

Senzgat[®]

Eye Drops

(Gatifloxacin Eye Drops)

COMPOSITION:

Gatifloxacin Sesquehydrate eq. to Gatifloxacin IP	0.3%w/v
Benzalkonium Chloride Solution IP	0.02% v/v
(As preservative)	
Water for Injections IP	q.s.

Description

Gatifloxacin is 8-methoxy fluoroquinolone with a 3-methylpiperazinyl substituent at C7.. It has a broader spectrum of antibacterial activity than the older fluoroquinolones and shows good activity against many gram positive and gram negative pathogens, atypical organisms and some anaerobes. Notably, Gatifloxacin eye drops is highly active against both penicillin-susceptible and resistant strains of *Streptococcus pneumoniae*. Gatifloxacin has also been shown to be active against most strains of the following organism like *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Haemophilus influenzae*, *Corynebacterium propinquum*

Gatifloxacin exhibits in vitro minimal inhibitory concentration (MICs) of 2 µg/ml or less (systematic susceptible breakpoint) against most ($\geq 90\%$) strains of the following ocular pathogens

Aerobes, gram positive: *Listeria monocytogenes*, *Staphylococcus saprophyticus*, *Streptococcus agalactiae*, *Streptococcus pyogenes*, *Streptococcus viridans* group, *Streptococcus* group C,F,G

Aerobes gram negative: *Acinetobacter lwoffii*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Escherichia coli*, *Citrobacter freundii*, *Citrobacter koseri*, *Haemophilus parainfluenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Morganella morganii*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Proteus mirabilis*, *Proteus vulgaris*, *Serratia marcescens*, *Vibrio cholerae*, *Yersinia enterocolitica*

Other microorganisms: *Chlamydia pneumoniae*, *Legionella pneumophila*, *Mycobacterium marinum*, *Mycobacterium fortuitum*, *Mycoplasma pneumoniae*

Anaerobic microorganisms: *Bacteroides fragilis*, *Clostridium perfringens*.

Mode Of Action

The antibacterial action of Gatifloxacin results from inhibition of the topoisomerase II (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 that plays a key role in the partitioning of the chromosomal DNA during bacterial cell division

Indications And Usage

Senzgat eye drops is indicated for the treatment of external bacterial infections of the eye like conjunctivitis, keratitis, bacterial corneal ulcers, dacrocystitis, meibomianitis, scleritis etc caused by susceptible organisms

Contraindications

Senzgat eye drops is contraindicated in patients with a history of hypersensitivity to gatifloxacin, to other quinolones or to any of the component of the formulation

Dosage And Administration

The recommended dosage regimen for the treatment of bacterial conjunctivitis is :

Day 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, The frequency can be adjusted based on severity of infection

Paediatric use: Safety and effectiveness in infants below the age of one year have not been established

Precautions

As with other anti-infectives prolonged use may result in overgrowth of non-susceptible organisms including fungi. If super infection 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

Information for patients: Avoid contaminating the applicator tip with material from the eye,, fingers or other source & discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction

Warning

Senzgat eye drops should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye. Use the solution within one month after opening the container

Adverse Reactions

The most frequently reported adverse events are conjunctival irritation, increased lacrimation, keratitis, and papillary conjunctivitis. These events occurred in approximately 5-10% of patients. Other adverse effects reported are dry eye, eye irritation, eye pain, eyelid edema, headache, red eye, reduced visual acuity and taste disturbance

STORAGE:

Keep in a cool dry place. Protect from light. Do not freeze.

KEEP OUT OF REACH OF CHILDREN.

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

Presentation

Senzgat is a sterile solution supplied in opaque plastic dropper bottle with a cap, containing 5 ml of the solution.

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.,

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