



Therapeutic Class ReviewSM

Ophthalmics -

Moxifloxacin Hydrochloride Ophthalmic Solution 0.5% (Vigamox[®])

March 2005

New Product for Review

moxifloxacin ophthalmic solution 0.5% (Vigamox)
[Alcon]

Dossier Provided by Manufacturer: Yes Quality of Dossier: 2

1. Low quality (dossier w/missing components)
2. Medium quality (all components, except pharmacoeconomic model)
3. High quality (all components, well done)

Executive Summary

- Moxifloxacin (Vigamox) ophthalmic solution is a fourth generation fluoroquinolone antibacterial product that does not contain benzalkonium chloride and is approved for treating bacterial conjunctivitis in adults and children.
- Unlike ciprofloxacin, ofloxacin, levofloxacin (Quixin) and gatifloxacin (Zymar), clinical studies with moxifloxacin are of poor quality and not published in peer-reviewed journals. These studies report that moxifloxacin (Vigamox) is:
 - non-inferior to ciprofloxacin and ofloxacin ophthalmic solutions for treating bacterial conjunctivitis in adults and children.
 - similar to placebo for treating bacterial conjunctivitis in infants <30 days old.
- There is no evidence to support the use of moxifloxacin (Vigamox) as a prophylactic agent during ophthalmologic procedures.

Decision

Maintain moxifloxacin (Vigamox) as non-formulary/non-preferred because this product offers no additional clinical advantages over other formulary options to treat bacterial conjunctivitis in adults and children.

Products

Drug Product	Date of FDA Approval	FDA Approved Indication(s)	Dose Route	Potential Off-Label Use(s)
ciprofloxacin 0.3% ophthalmic solution (generic) and ointment (Ciloxan)	03/30/1998	Treatment of a) Corneal Ulcers infections caused by susceptible strains of <i>Pseudomonas aeruginosa</i> , <i>Serratia marcescens</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Streptococcus pneumoniae</i> , and <i>Streptococcus</i> (Viridans Group), and b) Conjunctivitis caused by susceptible strains of <i>Haemophilus influenzae</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , and <i>Streptococcus pneumoniae</i> .	Ophthalmic	All ophthalmic antibiotic solutions have been used for various eye surgical prophylaxis, blepharitis, keratitis, endophthalmitis, and in neonates.
ofloxacin 0.3% ophthalmic solution (generic)	07/30/1993	Treatment of infections caused by susceptible strains of the following bacteria in Bacterial conjunctivitis (Gram-positive bacteria: <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , and <i>Streptococcus pneumoniae</i> . Gram-negative bacteria: <i>Enterobacter cloacae</i> , <i>Haemophilus influenzae</i> , <i>Proteus mirabilis</i> , and <i>Pseudomonas aeruginosa</i>) and Corneal ulcers (Gram-positive bacteria: <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Streptococcus pneumoniae</i> . Gram-negative bacteria: <i>Pseudomonas aeruginosa</i> and <i>Serratia marcescens</i> . Anaerobic species: <i>Propionibacterium acnes</i>).	Ophthalmic	
gatifloxacin 0.3% ophthalmic solution (Zymar)	03/28/2003	Treatment of bacterial conjunctivitis caused by susceptible strains of a) aerobic Gram-Positive Bacteria (<i>Corynebacterium propinquum</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Streptococcus mitis</i> , and <i>Streptococcus pneumoniae</i>) and b) Aerobic Gram-Negative Bacteria (<i>Haemophilus influenzae</i>)	Ophthalmic	
levofloxacin 0.5% ophthalmic solution (Quixin)	08/18/2000	Treatment of bacterial conjunctivitis caused by susceptible strains of a) aerobic Gram-Positive Bacteria (<i>Corynebacterium</i> species, <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Streptococcus pneumoniae</i> , <i>Streptococcus</i> (Groups C/F), <i>Streptococcus</i> (Group G) and Viridans group streptococci) and b) susceptible strains of aerobic Gram-Negative Bacteria (<i>Acinetobacter lwoffii</i> , <i>Haemophilus influenzae</i> and <i>Serratia marcescens</i>).	Ophthalmic	
moxifloxacin ophthalmic solution 0.5% (Vigamox)	04/15/2003	Treatment of bacterial conjunctivitis caused by susceptible strains of a) Aerobic Gram-positive microorganisms (<i>Corynebacterium</i> species, <i>Micrococcus luteus</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Staphylococcus haemolyticus</i> , <i>Staphylococcus hominis</i> , <i>Staphylococcus warneri</i> , <i>Streptococcus pneumoniae</i> and <i>Streptococcus viridans group</i>) b) Aerobic Gram-negative microorganisms (<i>Acinetobacter lwoffii</i> , <i>Haemophilus influenzae</i> and <i>Haemophilus parainfluenzae</i>) and c) Other microorganisms (<i>Chlamydia trachomatis</i>).	Ophthalmic	

References

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