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

Tobramycin and Fluorometholone Acetate Ophthalmic Suspension USP
0.3%w/v & 0.1 %w/v

OBRIN-F™

For the use of Registered Medical Practitioner only

Composition

Tobramycin USP…..... 0.3 % w/v
Fluorometholone Acetate USP…..... 0.1% w/v
Benzalkonium Chloride Solution USP …..... 0.02%v/v
(as preservative)
Water for Injection USP ..... q.s

Chemical Structure & Name

Tobramycin

C18H37N5O9

D-Streptamine, *O* – 3 – amino – 3 – deoxy - --- D – glucopyranosyl - (1–6) – *O* - [2, 6 – diamino - 2, 3, 6 – trideoxy - --- D – ribo – hexopyranosyl - (1–4)] – 2 – deoxy - .*O* – 3 – Amino – 3 – deoxy - --- D – glucopyranosyl - (1–4) – *O* - [2, 6 – diamino - 2, 3, 6 – trideoxy - --- D – *ribo* – hexopyranosyl - (1–6)] – 2 – deoxy – L - streptamine.

Fluorometholone Acetate

C24H31FO5

Pregna - 1, 4 – diene - 3, 20 -dione, 17 - (acetyloxy) - 9 - fluoro - 11 - hydroxy - 6 - methyl-,(6–, 11–) - 9 – Fluoro - 11–, 17 – dihydroxy - 6–- methyl pregna - 1, 4 - diene - 3, 20 - dione, 17 acetate

Category

Pharmacotherapeutic group: ophthalmologicals; anti-inflammatory agents and anti-infectives in combination; corticosteroids and anti-infectives in combination; fluorometholone and antiinfectives

ATC code: S01CA07

Description

A white color suspension filled in 5mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap.

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. Clinical studies have demonstrated that Fluorometholone Acetate Suspension is a potent corticosteroid.

In clinical studies of documented steroid-responders, fluorometholone acetate demonstrated a significantly longer average time to produce a rise in intraocular pressure than dexamethasone phosphate; however, in a small percentage of individuals, a significant rise in intraocular pressure occurred within one week. The ultimate magnitude of the rise was equivalent for both drugs.

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. aureusand S.

epidermidis(coagulase-positive and coagulase-negative), including penicillinresistant strains.

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

Pseudomonas aeruginosa, Escherichia coli, Klebsiellapneumoniae, Enterobacteraerogenes, Proteus mirabilis, Morganellamorganii, most Proteus vulgaris strains, Haemophilus influenzaeand H. aegyptius, Moraxella lacunata, and Acinetobactercalcoaceticus (Herellea vaginacola) and some Neisseria species.

Bacterial susceptibility studies demonstrate that in some cases microorganisms resistant to gentamicin remain susceptible to tobramycin. Bacterial resistance to tobramycin may develop upon prolonged use.

Pharmacokinetic

No data are available on the extent of systemic absorption from Tobramycin and Fluorometholone Acetate Ophthalmic Suspension USP; however, it is known that some systemic absorption can occur with ocularly applied drugs.

When a decision to administer both a corticoid and an antibiotic is made, the administration of such drugs in combination has the advantage of greater patient compliance and convenience, with the added assurance that the appropriate dosage of both is administered, plus assured compatibility of ingredients when both types of drug are in the same formulation and, particularly, that the correct volume of drug is delivered and retained.

Indications

Tobramycin and Fluorometholone Acetate Ophthalmic Suspension USP 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 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.

Dosage & Administration

One or 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 two (2) hours. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

Method of administration:

For ocular use only. Not for injection.

To prevent contamination of the dropper tip and suspension, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle. In order to prevent the drops from being absorbed via the nasal mucosa, particularly in children, the nasolacrimal ducts should be held closed for 2 to 3 minutes with the fingers after administering the drops. After cap is removed, if tamper evident snap collar is loose, remove before using the product.

If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

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 any component of the medication.

Warning and Precaution

NOT FOR INJECTION INTO THE EYE.

Sensitivity to topically applied aminoglycosides may occur in some patients. If a sensitivity reaction does occur, discontinue use.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye. 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. If used for more than 10 days, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative 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. 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.

Pediatric Use

Safety and effectiveness in pediatric 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.

As with other ophthalmic medications, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs upon application, the patient must wait until the vision clears before driving or using machinery.

Interactions

No specific interaction studies were performed with Tobramycin and Fluorometholone

Acetate Ophthalmic Suspension USP.

Pregnancy & Lactation

Pregnancy

Category C

Animal studies have not been conducted with Tobramycin and Fluorometholone Acetate Ophthalmic Suspension USP. Fluorometholone has been shown to be embryocidal and teratogenic in rabbits when administered at low multiples of the human dose. Fluorometholone was applied ocularly to rabbits daily on days 6 to 18 of gestation, and doserelated fetal loss and fetal abnormalities including cleft palate, deformed rib cage, anomalous limbs and neural abnormalities such as encephalocele, craniorachischisis, and spina bifida were observed. Reproduction studies have been performed in rats and rabbits with tobramycin at parenteral doses up to 100 mg/kg/day with no evidence of harm to the fetus (2000X the maximum recommended human dose). There are no adequate and well-controlled studies of Tobramycin and Fluorometholone Acetate Ophthalmic Suspension USP in pregnant women. Tobramycin and Fluorometholone Acetate Ophthalmic Suspension USP should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

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 Fluorometholone Acetate Ophthalmic Suspension USP is administered to a nursing woman.

Adverse reaction

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 are localized ocular toxicity and hypersensitivity, including lid itching and swelling, and conjunctival erythema. These reactions occur in less than 4% of patients. Similar reactions may occur with the topical use of other aminoglycoside antibiotics. Other adverse reactions have not been reported; however, if topical ocular tobramycin is administered concomitantly with systemic aminoglycoside 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 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.

Overdosage

Clinically apparent signs and symptoms of an overdose of (punctate keratitis, erythema, increased lachrymation, oedema, lid itching and elevation of intraocular pressure) may be similar to undesirable effects seen in some patients. Notify your physician in such cases of overdose with Tobramycin and Fluorometholone Acetate Ophthalmic Suspension.

Storage

Store between 15°C - 30 °C. Protect from light

Keep out of reach of children.

Shelf life

24 Months from the date of manufacture.

Presentation

A white colour suspension filled in 5mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap in printed carton along with leaflet.

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 :

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