

Obrin™ DX

Eye Drops

(Tobramycin and Dexamethasone Ophthalmic Solution
(0.3%w/v & 0.1%w/v))

COMPOSITION:

Tobramycin IP	0.3%w/v
Dexamethasone Sodium Phosphate IP equivalent to Dexamethasone Phosphate	0.1% w/v
Benzalkonium Chloride Solution IP	0.01% v/v
(As Preservative)	
Water for Injections IP	q.s.

DESCRIPTION

Tobramycin And Dexamethasone Ophthalmic Solution is a combination of antibiotics and corticosteroids used to treat bacterial eye and ear infections. It is used to treat eye infections such as conjunctivitis (infection of the outer white membrane of the eyeball) and corneal ulcers (ulcer that occurs in the transplant membrane of the eye called the cornea). This infection is highly contagious in nature and can pass from one to another. Signs and symptoms include pink/red-toned eyes, gritty feeling in eyes, itchiness in areas of eyes, teary eyes, and thick discharge around eyes.

Obrin DX contains Tobramycin and Dexamethasone. Tobramycin is an aminoglycoside which inhibits the growth of bacteria by interfering with protein synthesis and leads to cell death. Dexamethasone is a corticosteroid medicine that reduces swelling and redness by preventing infection-fighting white blood cells (WBCs)

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 organisms. In vitro studies have demonstrated that tobramycin is active against susceptible strains of the following microorganisms:

Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive 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*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Proteus mirabilis*, *Morganella morganii*, most *Proteus vulgaris* strains, *Haemophilus influenzae* and *H. aegyptius*, *Moraxella lacunata*, *Acinetobacter calcoaceticus* and some *Neisseria* species.

No data are available on the extent of systemic absorption from tobramycin and dexamethasone ophthalmic suspension; however, it is known that some systemic absorption can occur with ocularly applied drugs.

INDICATIONS AND USAGE

Tobramycin and dexamethasone 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 oedema 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 a combination drug with an anti-infective component 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.

The particular anti-infective drug in this product is active against the following common bacterial eye pathogens:

Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains.

Streptococci, including some of the Group A-beta-haemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae*.

Pseudomonas aeruginosa, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Proteus mirabilis*, *Morganella morganii*, most *Proteus vulgaris* strains, *Haemophilus influenzae* and *H. aegyptius*, *Moraxella lacunata*, *Acinetobacter calcoaceticus* and some *Neisseria* species.

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.

WARNINGS

Sensitivity to topically applied aminoglycosides may occur in some patients. Severity of hypersensitivity reactions may vary from local effects to generalized reactions, such as erythema, itching, urticaria, skin rash, anaphylaxis, anaphylactoid reactions, or bullous reactions. 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 subcapsular cataract formation. Intraocular pressure (IOP) should be routinely monitored even though it may be difficult in paediatric patients and uncooperative patients. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions and parasitic infections of the eye, steroids may mask infection or enhance existing infection.

In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids.

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 nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated. When multiple prescriptions are required, or whenever clinical judgement dictates, the patient should be examined with the aid of magnification, such as slit lamp bio microscopy and, where appropriate, fluorescein staining.

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

Information for Patients

Do not touch dropper tip to any surface, as this may contaminate the contents. Contact lenses should not be worn during the use of this product.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies have been conducted to evaluate the carcinogenic or mutagenic potential. No impairment of fertility was noted in studies of subcutaneous tobramycin in rats at doses of 50 and 100 mg/kg/day.

Pregnancy

There are no adequate and well-controlled studies in pregnant women. However, prolonged or repeated corticoid use during pregnancy has been associated with an increased risk of intra-uterine growth retardation. Tobramycin and dexamethasone ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

Nursing Mothers

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. 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 tobramycin and dexamethasone ophthalmic suspension is administered to a nursing woman.

Paediatric Use

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

Geriatric Use

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

ADVERSE REACTIONS

Adverse reactions have occurred with steroid/anti-infective combination drugs which can be attributed to the steroid component, the anti-infective component, or the combination. Exact incidence figures are not available.

The most frequent adverse reactions to topical ocular tobramycin (tobramycin ophthalmic solution, 0.3%) are hypersensitivity and localized ocular toxicity, including lid itching and swelling, and conjunctival erythema. These reactions occur in less than 4% of patients. The reactions due to the steroid component are: elevation of IOP with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing.

Secondary Infection

The development of secondary infection has occurred after use of combinations containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids. 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.

Dexamethasone and tobramycin may cause serious side effects. Call your doctor at once if you have:

- Severe eye redness, itching, or swelling;
- Blurred vision, tunnel vision, seeing halos around lights;
- Pain behind your eyes, sudden vision changes;

- Slow healing after eye surgery; or
- Signs of eye infection--redness, severe discomfort, crusting or drainage.

Common side effects of dexamethasone and tobramycin may include:

- Minor burning or stinging.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

Storage Instructions

KEEP IN A COOL PLACE

PROTECT FROM LIGHT.

KEEP OUT OF REACH OF CHILDREN.

FOR EXTERNAL USE ONLY

Presentation

Obrin Dx is a sterile clear colourless solution supplied in an opaque plastic bottle with a cap containing 10 mL of solution.

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 :

Senses Pharmaceuticals Pvt. Ltd.,

No.77, 3rd Road, Bommasandra Industrial Area,
Bommasandra 4th Phase, Bengaluru - 560 099.

TM: Trademark for Registration

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