

# Infladex-TN

Dexamethasone Sodium Phosphate BP 1 mg + Tobramycin BP 3 mg

Sterile and Pyrogen free Eye Drops

## Composition

Each ml contains Dexamethasone Sodium Phosphate BP 1 mg & Tobramycin BP 3 mg. Preservative: Benzalkonium Chloride BP 0.1 mg.

## Description

It is a sterile and pyrogen free ophthalmic solution containing corticosteroid (Dexamethasone) and antibiotic (Tobramycin) for topical administration to the eyes.

## Clinical Pharmacology

Like other amino-glycosides, the bactericidal activity of Tobramycin is accomplished by specific inhibition of normal protein synthesis in susceptible bacteria, but at the present time, very little is known about this action. It is thought that inhibition of protein synthesis is due to an action on ribosome that causes bacterial misreading of messenger RNA.

The action of Dexamethasone is to inhibit the phospholipase A<sub>2</sub>, the first step in prostaglandin synthesis. Also Dexamethasone inhibits the chemo-tactic infiltration of neutrophils into the site of inflammation. The result is that its anti-inflammatory activity is 25 times greater and its overall therapeutic effectiveness 8-10 times greater than that of hydrocortisone.

## Indications

This is indicated for steroid responsive inflammatory ocular conditions (palpebral and bulbar conjunctiva, cornea and anterior segment of the globe) where superficial bacterial ocular infection exists.

It is also indicated in chronic anterior uveities and corneal injury from chemical radiation or thermal burns, or penetration of foreign bodies.

The use of combination with an anti-infective component is indicated where the risk of superficial ocular infection is high.

## Dosage and Administration

Insert 1 drop into the conjunctival sac 3-5 times per day. During the initial 24 to 48 hours, the dosage may be increased to 1 drop every 2 hours.

## Contraindications

Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and many other viral diseases of the cornea and conjunctiva. Mycobacterial infection of the eye. Hypersensitivity to any component of the medication.

## Precautions

The possibility of fungal infections of the cornea should be considered after long-term steroid dosing. As like other antibiotic preparations, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super infection occurs, appropriate therapy should be initiated. Cross-sensitivity to other aminoglycoside antibiotics may occur; if hypersensitivity develops with the product, discontinue use and institute appropriate therapy.

## Pregnancy

There were no adequate and well controlled studies in pregnant women. This ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potent risk to the fetus.

## Nursing Mothers

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when this ophthalmic solution is administered to a nursing woman.

## Pediatric Use

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

## Side-Effects

The most frequent adverse reactions to topical ocular Tobramycin are hypersensitivity and localized ocular toxicity including lid itching, swelling and conjunctival erythema. This reaction occurs in less than 4% of patients.

The reactions due to the steroid component are; elevation of intraocular pressure with possible development of glaucoma, and infrequent optic nerve damage; posterior sub capsular cataract formation; and delayed wound healing.

## Overdosage

Overdose through local administration is not known. In case of accidental oral intake, specific measures to reduce resorption should be taken. There is no specific antidote.

## Pharmaceutical Precautions

Store at room temperature. Close the bottle immediately after use. Do not use for longer than one month after opening the bottle.

## Commercial Pack

Plastic dropper bottle of 5 ml.

### Manufactured by

Popular Pharmaceuticals Ltd. for



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.