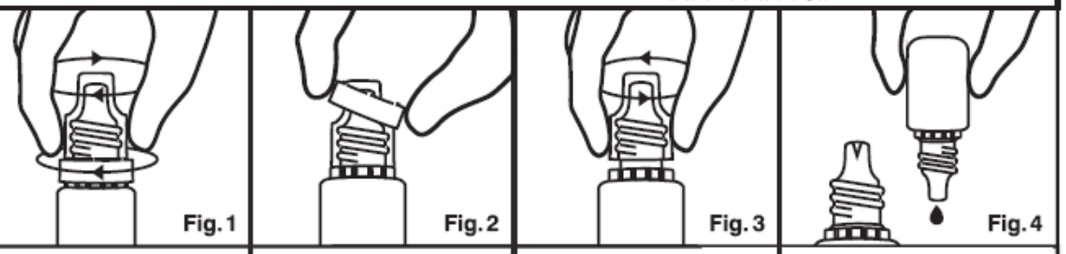
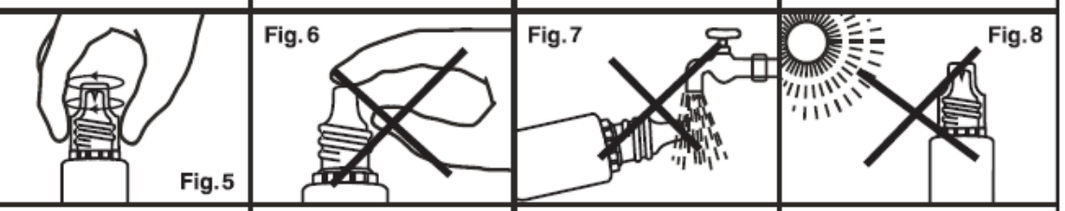
## INSTRUCTIONS FOR USE

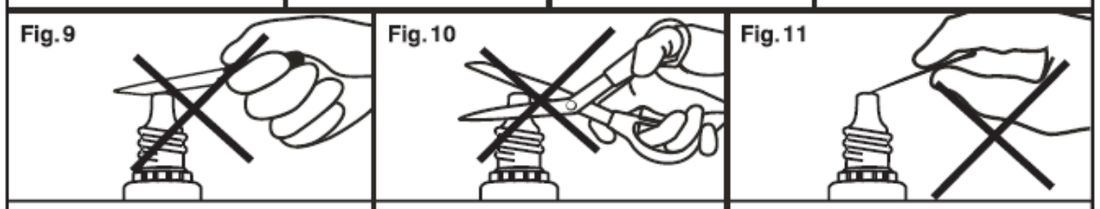
## उपयोग संबंधी निर्देश




| | | | |
|---|---|---|---|
| Turn right (clockwise) to break the seal and make a dispensing hole on the nozzle | Remove the ring and discard | Open the cap by tuning left (anti-clockwise) and it is ready for use. | Turn it up side down. Squeeze the walls of the bottle gently to deliver sterile drop into the eye. |
| सिल तोडने एवम नोज़ल में छिद्र करने के लिये ढक्कन को दाइने तरफ घुमायें। | छल्ले को निकाल कर फेंक दे। | ढक्कन को खोलने के लिये बांयी तरफ घुमायें। अब बोतल उपयोग के लिये तैयार है। | अब बोतल को उल्टा करें, बोतल की दिवार को हलकेसे दबाएँ और आँखों में दवा की बुंदें डालें। |




| | | | |
|---|---|---|---|
| Replace the cap. Tighten it firmly and keep the bottle closed for subsequent use. | Do not touch the nozzle. | Do not rinse the nozzle. | Do not expose to Sunlight. |
| पुनः उपयोग में लाने तक ढक्कन को कसकर बोतल वापस बंद कर दें। | बोतल के नोज़ल को हाथ न लगाएँ। | नोज़ल को कभी न धोएँ। | बोतल को धूप में न रखें। |




| | | |
|---|---|---|
| Do not cut with knife | Do not cut with scissor | Do not pierce with needle |
| चाकु से ना काटें। | कैंची से ना काटें। | सुई से छेद न करें। |

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**अलरगन इंडिया प्राईवेट लिमिटेड द्वारा**

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

# Tobramycin Sulphate Plus Fluorometholone Ophthalmic Suspension

# FML-T™

ALLERGAN

### DESCRIPTION

| Each mL contains : | |
|---|---|
| Tobramycin Sulphate USP equivalent to Tobramycin | 3 mg |
| Fluorometholone USP | 1 mg |
| Benzalkonium Chloride IP/USNF | 0.05 mg |
| Purified Water IP | q.s. |

**Fluorometholone Actions:**

Corticosteroids, such as Fluorometholone, inhibit the inflammatory response to a variety of inciting agents. They inhibit edema, fibrin deposition, capillary dilation & perforation, leukocyte migration, phagocytic activity, deposition of collagen and scar formation associated with inflammation. Corticosteroids inhibit the synthesis of histamine within the mast cells. They also decrease prostaglandin synthesis and retard epithelial regeneration. Corticosteroids are capable of raising the intra ocular pressure.

**Tobramycin Actions:**

Tobramycin is an Aminoglycoside antibiotic obtained from the culture of Streptomyces tenebranius. Tobramycin is bactricidal in actions and exerts its effects by inhibiting protein synthesis by binding irreversibly to 30 S ribosomal subunits. Tobramycin has been shown to be active in-vitro against Staphylococci including S. aureus and S. epidermidis, including penicillin resistant strains. Streptococci including S. pneumoniae, Pseudomonas aeruginose, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Haemophilus influenzae, Acinetobacter calcoaceticus & some Neisseria species. Bacterial susceptibility studies demonstrate that in some cases, microorganisms resistant to Gentamycin retain susceptibility to Tobramycin. Bacterial resistance may develop upon prolonged use.

**Indications:**

1. FML-T is effective in treatment of infectious conjunctivitis due to organisms sensitive to Tobramycin.
2. FML-T may be used for the treatment of the anterior segment inflammatory disorders which may be threatened with or complicated by bacteria sensitive to Tobramycin.
3. FML-T is effective following removal of foreign bodies as well as before and after surgery where the possibility of infection with susceptible organisms exists.

**Contraindications:**

Acute superficial herpes simplex (dendritic keratitis), vaccinia, Varicella and most viral diseases of the cornea and conjunctiva, ocular tuberculosis, and fungal diseases of the eye, and sensitivity to the drug. It is contraindicated in patients with history of hypersensitivity to Tobramycin, or to any of the components in this medication.

**Warnings:**

1. In those diseases causing thinning of the cornea, perforation has been reported with the use of topical steroids.
2. Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids.
3. Use of steroids medication in presence of stromal herpes simplex requires caution and should be followed by frequent mandatory slit-lamp microscopy.
4. As fungal infections of the cornea have been reported coincidentally with long-term local steroid applications, fungal invasion may be suspected in persistent corneal ulceration where a steroid has been used, or is in use.
5. Use of topical corticosteroids may cause increased intraocular pressure in certain individuals. This may result in damage to the optic nerve with defects in the visual field. It is advisable that the intraocular pressure be checked frequently.

**Use in Pregnancy :**

Safety of intensive or protracted use of topical steroids during pregnancy has not been substantiated. Category B Reproduction studies in animals using systemic Tobramycin dosages upto 33 times the usual human systemic dosage have not revealed evidence of impaired fertility or harm to fetus. There are however no controlled studies 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 serious adverse reactions from Tobramycin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Not for injection :**

Use the solution within one month after opening the container. Do not touch the nozzle tip to any surface since this may contaminate the solution. If the irritation persists or increases, discontinue use and consult physician. Indiscriminate and prolonged use of the preparation may lead to glaucoma, cataract and fungal infections.

**Precaution :**

Posterior sub capsular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids. Patients with histories of herpes simplex keratitis should be treated with caution. As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If the infection occurs discontinue use and institute alternative therapy.

**Adverse Reactions :**

Increased intraocular pressure, with optic nerve damage, defects in the visual fields, Also posterior sub capsular cataract formation, secondary ocular infections from fungi or viruses liberated from ocular tissues, and perforation of the globe when used in conditions where there is thinning of the cornea or sclera. systemic side effects may occur with extensive use of steroids. The most frequently reported drug-related adverse reaction was transient ocular burning or discomfort. Other reported reactions include increase lacrimation, itching and edema of the eyelid and conjunctival erythema. These reactions occur in less than 3% of patients receiving ophthalmic Tobramycin and usually disappear when the drug is discontinued.

**Dosage and Administration :**

1 to 2 drops instilled into conjunctival sac two to three times daily. During the initial acute phase the dosage may safely be increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

**Overdosage**

Clinically apparent symptoms of overdosage may be seen as punctate keratitis. Erythema, lid edema, etc. the drug should be withheld and appropriate change in therapy instituted.

**How supplied :**

FML-T (Tobramycin sulphate plus Fluorometholone ophthalmic suspension) is supplied in sterile 5 mL plastic dropper bottle.

**Note :** Store in a cool dry place. Shake well before use.

**KEEP MEDICAMENT OUT OF THE REACH OF CHILDREN**


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