

T-Mycin Plus

Tobramycin 0.3% & Dexamethasone 0.1%
Ophthalmic Suspension & Ophthalmic Ointment

Composition:

T-Mycin Plus Ophthalmic Suspension: Each ml contains Tobramycin USP 3 mg and Dexamethasone USP 1 mg.

Preservative: Benzalkonium Chloride Solution BP 0.01%.

Vehicle: Hydroxyethyl Cellulose USP-NF 0.25%.

T-Mycin Plus Ophthalmic Ointment: Each gm contains Tobramycin USP 3 mg and Dexamethasone USP 1 mg.

Pharmacology:

The bactericidal activity of Tobramycin is accomplished by specific inhibition of normal protein synthesis in susceptible bacteria. Dexamethasone, a potent corticosteroid, suppresses the inflammatory response to chemical, immunological or mechanical irritants.

Indications:

T-Mycin Plus Ophthalmic Suspension and Ophthalmic Ointment are indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists.

Dosage and administration:

For Ophthalmic Suspension: 1 drop into the conjunctival sac every 4 hours. During the initial 24 to 48 hours the dosage may be increased to 1 drop every 2 hours. Frequency should be decreased gradually by improvement in clinical signs.

For Ophthalmic Ointment: It should be applied thinly and evenly into the conjunctival sac(s) up to 3 or 4 times daily or may be used adjunctively with drops at bedtime.

Contraindications:

Herpes simplex keratitis (dendritic keratitis), vaccinia, varicella and many other viral diseases of the cornea and conjunctiva. Hypersensitivity to any component of this medication.

Side-effects:

The most frequent side effects to topical ocular Tobramycin are localized ocular toxicity and hypersensitivity, including lid itching and swelling and conjunctival erythema. The reactions due to the steroid component are elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation.

Warnings:

Prolonged use of topical ophthalmic steroids may result in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision and posterior subcapsular cataract formation. Intraocular pressure should be routinely monitored.

Precautions:

The possibility of fungal infections of the cornea should be considered after long-term steroid dosing. Prolonged use of antibiotic may result in overgrowth of nonsusceptible organisms.

Pregnancy:

It is not known whether the drug can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Combination of Tobramycin & Dexamethasone should be given to a pregnant woman only if clearly needed.

Lactating mothers:

It is not known whether Tobramycin & Dexamethasone ophthalmic suspension or ointment are excreted in human milk, therefore caution should be exercised when it is administered to a lactating mother.

Pediatric use:

Safety and effectiveness in pediatric patients below 2 years have not been established.

Storage:

- Store below 30°C temperature in a dry place, protect from light.
- Do not use longer than 30 days after first opening the tube/dropper.
- Keep out of the reach of children.

Packing:

T-Mycin Plus Ophthalmic Suspension: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.

T-Mycin Plus Ophthalmic Ointment: Each tube contains 3.5 g Sterile Eye Ointment.



Manufactured by:
ARISTOPHARMA LTD.
GAZIPUR, BANGLADESH

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