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# LEOS<sup>TM</sup>-GT

## Eye Drops

Gatifloxacin with Loteprednol Etabonate  
Ophthalmic Suspension (0.3% & 0.5% w/v)

### COMPOSITION:

Gatifloxacin Sesquihydrate equivalent to Gatifloxacin .....	0.3% w/v
Loteprednol Etabonate .....	0.5% w/v
Benzalkonium Chloride Solution IP .....	0.01% v/v
(As Preservative)	
Water for Injections IP .....	q.s.

### DESCRIPTION:

Leos GT is a combination of two medicines: Gatifloxacin (antibiotic) and Loteprednol (corticosteroid). As a result, it reduces symptoms associated with infection, such as redness and irritation of the eye, and decreases the risk of infections. Gatifloxacin With Loteprednol Etabonate Ophthalmic Suspension is used to prevent or treat only bacterial eye infections.

### PHARMACOLOGY:

Loteprednol (corticosteroids) are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. 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. Gatifloxacin is an 8-methoxyfluoroquinolone with a 3-methylpiperazinyl substituent at C7. The antibacterial action of gatifloxacin results from inhibition of DNA gyrase and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription, and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division. The mechanism of action of fluoroquinolones including gatifloxacin is different from that of aminoglycoside, macrolide, and tetracycline antibiotics. Therefore, gatifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to gatifloxacin. Gatifloxacin has been shown to be active against most isolates of the following organisms both microbiologically and clinically.

**Aerobic Gram-Positive Bacteria:** Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus mitis group, Streptococcus oralis & Streptococcus pneumoniae

**Aerobic Gram-Negative Bacteria:** Haemophilus influenza

### INDICATIONS/USES:

Leos GT 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 such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis. It is also indicated for the treatment of post-operative inflammation following ocular surgery.

### Drug Warnings

Do not take Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension if you are allergic or have had a severe reaction to the quinolone or fluoroquinolone antibiotics and corticosteroids, please inform your doctor if you are pregnant or breastfeeding before starting Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension. Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension is not recommended for children below one year of age as safety and effectiveness have not been established. Do not stop taking Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension even if you feel better without asking your doctor, as your symptoms may come back and may even worsen your condition. Please do not take more than the prescribed dose of Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension as it may cause glaucoma, increase the risk of cataracts (clouding of the eye), and secondary infection. To avoid any contamination, avoid touching the tip of the dropper. Do not put eye medication simultaneously; wait for at least 10 minutes before putting in the second medication. If you have or have ever had glaucoma (increased eye pressure), herpes simplex infection, or any other eye problem, do not take Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension until prescribed by your doctor. Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve and defects in visual acuity and

fields of vision. If this product is used for ten days or longer, intraocular pressure (IOP) should be monitored.

#### **Drug Interactions**

**Drug-drug interactions:** Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension may interact with other ophthalmic medications (bromfenac, diclofenac, flurbiprofen). Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension ofen, ketorolac, nepafenac, suprofen, bimatoprost, latanoprost, tafluprost), HIV medicines (ritonavir, cobicistat, darunavir, nelfinavir), antibiotic medication (clarithromycin), and vaccine (smallpox vaccine).

**Drug-Food Interactions:** No interaction found.

**Drug-Disease Interactions:** Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension should not be used in patients with fungal infections, viral infections such as herpes simplex or varicella, or parasitic infections such as amoebiasis, tuberculosis, damaged cornea, ulceration, and glaucoma (increased pressure inside the eye).

#### **Precautions**

##### **General:**

Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis. Fungal infections of the cornea are particularly prone to develop coincidentally with long term local steroid application.

Patients with bleeding tendencies: This fixed dose combination should be used with care in patients with known bleeding tendencies, or in patients who are receiving other medications which may prolong bleeding time.

**Ability to drive:** As this fixed dose combination may cause transient blurring on instillation, the use of hazardous machinery or driving is not recommended unless vision is clear.

##### **Pregnancy:**

Since there are no adequate and well controlled studies in pregnant women, Gatifloxacin & Loteprednol combination ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

##### **Lactation:**

Since many drugs are excreted in human milk, caution should be exercised when Loteprednol & Gatifloxacin combination ophthalmic solution is administered to a nursing woman.

##### **Paediatric use**

Safety and efficacy in paediatric patients have not been established.

##### **Geriatric use**

Safety and efficacy in geriatric patients have not been established.

##### **Adverse effects**

The adverse events reported with the fixed dose combination were irritation, pain, redness, photophobia, stinging, itching, discharge & blurred vision. Redness was the most commonly observed adverse event occurring in 6% of patients. Itching, discharge, photophobia & blurred vision were seen in less than 2% cases.

Side Effects of Gatifloxacin with Loteprednol Etabonate Ophthalmic Suspension

- Eye irritation
- Eye redness
- Pain on the administration of medicine
- Blurred vision
- Decreases in taste sensitivity (dysgeusia)
- Anterior chamber inflammation

**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:** Leos-GT is a sterile 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 :

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