

# MIAGAT

Sterile Ophthalmic Solution

## Composition:

Each 1ml of **Miagat** ophthalmic solution contains Gatifloxacin 3mg (0.3%), Benzalkonium chloride 0.005% as preservative.

## Excipients:

Edetate disodium, sodium chloride, hydrochloric acid and/or sodium Hydroxide QS to adjust pH, water for injection QS to 5 ml.

## Mechanism of action:

Gatifloxacin (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.

## Pharmacokinetic:

When Gatifloxacin solution was applied in one eye in an escalated dosing regimen, starting with a single 2 drop dose, then 2 drops 4 times daily for 7 days and finally 2 drops 8 times daily for 3 days. At all-time points, Gatifloxacin levels were below the lower limit of quantification (5 ng/mL) in all subjects.

## Indications:

**Miagat** ophthalmic solution 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:

- 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 & 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 & younger patients.

## Contraindications:

**Miagat** ophthalmic solution is contraindicated in patients with a history of hypersensitivity to Gatifloxacin, to other quinolones, or to any of the components in this medication.

## Warnings and precautions:

- NOT FOR INJECTION. **Miagat** ophthalmic solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

- As with other anti-infective, prolonged use of Gatifloxacin may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs discontinue use and institute alternative therapy.

- Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

- Avoid contact of the drop head with any surface, to prevent contamination of the solution.

## Pregnancy and lactation:

Pregnancy: **Category C.** Because there are no adequate and well-controlled studies in pregnant women, **Miagat** ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether 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:

The drug interactions of Gatifloxacin are related to the systemic application of it, where studies indicated that systemic administration elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, and enhance the effects of the oral anticoagulant warfarin and its derivatives, and use of Gatifloxacin has been associated with transient elevations in serum creatinine in patients receiving systemic cyclosporine concomitantly.

## Undesirable effects:

- The most frequently reported adverse events occurred in approximately 5-10% of patients: conjunctival irritation, increased lacrimation, keratitis, and papillary conjunctivitis.

- Other reported reactions occurring in 1-4% of patients: chemosis, conjunctival hemorrhage, dry eye, eye discharge, eye irritation, eye pain, eyelid edema, headache, red eye, reduced visual acuity and taste disturbance.

## Storage conditions:

Store at (15-25)°C. Protected from freezing.

## Packaging:

**Miagat** ophthalmic solution is supplied in polyethylene bottle 5 mL with dropper, tightly sealed with a polyethylene closer within a carton box

Produced by MIAMED Pharmaceutical Industries –Damascus countryside –Syria

This is a medication
- A medication is a product but unlike any other products.
- A medication is a product which affect your health, and its consumption contrary to instructions is dangerous for you.
- follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
Keep medications out of reach of children

Council of Arab Health Ministers

Arab pharmacist Association



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