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

Tobramycin Ophthalmic Solution USP 0.3% w/v

OBRIN™

EYE / EAR DROPS

For the use of Registered Medical Practitioner only

Composition

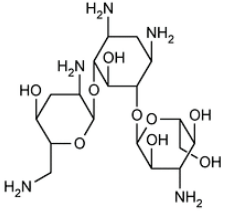
Tobramycin USP …..... 0.3 % w/v

Benzalkonium Chloride Solution USP ..... 0.02% v/v

(as preservative)

Water for Injection USP…..... q.s

Chemical Structure & Name



C18H37N5O9

D-Streptamine, O – 3 – amino – 3 – deoxy - – - D – glucopyranosyl - (1–6) – O - [2, 6 – diamino -2, 3, 6 – trideoxy - – - D – ribo – hexopyranosyl - (1–4)] – 2 – deoxy - .O – 3 – Amino – 3 – deoxy - – - D – glucopyranosyl - (1–4) – O - [2, 6 – diamino - 2, 3, 6 –trideoxy - – - D-ribo – hexopyranosyl - (1–6)] – 2 – deoxy – L - streptamine.

Category

Pharmacotherapeutic group: ophthalmologicals; anti-infectives

ATC code: S01A A12

Description

Eye / Ear drops (solution).

A clear colorless solution filled in 5mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap.

Pharmacology

Tobramycin is a potent, broad-spectrum, fast-working bactericidal aminoglycoside antibiotic. It exerts its primary effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome.

In vitro studies have demonstrated tobramycin is active against susceptible strains of the following microorganisms: Staphylococci, including S. *aureusand* S. *epidermidis(coagulasepositive 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, Klebsiellapneumoniae, Enterobacteraerogenes, Proteus mirabilis, Morganellamorganii, most Proteus vulgaris strains, Haemophilus influenzaeand H. aegyptius, Moraxella lacunata, Acinetobactercalcoaceticusand some Neisseria species.*

Bacterial susceptibility studies demonstrate that in some cases, microorganisms resistant to gentamicin retain susceptibility to tobramycin.

Pharmacokinetic:

Following topical ocular administration, only a small amount of tobramycin crosses the undamaged corneal barrier.

Indications

Tobramycin Ophthalmic Solution USP is indicated for the treatment of eye / ear infections caused by bacteria sensitive to to bramycin.

Dosage & Administration

Posology

• In mild to moderate disease: 1 or 2 drops in the eye(s) every 4 hours,

• In more severe infections: 2 drops in the eye(s) hourly until improvement, following which treatment should be reduced prior to discontinuation.

Pediatric Use

Clinical studies have demonstrated that tobramycin is also safe and effective for use in children. However, safety and effectiveness in pediatric patients below the age of 2 months has not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Method of Administration

Eye / Ear use only. Not for injection.

To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle. In order to prevent the drops from being absorbed via the nasal mucosa, particularly in children, the nasolacrimal ducts should be held closed for 2 to 3 minutes with the fingers after administering the drops.

After cap is removed, if tamper evident snap collar is loose, remove before using the product. If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

Contraindications

The use of Tobramycin Ophthalmic Solution USP is contraindicated in patients allergic to any of its components and to aminoglycosides.

Warning and Precaution

As with other antibiotics, prolonged use of tobramycin may result in growth of resistant strains including fungi. It is therefore advisable to

grow a culture before and after the treatment if clinical results are not satisfactory. If super infection occurs, appropriate therapy should be initiated.

Tobramycin Ophthalmic Solution USP is not intended for ocular injection. Sensitivity to topically applied aminoglycosides may occur in some patients; if a sensitivity reaction to Tobramycin Ophthalmic Solution USP occurs, discontinue use. In case of concomitant systemic treatment with important dosages of other antibiotics of the aminoglycoside group it is recommended to monitor the total serum concentration.

Cross-sensitivity to other aminoglycoside antibiotics may occur; if hypersensitivity develops with this product, discontinue use and institute appropriate therapy.

Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial ocular infection. The preservative in Tobramycin Ophthalmic Solution USP, benzalkonium chloride, may cause eye irritation. Contact lenses must be removed prior to application, with at least a 15-minute wait before reinsertion. Benzalkonium chloride is known to discolor soft contact lenses. Contact with soft contact lenses must be avoided.

After application of the eye drops following measures are useful to reduce systemic resorption:

– Keep the eyelid closed for 2 minutes;
– Close the lachrymal duct with the finger for 2 minutes.

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.

Interactions

No specific interaction studies were performed with Tobramycin Ophthalmic Solution USP. Interactions with tobramycin have been reported after systemic administration. However, the systemic absorption of tobramycin ophthalmic solution is so low that risk of any interaction is minimal.

Pregnancy & Lactation

No adequate and well-controlled studies with Tobramycin Ophthalmic Solution USP in pregnant women have been conducted. Reproduction studies in three types of animals at doses up to thirty-three times the normal human systemic dose have revealed no evidence of impaired fertility or harm to the fetus due to tobramycin. Because animal studies are not always predictive of human response, Tobramycin Ophthalmic Solution USP should be used during pregnancy only if the potential benefit outweighs the potential risk to the foetus. Because of the potential for adverse reactions in nursing infants from Tobramycin Ophthalmic Solution USP, 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 reaction

The most frequent adverse reactions to Tobramycin Ophthalmic Solution USP are hypersensitivity and localized ocular toxicity, including lid itching and swelling, and conjunctival erythema. However, these reactions occur in less than three of 100 patients, and may also occur with other topical aminoglycosides. Other adverse reactions have not been reported from Tobramycin ophthalmic solution therapy.

Overdosage

Clinically apparent signs and symptoms of an overdose of Tobramycin Ophthalmic Solution USP (punctate keratitis, erythema, increased lachrymation, oedema and eye-lid itching) may be similar to undesirable effects seen in some patients. Notify your physician in such cases.

Storage

Store between 15°C - 30 °C. Protect from light

Keep out of reach of children.

Shelf life

24 Months from the date of manufacture.

Presentation

A clear colourless solution filled in 5mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap in printed carton along with leaflet.

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 :

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Email: info@sensespharma.com

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