Xegal® Eye Drops

(Gatifloxacin INN 0.3%)

Description: 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. There is no cross-resistance between gatifloxacin and the aforementioned classes of antibiotics. Cross resistance has been observed between systemic gatifloxacin and some other fluoroquinolones. Resistance to gatifloxacin in vitro develops via multiple-step mutations.

Indications: Gatifloxacin eye drops is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: Aerobic Gram-Positive Bacteria: Corynebacterium propinquum, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus mitis, Streptococcus pneumoniae. Aerobic Gram-Negative Bacteria: Haemophilus influenzae.

Dosage and Administration: The recommended dosage regimen for the treatment of bacterial conjunctivitis is: Days 1 and 2: Instill one drop every two hours in the affected eye(s) while awake, up to 8 times daily. Days 3 through 7: Instill one drop up to four times daily while awake. Pediatric Use: Safety and effectiveness in infants below the age of one year have not been established.

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

Contraindications : Gatifloxacin eye drops is contraindicated in patients with a history of hypersensitivity to gatifloxacin, to other quinolones, or to any of the components in this medication. Adverse Effects: The most frequently reported adverse events in the overall study population were conjunctival irritation, increased lacrimation, keratitis, and papillary conjunctivitis. These events occurred in approximately 5-10% of patients. Other reported reactions occurring in 1-4% of patients were chemosis, conjunctival hemorrhage, dry eye, eye discharge, eye irritation, eye pain, eyelid edema, headache, red eye, reduced visual acuity and taste disturbance. Precautions: As with other anti-infectives, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis. In patients receiving systemic quinolones, including gatifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to gatifloxacin occurs,

discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

High Risk Group:

Pregnancy: Pregnancy category C. There were no teratogenic effects observed in rats or rabbits following oral gatifloxacin doses up to 50 mg/kg/day (approximately 1000-fold higher than the maximum recommended ophthalmic dose). In a perinatal/postnatal study, increased late post-implantation loss and neonatal/perinatal mortalities were observed at 200 mg/kg/day (approximately 4500 times the maximum recommended ophthalmic dose). Because there are no adequate and well-controlled studies in pregnant women, gatifloxacin eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Lactation: Gatifloxacin is excreted in the breast milk of rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when gatifloxacin is administered to a nursing woman.

Drug Interactions: Specific drug interaction studies have not been conducted with gatifloxacin eye drops. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, and enhance the effects of the oral anticoagulant warfarin and its derivatives, and has been associated with transient elevations in serum creatinine in patients receiving systemic cyclosporine concomitantly.

Pharmaceutical Precautions: Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack: Xegal® Eye Drops: Plastic dropper bottle contains 5 ml sterile eye drops. Each ml contains Gatifloxacin INN 3 mg.

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH