

# Obrin-F™

## Eye Drops

### Tobramycin and Fluorometholone Acetate Ophthalmic Suspension IP

#### COMPOSITION:

Tobramycin IP.....	0.3% w/v
Fluorometholone acetate USP .....	0.1% w/v
Benzalkonium Chloride solution IP.....	0.02% v/v
(As Preservative)	
Water for Injections IP.....	q.s.

#### 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. 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.

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.

No data are available on the extent of systemic absorption from OBRIN-F Ophthalmic Suspension; 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 and Usage:

OBRIN-F 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 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 anti-infective drug in this product, tobramycin, 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-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*, and *Acinetobacter calcoaceticus* (*Herellea vaginacola*) 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 any component of the medication.

#### Warnings:

**NOT FOR INJECTION INTO THE EYE.** Sensitivity to topically applied aminoglycosides may occur in some patients. If a sensitivity reaction does occur, discontinue use.

#### 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 biomicroscopy and, where appropriate, fluorescein staining.

#### **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. No studies of impairment of fertility by fluorometholone acetate are available.

#### **Pregnancy**

**Pregnancy Category C.** Animal studies have not been conducted with OBRIN-F Ophthalmic Suspension. 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 dose-related 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 OBRIN-F Ophthalmic Suspension in pregnant women. OBRIN-F Ophthalmic Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

#### **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 OBRIN-F Ophthalmic Suspension is administered to a nursing woman.

#### **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.

#### **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.

**Secondary Infection:** The development of secondary infection has occurred after use of combinations containing steroids and antimicrobials.

#### **Dosage and Administration:**

As directed by the Physician

#### **Storage Instructions:**

**KEEP IN A COOL PLACE**

**PROTECT FROM LIGHT.**

**KEEPOUT OF REACH OF CHILDREN**

**FOR EXTERNAL USE ONLY**

**SHAKE WELL BEFORE USE**

#### **Presentation:**

OBRIN-F is a sterile ophthalmic suspension supplied in plastic opaque dropper bottle with a cap containing 5ml of the suspension

Use the suspension within one month after opening the container

#### **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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