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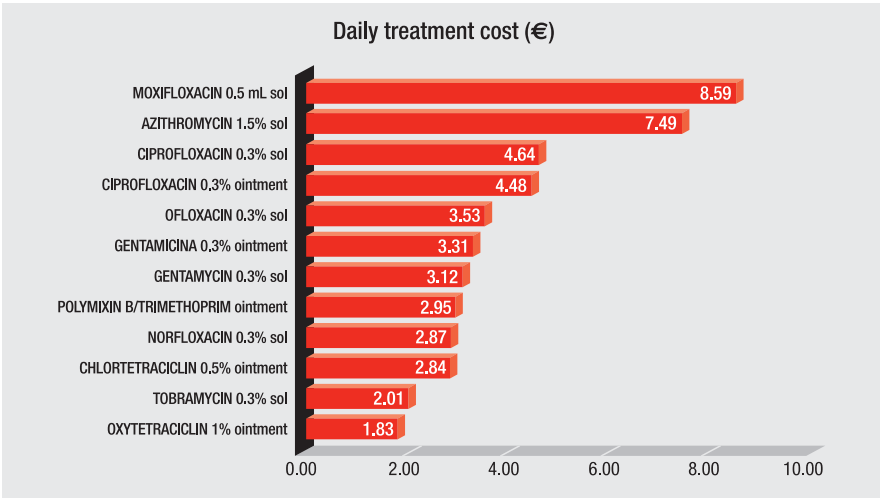
Moxifloxacin 0.5% eye drop solution▲ (Vigamox®) for bacterial conjunctivitis

Cheaper eye drops are just as useful to us



If antimicrobial eye drops are necessary, more efficient ones are available

- Moxifloxacin 0.5% eye drop solution is indicated in the management of purulent bacterial conjunctivitis.
- In the only study published comparing moxifloxacin to polymyxin B sulfate/trimethoprim ophthalmic solution, the former showed a greater percentage of clinical recovery after 48 hours, but not after 7 days.
- Moxifloxacin has shown therapeutic equivalence to other fluoroquinolones in eye drop solution.

Indications[1]

Moxifloxacin eye drops are indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of *Corynebacterium spp, Micrococcus luteus, S. aureus, S. epidermidis, S. haemolyticus, S. hominis, S. warneri, S. pneumoniae*

Mechanism of action and pharmacokinetics[1]

Fourth generation fluoroquinolones are effective against a great number of gram positive aerobic microorganisms, gram negative aerobic and anaerobic microorganisms. They should not be employed in bacterial conjunctivitis where there is suspicion that the cause could be *Pseudomonas aeruginosa* because of intrinsic resistence to moxifloxacin. There is crossover resistence to other fluoroquinolones. After ophthalmic administration of moxifloxacin, the Cmax and AUC values detected are low.

Posology and administration[1]

One eye drop three times a day in the affected eye(s). Generally, the infection improves in 5 days, after which treatment should continue for 2-3 three days more. If no improvement is observed after 5 days, then the diagnosis and/or treatment should be reconsidered. The duration of treatment depends on the severity of the infection, the clinical course and purulence of the infection.

Recommendations for ophthalmic use

Avoid touching the eyelids, and surrounding areas, or other surfaces with the edge of the

The qualification assigned to the drug was agreed by the Drug Assessment Committees of Andalusia, Basque Country, Catalonia Institute of Health, Aragon and Navarre. The current report is based on the available information and is susceptible to be updated according to the latest evidence. Let us remind the reader about the importance of notifying the Pharmacovigilance Centre when there are suspicions of adverse reactions to drugs.

bottle to avoid possible contamination. To prevent the absorption of the eye drops through the nasal mucosae, the nasolacrimal duct should be occluded with a finger for 2-3 minutes after administering the eye drops.

If more than one ophthalmic solution is administered, this can be done so at intervals of at least 5 minutes.

Clinical efficacy

There is only one published multicenter, randomised, double-blind clinical trial which compared the time for recovery of signs and symptoms of bacterial conjunctivitis in 56 patients under 18 years (84 eyes) between moxifloxacin 0.5%, one eye drop three times a day (n=28; 43 eyes, 36 of which had positive cultures) and polymyxin B sulfate 10,000 UI/ml + trimethoprim 1%, one eye drop, four times a day (n=28; 41 eyes, 32 of which had positive cultures).

After 48 hours of therapy, the percentage of eyes with clinical curations, defined as the complete recovery of all ocular symptoms and signs, was evaluated. Moxifloxacin showed a significantly higher percentage of total relief when compared to the group under polymyxin B sulfate/trimethoprim independently of whether the patients had a positive culture or not (81% vs 44% respectively, p=0.001) or both eyes treated (84% vs 44% respectively, p=0.0001).

Treatment continued for 7 days, after which telephone calls were made to patients. All patients under both therapies were relieved of the three main symptoms of conjunctivitis (bulbar conjunctival secretion, palpebral conjuctival secretion and conjunctival exudate). The study presented methodological errors as the unit of analysis (eyes) did not coincide with the unit of randomization (patients)[4]. Moreover, the primary endpoint was measured exclusively after 48 hours of treatment when the duration of the trial was 7 days.

In three unpublished studies[2] moxifloxacin showed therapeutic equivalence when compared to the other ophthalmic solutions of ofloxacin 0.3%, ciprofloxacin 0.3% and levofloxacin 0.5%.

Safety

Adverse reactions

The safety of the solution has been evaluated in unpublished trials in approximately 1500 patients who received moxifloxacin 0.5% ophthalmic solution, (one eye drop three times a day)[1,2]. No severe adverse ophthalmic or systemic reactions were reported and only 1-2% of the patients reported eye pain or irritation. These reactions were mild in 97% of the patients who reported adverse effects, and treatment was discontinued in only one patient.

Local: Frequent (≥1/100, <1/10): eye pain, eye irritation, dryness, or itching. Less frequent (≥1/1000, <1/100): queratitis punctata, conjunctival haemorrhage, ocular oedema, blurred vision, acute loss of vision, palpebral erythema, foreign body sensation, defects in corneal epithellium, corneal spots, and eyelid disorders.

Systemic: Frequent (≥1/100, <1/10): taste disorders. Less frequent (≥1/1000, <1/100): vomiting, increases in transminase levels, headache, paresthesia, nasal irritation, pain in the pharynx and larynx, foreign body sensation in the throat, haemoglobin level reduction.

The safety profile of moxifloxacin compared to other fluoroquinolones (ciprofloxacin and oxofloxacin) has been evaluated in two unpublished trials, the results of which have been analysed in one study that showed a similar safety profile[5].

Contraindications[1]

Hypersensitivity to the main active substance, to any of the excipients or any other quinolones.

Warnings and precautions[1]

Treatment should be discontinued in case of allergic reaction to ophthalmic moxifloxacin. Prolonged use can produce overgrowth of non-sensitive microorganisms, including fungi.

It is not recommended in neonates. It should not be employed as prophylaxis or treatment of gonococcical conjunctivitis, including neonatal gonococcical opthalmia, or for the management of *Chlamydia trachomatis.*

Contact lenses are not recommended when signs or symptoms of bacterial conjunctivitis appear.

Use in special situations[1]

Pregancy and lactation: can be employed. **Liver and renal impairment:** no dose adjustments required. **Children:** the safety profile and efficacy of moxifloxacin has not been evaluated in neonates and therefore it should be avoided. Nor has the treatment of *Chlamydia trachomatis* been evaluated in children under 2 years. **Elderly:** no dose adjustments are required.

Interactions[1]

Given the low systemic concentrations of moxifloxacin after ophthalmic administration it is hardly likely that drug interactions occur.

Risk Management Plan of the European Medicines Agency (EMA)

The EMA[2] proposes a risk management plan after authorization to evaluate the following risk potential: corneal problems and problems affecting the connective / muscular-skeletal systems.

Place in therapeutics

Bacterial conjunctivitis is the inflammation of the conjunctiva caused by direct contact with infectious secretions. The most common microorganisms include *Staphylococcus aureus* in adults, and *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis* in children[7]. The diagnosis is generally clinical[8].

Bacterial conjunctivitis is frequently benign and self-limiting (2-5 days)[7]. Although the use of antimicrobials is associated with better rates of clinical and microbiological remission[9,10], it is advisable to employ ophthalmic routes of administration of antimicrobial agents. Treatment should be initiated when no improvement is seen after a few days[8]. The choice of antimicrobial depends on the pattern of local resistance. Ointments are more indicated in children where compliance is usually worse.

The only trial published on moxifloxacin compared to polymyxin B sulfate/trimethoprim not free of methodological errors, showed superior clinical efficacy after 48 hours of treatment but not after 7 days. The safety profile is similar to other fluoroquinolones presenting the risk of corneal deposits and connective tissue alterations as reflected in the risk plan. The doses employed in studies are similar to the other eye drops compared[2]. Increasing rates of resistance have been observed with regard to moxifloxacin and the frequent microorganisms im plicated in eye infections[11]. Therefore, the recommended option is to employ ophthalmic antimicrobials whose safety profile and efficacy is better known taking into account local resistance and costs.

Presentations

Vigamox® (Alcon Cusí S.A.) 5 mg/mL eye drops, solution 5 mL (8.59 €)

References

A complete report on moxifloxacin 5% ophthalmic solution can be consulted at:
http://www.dtb.navarra.es

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