OBREX
(Tobramycin 0.3%)

Sterile Ophthalmic Solution &
Gamma Irradiated Ophthalmic Ointment

Composition:

Solution

Each ml Contains:
Tobramycin U.S.P. 3mg.
Preservative: Benzalkonium chloride.
Vehicle: Hydroxypropyl methylcellulose.

Ointment

Each gram contains:
Tobramycin U.S.P.3mg.

OBREX FORTE
(Tobramycin 1.5%)

Sterile Ophthalmic Solution

Composition:
Each ml Contains:
Tobramycin U.S.P. 15mg.
Preservative free.
Vehicle: Hydroxypropy! methylcellulose.

ACTIONS

Tobramycin is an aminoglycoside antibiotic obtained from cultures of Streptomyces tenebrarius. Tobramycin is usually bactericidal in action althought the exact mechanism of action has not been fully elucidated the drug appears to inhibit synthesis of susceptible bacteria by irreversible binding to 30S ribosomal subunits. In vitro date: In vitro studies have demonstrated Tobramycin is active against susceptible strains of the following organisms: Staphylococci including S. aureus and S. epidemidis (coagulase-positive and coagulase ncgative), including penicillin-resistant strains. Streprococci including some of the Group A beta hemolytic species, some nonhemolytic species and Streptococcus pneumoniae. Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae. Enterobacter aerogenes. Proteus mirabilis (indole-negative) and indole positive Proteus species, Haemophilus influenzae and H. aegyptius, Moraxella Iacunata and Acinetobacter celcoaceticus (herellea vaginacola) and some Neisseria species. Bacterial susceptibility studies demonstrate that in some cases microorganisms resistant to gentamicin retain susceptibility to Tobramycin. Bacterial resistance may develop upon prolonged use.

INDICATIONS:

OBREX & OBREX FORTE 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 **OBREX & OBREX FORTE.** Clinical studies have shown Tobramycin to be safe and effective, for use in children.

DOSAGE & ADMINISTRATION:

SOLUTION:

For mild to moderate-infections 1 to 2 drops **OBREX SOLUTION** should be instilled into the infected eye (s) every 4 hours. For severe infections including Pseudomonas aeruginosa infections, 2 drops of **OBREX SOLUTION** or one drop of **OBREX FORTE** solution should be instilled into the infected eye (s) every hour initially. When improvement occurs, frequency of application should be decreased. Therapy should be continued for at least 48 hours afte the infection has been controlled, or as directed by the physician

OINTNENT:

For mild to moderate infections, apply a small amount in the conjunctival sac (by pulling the lower lid down to form a pocket) three to four times daily or once or twice at night or as directed by the physician.

CONTRAINDICATIONS:

OBREX, OBREX FORTE Sterile Ophthalmic Solutions & **OBREX EYE OINTMENT** is contraindicated in patients with known hypersensitivity to drug.

PRECAUTIONS & WARNINGS:

GENERAL:

As with other antibiotic prolonged use may result in overgrowth of non-susceptible organisms including fungal infections. If super infection occurs during Tobramycin therapy, the drug should be discountinued and appropriate therapy should be initiated. If Tobramycin is administered topically in conjunction with systemic aminoglyconside therapy, serum aminoglyconside concentrations should be monitored. Use the Solution & Ointment within one month after opening the container. Do not touch the nozzle tip to any surface. Since this may contaminate drug. If irritation persists or increase, discontinue use and consult physician.

Pregnancy: Category B

reproduction studies in animals using systemic Tobramycin dosage up to 33 times the usual human systenic dosage have not revealed evidence of impaired fertility or harm to the fetus. There is however no controlled studies to date using topical or systemic Tobramycin in pregnant women and ophthalmin Tobramycin should be use during pregnancy only when clearly needed.

Nursing Mothers:

Because of the potential for serious adverse reactions from the drug in nursed infants, ophthalmic Tobramycin should not be use in nursing mothers. A decision should be made whether to discontinue nursing or discontinue the drug taking into account the importance of the drug to the mother.

ADVERSE REACTIONS:

OBREX and **OBREX FORTE** appears to have low order of toxicity when applied topically to the eye. However, sensitization to the drug may occasionally result from topical applications, If a sensitivity reaction occurs during topical Tobramycin therapy, the drug should be discontinued. The most frequnst adverse reactions to Tobramycin ophthalmic solution are localized ophthalmic toxicity and hypersensitivity including increased lacrimation, itching and edema of the eyelid and conjunctival erythema. These reactions occur in less than 3% of patients receiving opthalmic Tobramycin and usually disappear when the drug is discontinued. Puncate keratitis has also been reported following excessive application of Tobramycin

OVERDOSAGE:

Olinically apparent signs and symptoms of an overdose of Obrex & Obrex Forte ophthalmic solution & ointment (puncate keratitis, erythema, increased lacrimation, edema & lid itching) may be similar to adverse reactions seen in some patients

HOW SUPPLIED:

Solutions:

OBREX & OBREX FORTE As 5ml sterile ophthalmic solution in plastic dropper bottles.

Ointment:

As 5gm Sterile Ophthalmic Ointment in tube.

STORAGE:

Store below 30°C.
Protect from light and moisture.
Keep out of the reach of children.
Use only on medical advice.
For ophthalmic use only.
Once opened use within only one month.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ ہدایات: دوا کو روشنی، گرمی اور نمی سے بچائیں، ٹھنڈی اور خشک جگہ پر رکھیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔ دوا کو کھولنے کے بعد ایک ماہ کے اندر استعمال کریں۔
انتباہ: صرف رجسٹرڈ میڈیکل پریکٹیشنر کے نسخے پر فروخت کے لیے۔

Manufactured by:
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