

MOXIFUR

(Moxifloxacin Ophthalmic Solution USP)

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

DESCRIPTION

Moxifur (Moxifloxacin Ophthalmic Solution USP) is a sterile 1 ml clear, pale yellow coloured, isotonic, preservative free ophthalmic solution.

COMPOSITION

Each mL Contains :

Moxifloxacin Hydrochloride USP

Eq. to Moxifloxacin 0.5% w/v

Aqueous Buffered Vehicle q.s.

INDICATIONS:

Moxifur (Moxifloxacin Ophthalmic Solution USP) is indicated as prophylaxis antibiotic in preventing postoperative anterior chamber reaction and ultimately endophthalmitis in cataract extraction

PHARMACOLOGICAL CLASSIFICATION:

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

PHARMACOLOGY

Concentration dependent bactericidal killing via selective bacterial topoisomerase II and IV inhibition.

As a fourth generation fluoroquinolone, moxifloxacin has a different chemical structure and mechanism of action compared to older generation fluoroquinones with better gram-positive coverage and ocular penetration.

It also provides coverage for gram-negative and atypical pathogens.

DOSAGE AND ADMINISTRATION:

For intraocular use only.

Intracameral moxifloxacin prepared by dilution of 3 cc moxifloxacin 0.5% with 7 cc balanced salt solution and with the administration of 0.3 to 0.4 cc (450 to 600 mcg.) as the final step in cataract surgery via the side port after the main incision has been sealed and hydrated the main incision would provide adequate concentration and duration to achieve MIC90 that produces optimal bactericidal effect.

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 (Moxifloxacin Ophthalmic Solution USP) 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 serious infection 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 (Moxifloxacin Ophthalmic Solution USP) plasma concentrations of moxifloxacin are much lower than after therapeutic oral doses of moxifloxacin,

however, caution should be exercised and treatment with Moxifur (Moxifloxacin Ophthalmic Solution USP) should be discontinued at the first sign of tendon inflammation.

Data are very limited to establish efficacy and safety of Moxifur (Moxifloxacin Ophthalmic Solution USP) in the treatment of conjunctivitis in neonates. Therefore use of this medicinal product to treat conjunctivitis in neonates is not recommended.

Moxifur (Moxifloxacin Ophthalmic Solution USP) 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 trachomatis* 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 trachomatis* 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 (Moxifloxacin Ophthalmic Solution USP). Given the low systemic concentration of moxifloxacin following topical ocular administration of the medicinal product, drug interactions are unlikely to occur.

OVERDOSE AND TREATMENT:

Toxic effects on anterior chambers has reported to occur at concentration greater than 500µg/mL in cultured human corneal endothelial cells. Proposed that endothelial damage occurs at concentration exceeding 500µg/ml for greater than 6-24 hours and decreased cell viability at 1000µg/ml for greater than 24 hours. Several prospective studies demonstrated that IC moxifloxacin tested up to 500µg/ 0.1ml was not associated with significantly increased risk in final visual acuity, intraocular pressure, corneal thickness, corneal clarity and edema, and anterior chamber cells and flare. Studied toxicity on human retinal vascular endothelial cells on three different antibiotics discussed. Moxifloxacin was noted to show significant increase in cell membrane damage starting at 125µg/ml (p=0.004) in a dose-dependent manner.

The total amount of moxifloxacin in a single container is too small to induce adverse effects after accidental ingestion.

STORAGE CONDITION:

Preserve in tight containers. Store between 2°C to 25°C.

SHELF LIFE:

24 Months.

HOW SUPPLIED:

Moxifur (Moxifloxacin Ophthalmic Solution USP) 1ml is available in sterile 2ml Glass vial with pouch pack.



Manufactured in India by:

APPASAMY OCULAR DEVICES (P) LTD.

Plot No. 74-D, Katha, Baddi, Distt. Solan (H.P.)-173205 India.

Phone : + 91-1795-247820, Email : aodbaddi10@gmail.com

Website: www.appasamy.com