Important information. Please read carefully.

Zanaflox™

Eye Drops 0.5%w/v

Ophthalmic Solution

COMPOSITION
Moxifloxacin 0.5% w/v (as Moxifloxacin Hydrochloride)
Each ml contains 5mg of Moxifloxacin (as 5.45mg of Moxifloxacin HCl)

PHARMACODYNAMICS
Moxifloxacin is a fluoroquinolone bactericidal and acts by inhibiting the topoisomerase II (DNA gyrase) and topoisomerase IV, which are essential enzymes in the reproduction of bacterial DNA.

PHARMACOKINETICS
Absorption: Moxifloxacin is readily absorbed form the gastrointestinal tract after oral doses with an absolute bioavailability of about 90%.

Distribution: Moxifloxacin is widely distributed throughout the body tissues and is about 30 to 50% bound to plasma proteins.

Metabolism: Moxifloxacin has an elimination half-life of about 12 hours, allowing once-daily dosing. It is metabolized mainly via sulfate and glucuronide conjugation.

Elimination: Moxifloxacin is excreted in the urine and the faeces as unchanged drug and as metabolites, the sulfate conjugate primarily in the faeces and the glucuronide exclusively in the urine.

INDICATIONS
Zanaflox is indicated for the treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of the following organisms:

Gram-positive bacteria:
*Corynebacterium species**
Microbacterium species
*Micrococcus luteus** [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains]
Staphylococcus aureus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus epidermidis [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus haemolyticus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus hominis [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
*Staphylococcus warneri** [including erythromycin resistant strains]
*Streptococcus mitis** [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains]
Streptococcus pneumoniae [including penicillin, erythromycin, gentamicin, tetracycline and/or trimethoprim resistant strains]
Streptococcus viridans [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains]

Gram-negative bacteria:
Acinetobacter species
Haemophilus "alconae" [including ampicillin resistant strains]
Haemophilus influenzae [including ampicillin resistant strains]

*Klebsiella pneumoniae**
*Moraxella catarrhalis**
*Pseudomonas aeruginosa**

Other microorganisms:
Chlamydia trachomatis
* Efficacy for this organism was studied in fewer than 10 infections.
Preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required).

DOSAGE AND ADMINISTRATION
For topical eye use only. Instill one drop in the affected eye(s) 3 times a day for 7 days.

Not to be used for children below 1 year old.

CONTRAINDICATIONS
• Hypersensitivity to quinolones, including moxifloxacin or any of the components in this medication.

WARNING AND PRECAUTIONS
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, dyspnea, urticaria, and itching. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug.

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Exacerbation of myasthenia gravis
Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in person with myasthenia gravis. Post marketing serious adverse events, including deaths and requirement for ventilator support have been associated with flouroquinolones use in persons with myasthenia gravis. Avoid flouroquinolones in patients with known history of myasthenia gravis.

DRUG INTERACTIONS
While drug-drug interaction studies have not been conducted with moxifloxacin, they have been performed with the oral product at much higher systemic exposures than are achieved by the topical ocular route. Unlike some other fluoroquinolones, no clinically significant drug-drug interactions between systemically administered moxifloxacin and itraconazole, theophylline, warfarin, digoxin, oral contraceptives, probenicid, ranitidine or glyburide have been observed. *In vitro* studies indicate that moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2 indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isozymes.

PREGNANCY AND LACTATION
Moxifloxacin should be avoided during pregnancy and lactation.

SIDE EFFECTS
No serious ophthalmic or systemic adverse reactions related to moxifloxacin were reported.
The common side effect is transient ocular discomfort (burning/stinging). Other side effects are headache, keratitis, ocular pain, ocular pruritus, ocular hyperemia, pharyngitis and subconjunctival hemorrhage.

Exacerbation of myasthenia gravis
Post Marketing Experience

SYMPTOMS AND TREATMENT FOR OVERDOSAGE
No information is available on overdosage in humans. If a topical overdose of moxifloxacin occurs, the eye(s) may be flushed with tap water.

STORAGE CONDITION
Store below 30°C. Discard 4 weeks after first opening.

SHELF-LIFE
The expiry date is indicated on the packaging.

PRODUCT DESCRIPTION
Clear, yellow, sterile aqueous ophthalmic solution without the presence of precipitation and/or particles.
Available in sterile plastic dropper bottles of 5ml.

KEEP OUT OF REACH OF CHILDREN/ JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

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Manufactured and Marketed by
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