OBRADEX

(Tobramycin 3mg and Dexamethasone 1mg)
Sterile Ophthalmic Suspension &
Sterile Gamma Irradiated Ointment

اوبراڈیکس
ٹوبرامائیسن
ڈیکسامیتھاسون

Composition:
Suspension
Each ml contains:
Tobramycin.....3 mg.
Dexamethasone.....1 mg.
(USP Specs.)
Preservative:
Benzalkonium Chloride.
Ointment:
Each gram contains:
Tobramycin.....3 mg.
Dexamethasone.....1 mg.
(USP Specs.)
Clinical Pharmacology:
Corticoids suppress the inflammatory response to a variety of agents and they probably delay or slow healing. Since corticoids may inhibit the body's defense mechanism against infection, a concomitant antimicrobial drug may be used when this inhibition is considered to be clinically significant. Dexamethasone is a potent corticoid. The antibiotic component in the combination (Tobramycin) is included to provide action against susceptible strains of different microorganisms.
Indications and Usage:
Obradex Ophthalmic Suspension is indicated for steroid responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitis is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns or penetration of foreign bodies. The use of combination drug with anti-infective components is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.
Contraindications:
Epithelial herpes simplex *keratitis (dendritic keratitis), vaccinia, varicella*, and many other viral diseases of the cornea and conjunctiva, mycobacterial infection of the eye, fungal diseases of ocular structures. Hypersensitivity to a component of the medication. The use of this combination is always contraindicated after uncomplicated removal of a corneal foreign body.
Warnings: Not for injection into the eye Sensitivity to topically applied amino glycosides may occur in some patients. If a sensitivity reaction does occur, discontinue use. Prolonged use of steroids may result in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsullar cataract formation. Intraocular pressure should be routinely monitored even though it may be difficult in children and non-cooperative patients. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

Precautions:
General: The possibility of fungal infections of the cornea should be considered after long-term steroid dosing. As with other antibiotic preparations, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super infection occurs, appropriate therapy should be initiated. When multiple prescriptions are required, or whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.
Carcinogenesis, Mutagenesis, Impairment of Fertility: No studies have been conducted to evaluate the carcinogenic or mutagenic potential.
Pregnancy Category C: Corticosteroids have been found to be teratogenic in animal studies.
Nursing Mothers: It is not known whether this drug is excreted in human milk.
Pediatric Use: Safety and effectiveness in children have not been established.
Adverse Reactions:
Exact incidence figures are not available. The most frequent adverse reactions to topical ocular Tobramycin are localized ocular toxicity and hypersensitivity, including lid itching and swelling and conjunctival erythema. However, if topical ocular Tobramycin is administered concomitantly with systemic amino glycoside antibiotics, care should be taken to monitor the total serum concentration. The reactions due to the steroid component are: elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage; posterior sub capsular cataract formation; and delayed wound healing.
Secondary infection:
The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used. Secondary bacterial ocular infection following suppression of host responses also occurs.
Dosage and administration:
Suspension:
One to two drops instilled into the conjunctival sac(s) every four to six hours. During the initial 24 to 48 hours, the dosage may be increased to one or two drops every 2 hours. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.
Ointment:
Apply a small strip of ointment (approximately 1/2 inch) into the conjunctival sac(s) of affected eye every 6 to 8 hours. Care should be taken not to discontinue therapy prematurely no more than 8g should be prescribed initially.
How Supplied:
Suspension:
5 ml sterile ophthalmic suspension in drop bottle.
Ointment:
Obradex ophthalmic sterile ointment is supplied as pack of 3.5 grams in tubes (gamma irradiated)
Storage:
Store below 30°C and store suspension upright and shake well before use.
Instructions:
Protect from heat and sunlight. Keep out of the reach of children.
Use within four weeks after first opening.
On prescription only.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ گرمی اور دھوپ سے بچائیں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔
پہلی دفعہ بوتل کھولنے کے بعد دوا کو چار ہفتوں تک استعمال کیا جا سکتا ہے۔
صرف مستند ڈاکٹر کے نسخہ پر استعمال کریں۔
استعمال سے پہلے اچھی طرح ہلا لیں۔

Manufactured by:
Vega Pharmaceuticals (Pvt.) Ltd.
30 Km, Multan Road, Lahore, Pakistan.