4 mL bottle filled with 3 mL sterile ophthalmic solution of moxifloxacin hydrochloride, 0.5% as base.

Sterile topical ophthalmic solution

Instill one drop in the affected eye 3 times a day for 7 days. (2)

Chlamydia trachomatis
Haemophilus influenzae, Haemophilus parainfluenzae*, group A, Acinetobacter lwoffii*, Streptococcus viridans
Staphylococcus warneri*, Streptococcus pneumoniae, Staphylococcus haemolyticus, Staphylococcus hominis,
Corynebacterium*

*Efficacy for this organism was studied in fewer than 10 infections. (1)

-----------DOSE AND ADMINISTRATION-----------
Instill one drop in the affected eye 3 times a day for 7 days. (2)

-----------DOSE FORMS AND STRENGTHS-----------
4 mL bottle filled with 3 mL sterile ophthalmic solution of moxifloxacin hydrochloride, 0.5% as base. (3)

--------CONTRAINDICATIONS--------
VIGAMOX® solution is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication. (4)

--------WARNINGS AND PRECAUTIONS--------
Topical ophthalmic use only. (5.1)
Hypersensitivity and anaphylaxis have been reported with systemic use of moxifloxacin. (5.2)
Prolonged use may result in overgrowth of non-susceptible organisms, including fungi. (5.3)
Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis. (5.4)

--------ADVERSE REACTIONS--------
The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, oral pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Alcon Laboratories, Inc. at 1-800-757-9188 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

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*Sections or subsections omitted from the full prescribing information are not listed.

Pediatric Use

5.2 Hyperosmolarity

Drug-drug interaction studies have not been conducted with VIGAMOX® solution. In vitro studies indicate that moxifloxacin does not inhibit CYP1A2, CYP2D6, CYP2C19, or CYP3A4, indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isoforms.

8 USE IN SPECIFIC POPULATIONS

8.3 Nursing Mothers

Moxifloxacin has not been measured in human milk, although it can be presumed to be secreted in human milk. Caution should be exercised when VIGAMOX® solution is administered to a nursing mother.

8.4 Pediatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

11 DESCRIPTION

Chemical Name:
1-Cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-[4(4a,7a)-octahydro-6H-pyrrolo[3,4-b]pyridin-3-yl]-4(3H)-pyridin-6-yl-4-oxo-3-quinolinecarboxylic acid, monohydrate. Moxifloxacin hydrochloride is a yellowish to greyish crystalline powder. Each mL of VIGAMOX® solution contains 5.4 mg moxifloxacin hydrochloride, equivalent to 5 mg moxifloxacin base.

0.5% as base.

Chemical Name:
1-Cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-[4(4a,7a)-octahydro-6H-pyrrolo[3,4-b]pyridin-3-yl]-4(3H)-pyridin-6-yl-4-oxo-3-quinolinecarboxylic acid, monohydrate. Moxifloxacin hydrochloride is a yellowish to greyish crystalline powder. Each mL of VIGAMOX® solution contains 5.4 mg moxifloxacin hydrochloride, equivalent to 5 mg moxifloxacin base.

Contains: Active: Moxifloxacin 0.5% (5 mg/mL), Inactives: Boric acid, sodium chloride, and purified water. May also contain hydrochloric acid and sodium hydroxide to adjust pH to approximately 6.8.
Moxifloxacin was not mutagenic in four bacterial strains used in the Ames Salmonella/microsome assay. As with other quinolones, the positive response observed with moxifloxacin in strains TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when V79 cells were used. Moxifloxacin was clastogenic in the V79 chromosomal aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity in vitro in a micronucleus test or a dominant lethal test in mice.

Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 21,700 times the highest recommended total daily human ophthalmic dose. At 500 mg/kg orally there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

14 CLINICAL STUDIES
In two randomized, double-masked, multicenter, controlled clinical trials in which patients were dosed 3 times a day for 4 days, VIGAMOX® solution produced clinical cures on day 5-6 in 66% to 69% of patients treated for bacterial conjunctivitis. Microbiological success rates for the eradication of baseline pathogens ranged from 84% to 94%. Please note that microbiological eradication does not always correlate with clinical outcome in anti-infective trials.

16 HOW SUPPLIED/STORAGE AND HANDLING
VIGAMOX® solution is supplied as a sterile ophthalmic solution in Alcon’s DROP-TAINER® dispensing system consisting of a natural low density polyethylene bottle and dispensing plug and an polypropylene closure. Tamper evidence is provided with a shrink band around the closure and neck area of the package.

3 mL, in a 4 mL bottle - NDC 0065-4013-03
Storage: Store at 2°-25°C (36°-77°F).

17 PATIENT COUNSELING INFORMATION
Patients should be advised not to touch the dropper tip to any surface in order to avoid contaminating the contents. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis. Systemically administered quinolones including moxifloxacin have been associated with hypersensitivity reactions, even following a single dose. Patients should be told to discontinue use immediately and contact their physician at the first sign of a rash or allergic reaction.

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