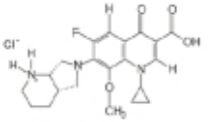
MOXIFUR Eye Drops
(Moxifloxacin Eye Drops IP 0.5%w/v)

THIS LEAFLET CONTAINS IMPORTANT PRODUCT USE AND SAFETY INFORMATION, PLEASE READ CAREFULLY AND RETAIN FOR FURTHER FUTURE REFERENCE.

DESCRIPTION

Moxifur Eye Drops (Moxifloxacin Eye Drops IP 0.5%w/v) is a sterile solution for topical ophthalmic use. Moxifloxacin hydrochloride is an 8-methoxy fluoroquinolone anti-infective, with a diazabicyclononyl ring at the C7 position.

Chemical Name: 1-Cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-[(4aS,7aS)-octahydro-6H-pyrrolol[3,4b] pyridin6-yl]-4-oxo-3-quinolinecarboxylic acid, monohydrochloride. Moxifloxacin hydrochloride is a slightly yellow to yellow crystalline powder.



$C_{21}H_{24}FN_3O_4 \cdot HCl$ Mol Wt 437.9

COMPOSITION

Each mL contains :	
Moxifloxacin Hydrochloride IP eq. to Moxifloxacin	0.5% w/v
Sterile Aqueous Vehicle	q.s.

INDICATIONS:

Topical treatment of purulent bacterial conjunctivitis, caused by moxifloxacin susceptible strains. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

PHARMACOLOGICAL CLASSIFICATION:

Pharmacotherapeutic group: Ophthalmologicals; anti-infectives, other anti-infectives,

PHARMACODYNAMICS/ PHARMACOKINETICS:

Pharmacodynamics:

Moxifloxacin, a fourth-generation fluoroquinolone, inhibits the DNA gyrase and topoisomerase IV required for bacterial DNA replication, repair, and recombination.

Pharmacokinetics:

Following topical ocular administration of Moxifur Eye Drops (Moxifloxacin Eye Drops IP 0.5%w/v), moxifloxacin was absorbed into the systemic circulation. Plasma concentrations of moxifloxacin were measured in 21 male and female subjects who received bilateral topical ocular doses of the medicinal product 3 times a day for 4 days. The mean steady-state Cmax and AUC were 2.7 ng/ml and 41.9 ng·hr/ml, respectively. These exposure values are approximately 1,600 and 1,200 times lower than the mean Cmax and AUC reported after therapeutic 400 mg oral doses of moxifloxacin. The plasma half-life of Moxifloxacin was estimated to be 13 hours.

DOSAGE AND ADMINISTRATION

For ocular use only.

Not for injection. Moxifur Eye Drops (Moxifloxacin Eye Drops IP 0.5%w/v), solution should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye.

Use in adults including the elderly (≥ 65 years)

The dose is one drop in the affected eye(s) 3 times a day.

The infection normally improves within 5 days and treatment should then be continued for a further 2-3 days. If no improvement is observed within 5 days of initiating therapy, the diagnosis and/or treatment should be reconsidered. The duration of treatment depends on the severity of the disorder and on the clinical and bacteriological course of infection.

Paediatric patients.

No dosage adjustment is necessary. Use in hepatic and renal impairment No dosage adjustment is necessary.

To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle.

In order to prevent the drops from being absorbed via the nasal mucosa, particularly in new-born infants or children, the nasolacrimal ducts should be held closed for 2 to 3 minutes with the fingers after administering the drops. After cap is removed, if tamper evident snap collar is loose, remove before using the product.

If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

CONTRA-INDICATIONS:

Hypersensitivity to the active substance, to other quinolones.

WARNING AND PRECAUTION:

In patients receiving systemically administered quinolones, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnoea, urticaria, and itching.

If an allergic reaction to Moxifur Eye Drops (Moxifloxacin Eye Drops IP 0.5%w/v) occurs, discontinue use of the medicinal product. Serious acute hypersensitivity reactions to moxifloxacin or any other product ingredient may require immediate emergency treatment. Oxygen and airway management should be administered where clinically indicated.

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

Tendon inflammation and rupture may occur with systemic fluoroquinolone therapy including moxifloxacin, particularly in older patients and those treated concurrently with corticosteroids. Following ophthalmic administration of Moxifur Eye Drops (Moxifloxacin Eye Drops IP 0.5%w/v) plasma concentrations of moxifloxacin are much lower than after therapeutic oral doses of moxifloxacin, however , caution should be exercised and treatment with Moxifur Eye Drops (Moxifloxacin Eye Drops IP 0.5%w/v) should be discontinued at the first sign of tendon inflammation.

Data are very limited to establish efficacy and safety of Moxifur Eye Drops (Moxifloxacin Eye Drops IP 0.5%w/v) in the treatment of conjunctivitis in neonates. Therefore use of this medicinal product to treat conjunctivitis in neonates is not recommended.

Moxifur Eye Drops (Moxifloxacin Eye Drops IP 0.5%w/v) should not be used for the prophylaxis or empiric treatment of gonococcal conjunctivitis, including gonococcal ophthalmia neonatorum, because of the prevalence of fluoroquinolone-resistant Neisseria gonorrhoeae. Patients with eye infections caused by Neisseria gonorrhoeae should receive appropriate systemic treatment.

The medicinal product is not recommended for the treatment of Chlamydia trachomatis in patients less than 2 years of age as it has not been evaluated in such patients. Patients older than 2 years of age with eye infections caused by Chlamydia trachomitis should receive appropriate systemic treatment.

Neonates with ophthalmia neonatorum should receive appropriate treatment for their condition, e.g. systemic treatment in cases caused by Chlamydia trachomitis or Neisseria gonorrhoeae.

Patients should be advised not to wear contact lenses if they have signs and symptoms of a bacterial ocular infection.

INTERACTIONS WITH OTHER MEDICAMENTS:

No specific interaction studies have been performed with Moxifur Eye Drops (Moxifloxacin Eye Drops IP 0.5%w/v). Given the low systemic concentration of moxifloxacin following topical ocular administration of the medicinal product, drug interactions are unlikely to occur.

OVERDOSE AND TREATMENT:

The limited holding capacity of the conjunctival sac for ophthalmic products practically precludes any overdosing of the medicinal product. The total amount of moxifloxacin in a single container is too small to induce adverse effects after accidental ingestion.

SHELF LIFE

24 Months.

STORAGE

Store protected from light, moisture & direct sunlight. Do not allow to freeze.

HOW SUPPLIED

Moxifur Eye Drops / 5mL (Moxifloxacin Eye Drops IP 0.5%w/v) is supplied in 5 mL sterile poly bottle.

Manufactured in India by:

APPASAMY OCULAR DEVICES (P) LTD.

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