INSTRUCTIONS FOR USE

1. Turn right (clockwise) to break the seal and make a dispensing hole on the nozzle.
2. Remove the ring and discard.
3. Open the cap by turning left (anti-clockwise) and it is ready for use.
4. Turn it up side down. Squeeze the walls of the bottle gently to deliver sterile drop into the eye.
5. Replace the cap. Tighten it firmly and keep the bottle closed for subsequent use.
6. Do not touch the nozzle.
7. Do not rinse the nozzle.
8. Do not expose to Sunlight.
9. Do not cut with knife.
10. Do not cut with scissors.

DESCRIPTION

Each mL contains:
- Tobramycin Sulfate USP equivalent to Tobramycin 3 mg
- Benzenethonium Chloride IP/USP 0.04 mg
- Purified Water IP

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

TOBRAMYCN
OPHTHALMIC SOLUTION USP
EYEBREX™ 0.3% Liquifilm™
sterile ophthalmic solution

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Each mL contains:
- Tobramycin Sulfate USP equivalent to Tobramycin 3 mg
- Benzenethonium Chloride IP/USP 0.04 mg
- Purified Water IP

ACTIONS

Eyebrex is an aminoglycoside antibiotic obtained from cultures of Streptomyces tenebrosus. Tobramycin is usually bactericidal in action. Although the exact mechanism of action has not been fully elucidated, the drug appears to inhibit synthesis of susceptible bacteria by interfering with 30 S ribosomal subunits. In vitro data indicate that tobramycin is active against susceptible strains of the following pathogenic organisms: Staphylococcus aureus and Staphylococcus epidermidis, including coagulase-positive and coagulase-negative strains. Streptococci and some other gram-positive and gram-negative bacteria, including Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis, and Pseudomonas aeruginosa. Tobramycin is also effective against Haemophilus influenzae, Moraxella lacunata, and Achromobacter xylosoxidans. In vitro, the drug is effective against gram-negative bacteria. Clinical studies demonstrate that in some cases, organisms resistant to gentamicin may be susceptible to tobramycin. Tobramycin resistance may develop upon prolonged use.

INDICATIONS AND USAGE

Eyebrex is a topical antibiotic indicated in the treatment of anterior external infections of the eye and as an agent to be used to prevent or treat infections of the eye associated with topical antibiotic therapy in the eyes of children and adults. Clinical studies have shown tobramycin to be safe and effective for the use in children.

CONTRAINDICATIONS

Eyebrex ophthalmic solution is contraindicated in patients with known hypersensitivity to any component in the formulation.

WARNINGS/PRECAUTIONS

GENERAL: As with other antibiotics, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfections occur during tobramycin therapy, the drug should be discontinued and appropriate therapy should be instituted. If tobramycin is administered topically in conjunction with systemic aminoglycoside therapy, serum aminoglycoside concentration should be monitored.

NOT FOR INJECTION: Use the solution within one month after opening the container. Do not touch the nozzle to any surface since this may contaminate solution. If irritation persists or increases discontinuation should be considered and consultation should be sought.

PREGNANCY: Category B. Reproduction studies in animals using tobramycin dosage up to 33 times the usual human systemic dosage have not revealed evidence of impaired fertility or harm to the fetus. There are no controlled studies in humans to date using topical or systemic tobramycin in pregnant women and ophthalmic tobramycin should be used during pregnancy only when clearly needed.

NURSING MOTHERS: Because of the potential for serious adverse reactions from the drug in nursing infants, ophthalmic tobramycin should not be normally used in nursing women. 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

Eyebrex appears to have low toxicity when applied topically to the eye. However, sensitivity to the drug may occasionally occur. Ocular irritation is common when topical tobramycin therapy is prolonged. If a sensitivity reaction occurs during topical tobramycin therapy the drug should be discontinued. The most frequent adverse reactions to tobramycin ophthalmic solution are localised ocular toxicity and hypersensitivity including increased lacrimation, itching and redness of the eye and conjunctival injection. These reactions occur in less than 3% of patients receiving ophthalmic tobramycin and usually disappear when the drug is discontinued. Punctate keratitis has also been reported following excessive application of tobramycin.

DOSEAGE AND ADMINISTRATION

For mild to moderate infection 1 or 2 drops of Eyebrex solution should be instilled into the infected eye(s) every 4 hours. For severe infections including Pseudomonas aeruginosa infections, 2 drops of the solution should be instilled into the infected eye(s) every hour initially. When improvement occurs, frequency of administration should be decreased. Therapy should be continued for at least 48 hours after the infection has been controlled.

OVERDOSAGE

Clinically apparent signs and symptoms of an overdose of Oxytetracycline solution (punctate keratitis, erythema, increased lacrimation, itching, and redness) may be similar to adverse reactions seen in some Patients.

HOW SUPPLIED

Eyebrex [®] Tobramycin ophthalmic solution is available in 5 mL plastic dropper bottles.

Note: Store in a cool place.

KEEP MEDICAMENT OUT OF REACH OF CHILDREN

Marketed by: Allergan India Private Limited
Manufactured in India by: Piramal Healthcare Limited
Plot No. 67-70 Sector 2, Phulari 454 775
Dell Co., Noida, Uttar Pradesh
Trade Mark