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# Obrin<sup>TM</sup> LT

## Eye Drops

### Loteprednol Etabonate and Tobramycin Ophthalmic Suspension (0.5% w/v & 0.3% w/v)

#### COMPOSITION:

Loteprednol Etabonate .....	0.5% w/v
Tobramycin IP .....	0.3% w/v
Benzalkonium Chloride Solution IP .....	0.02% v/v
(As Preservative)	
Water for Injections IP .....	q.s.

#### DESCRIPTION:

Loteprednol Etabonate and Tobramycin Ophthalmic Suspension is used to treat inflammation or swelling in the eye that is caused by a bacterial infection. It is a combination of a steroid (loteprednol) and an antibiotic (tobramycin). Loteprednol reduces swelling and inflammation. Tobramycin works by killing the bacteria or preventing it from growing.

#### CLINICAL PHARMACOLOGY:

Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the oedema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortin. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2. Corticosteroids are capable of producing a rise in intraocular pressure. Loteprednol etabonate is structurally similar to other corticosteroids. However, the number 20 position ketone group is absent. It is highly lipid soluble which enhances its penetration into cells. Loteprednol etabonate is synthesized through structural modifications of prednisolone related compounds so that it will undergo a predictable transformation to an inactive metabolite. Based upon in vivo and in vitro preclinical metabolism studies, loteprednol etabonate undergoes extensive metabolism to inactive carboxylic acid metabolites.

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.

#### Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

#### Paediatric

Appropriate studies performed to date have not demonstrated paediatric-

specific problems that would limit the usefulness of loteprednol and tobramycin eye drops in children.

### **Geriatric**

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of loteprednol and tobramycin eye drops in the elderly.

### **Breast feeding**

There are no adequate studies in women for determining infant risk when using this medication during breast feeding. Weigh the potential benefits against the potential risks before taking this medication while breast feeding.

### **Other Medical Problems**

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Cataract surgery, recent or
- Cornea (part of the eye) problems, history of or
- Sclera (part of the eye) problems, history of—May cause side effects to become worse.
- Fungal (caused by a fungus) eye infection or
- Herpes simplex eye infection or
- Mycobacterial (tuberculosis) eye infection or
- Vaccinia (smallpox) eye infection or
- Varicella (chickenpox) eye infection—Should not be used in patients with these conditions.
- Glaucoma—Use with caution. May make this condition worse.

### **Dosing**

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

### **Missed Dose**

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double dose.

**Storage :** Keep in a cool place, Protect from light.

**KEEP OUT OF REACH OF CHILDREN**

**NOT FOR INJECTION**

**FOR EXTERNAL USE ONLY**

**SHAKE WELL BEFORE USE**

**Presentation:** Obrin LT is a sterile white to off white colour ophthalmic suspension supplied in opaque plastic dropper bottle with a cap, Containing 5 mL of the suspension.

### **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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