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

Obrin™

Eye / Ear Drops

(Tobramycin Ophthalmic solution USP)

COMPOSITION:

Tobramycin IP.....0.3% w/v
Benzalkonium Chloride solution IP.....0.02% v/v
(As preservative)
Water for Injections IP.....q.s.

List of Inactive ingredients:
Boric Acid
Polysorbate 80
Sodium Sulphate Anhydrous
Sodium Chloride

Pharmacological Action:

Tobramycin is a basic water-soluble aminoglycoside antibiotic. 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, and Acinetobacter calcoaceticus and some Neisseria species.

Bacterial susceptibility studies demonstrate that in some cases microorganisms resistant to gentamicin remain susceptible to tobramycin.

Indications:

Tobramycin 0.3% works by stopping the growth of bacteria. This medication used in eye / ear to treat bacterial infections.

Contraindications:

Tobramycin 0.3% is contraindicated in patients with known hypersensitivity to any of its components.

Warnings:

Sensitivity to topically applied aminoglycosides may occur in some patients. If a sensitivity reaction to Tobramycin 0.3% occurs, discontinue usage.

Precautions

General

As with other antibiotic preparations, prolonged use may result in overgrowth of non susceptible organisms, including fungi.

If severe infection occurs, appropriate therapy should be initiated.

Pregnancy:

No adequate and well-controlled studies are available in pregnant women. Hence Obrin (Tobramycin 0.3%) can be used during pregnancy only if clearly needed.

Nursing mothers:

Because of the potential for adverse reactions in nursing infants from Tobramycin 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.

Adverse Reactions:

The most frequent adverse reactions to Tobramycin 0.3% is localized ocular toxicity and hypersensitivity, including lid itching and swelling, and conjunctival erythema. Similar reactions may occur with the topical use of other aminoglycoside antibiotics. Other adverse reactions have not been reported from tobramycin 0.3% therapy; however, if topical ocular tobramycin 0.3% is administered concomitantly with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration.

Overdosage:

An overdose of this medication is unlikely to occur. If you do suspect an overdose, wash the eye with water and call an emergency room or poison control center near you.

Dosage and Administration

In mild to moderate infections, 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, following which treatment should be reduced prior to discontinuation.

Storage Instructions:

Use the solution within one month after opening the container.

Do not touch tip of container to any surface. Replace cap after using. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

KEEP IN A COOL PLACE

PROTECT FROM LIGHT

Presentation:

Obrin (Tobramycin 0.3%) is a sterile solution supplied in opaque plastic dropper bottle with a cap, containing 5 ml of the solution.

Directions for use:

Turn the tamper proof cap anti-clockwise to break the seal.

Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

Senses Pharmaceuticals Pvt. Ltd.,

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