as resistant by systemic breakpoints are indeed successfully treated topically.
In vitro studies have shown Tobramycin to be active against most strains of common ocular pathogens and common skin flora bacteria as listed below:

Aerobic Gram-Positive Microorganisms
Corynebacterium species
Staphylococcus aureus Methicillin
Staphylococcus epidermidis Methicillin
Other Coagulase-negative Staphylococci

Aerobic Gram-Negative Microorganisms
Acinetobacter species
Citrobacter species
Escherichia coli
Enterobacter species
Haemophilus influenzae
Klebsiella species
Moraxella species
Proteus species
Pseudomonas aeruginosa

MODERATELY SUSCEPTIBLE SPECIES
(*in vitro,* intermediate susceptibility)
Aerobic Gram-Negative Microorganisms
Serratia marcescens

INHERENTLY RESISTANT SPECIES
Aerobic Gram-Positive Microorganisms
Enterococcus species
Staphylococcus aureus Methicillin
Staphylococcus epidermidis Methicillin
Streptococcus pneumoniae
Streptococcus species

Aerobic Gram-Negative Microorganisms
Burkholderia cepacia
Stenotrophomonas maltophilia

Anaerobic microorganisms
Strict anaerobic bacteria

Others
Chlamydia species
Mycoplasma species
Rickettsia species

Pharmacokinetics
Tobramycin is absorbed into the cornea following ocular administration. Following systemic administration to patients with normal renal function, a plasma half-life of approximately 2 hours has been observed. Tobramycin is eliminated almost exclusively by glomerular filtration with little if any biotransformation. Plasma concentrations of Tobramycin following the 2-day topical ocular regimen were below the limit of quantification in most subjects or low (≤0.25 microgram/ml).

Indications
Ocutacin (Tobramycin) Eye Drops is a topical antibiotics 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 Tobramycin.

Contraindications
Tobramycin is contraindicated in patients with known hypersensitivity to Tobramycin or to other aminoglycosides or any other ingredients in this product.

Warnings
Not for injection
Hypersensitivity
Sensitivity to topically administered aminoglycosides may occur in some patients. Severity of hypersensitivity reactions may vary from local effects to generalized reactions such as erythema, itching, urticarial, skin rash, anaphylaxis, anaphylactoid reactions, or bullous reactions. If hypersensitivity develops with this product, discontinue use and institute appropriate therapy.

If topical Tobramycin is administered concomitantly with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration. Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic tobramycin therapy. Although these effects have not been reported following topical ocular use of tobramycin, caution is advised when used concomitantly.

Adverse Reactions
The most frequent adverse reactions to Tobramycin are localized ocular toxicity and hypersensitivity, including punctate keratitis, eye and lid itching, lid swelling, ocular hyperaemia, conjunctival erythema and lacrimation. These reactions occur in approximately 3% of patients treated with Tobramycin.

Other adverse reactions associated with ophthalmic Tobramycin are burning and stinging of the eyes. For ophthalmic ointment dosage form: blurred vision.

Precautions
General
As with any antibiotic, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated.

Cross-sensitivity to other aminoglycoside antibiotics may occur. The possibility that patients that become sensitized to topical ocular Tobramycin may also be sensitive to other topical and/or systemic aminoglycosides should be considered.

Ophthalmic solutions may retard corneal wound healing

Use In Pregnancy
Pregnancy Category B
There are no adequate, well-controlled studies using the topical administration of in pregnant women.

Use in Lactation
There are no adequate, well-controlled studies using the topical administration of Tobramycin in women who are breast feeding. It is unknown whether Tobramycin is excreted in human milk following topical ocular administration. Tobramycin is excreted in human milk after systemic administration. Risk to the breast fed child cannot be excluded. Tobramycin should be used only if the potential benefit for the mother justifies the potential risk to the infant.

Pediatric Use
Safety and effectiveness in children below the age of 1 year have not been established.

Contact lenses
Tobramycin Eye Drops should not be instilled while the patient is wearing contact lenses. Contact lens wear is not recommended during treatment of an ocular infection.

If patients continue to wear contact lenses while under treatment with Tobramycin Eye Drops, they should remove their lens(es) prior to instilling the drops in the affected eye(s). Lens(es) should not be inserted into the eye(s) until 15 minutes after instillation of the drops.

Effects on ability to drive and use machines
As with other ophthalmic medications, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs upon application, the patient must wait until the vision clears before driving or using machinery.

Drug Interactions
If topical Tobramycin is used while the patient is on a systemic aminoglycoside antibiotic, the patient's total serum aminoglycoside concentration should be monitored.

Concurrent and/or sequential use of Tobramycin with other drugs with neurotoxic or ototoxic potential should be avoided.

Do not use Tobramycin simultaneously with a topical beta lactam type antibiotic as this is likely to result in inactivation of Tobramycin.

Dosage and Administration
In mild to moderate disease, instill one or two drops into the affected eye(s) every four hours. In severe infections, instill two drops into the eye(s) hourly until improvement.

Treatment should be reduced prior to discontinuation. The usual duration of treatment is 7-10 days.

Presentation
Dropper bottle of 5 ml