

CLINICAL UPDATE

| Brand Name | N/A |
|-------------------|----------------------------|
| Generic Name | moxifloxacin hydrochloride |
| Drug Manufacturer | Mylan Labs |

Clinical Update

TYPE OF CLINICAL UPDATE

New Dosage Form (ophthalmic syringe)

FDA APPROVAL DATE

N/A

LAUNCH DATE

November 17, 2020

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

N/A

DISPENSING RESTRICTIONS

Open

Overview

INDICATION(S) FOR USE

Moxifloxacin Injection is a fluoroquinolone anti-infective indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: Corynebacterium species*, Micrococcus luteus*, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri*, Streptococcus pneumoniae, Streptococcus viridans group, Acinetobacter lwoffii*, Haemophilus influenzae, Haemophilus parainfluenzae*, Chlamydia trachomatis.

MECHANISMS OF ACTION

Moxifloxacin is a member of the fluoroquinolone class of antibacterial agents.

DOSAGE FORM(S) AND STRENGTH(S)

Intraocular syringe/injection: 1.6mg/mL

DOSE & ADMINISTRATION

The dose of Moxifloxacin Injection is 400 mg intravenously once every 24 hours.

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^{*}Efficacy for this organism was studied in fewer than 10 infections.



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EFFICACY

The safety and efficacy of Moxifloxacin Injection in pediatric patients for the treatment of cIAI has not been demonstrated.

In controlled multiple-dose clinical trials, 23% of patients receiving oral moxifloxacin were greater than or equal to 65 years of age and 9% were greater than or equal to 75 years of age. The clinical trial data demonstrate that there is no difference in the safety and efficacy of oral moxifloxacin in patients aged 65 or older compared to younger adults.

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