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1.5 Quality Information Summary

Enclosed

1.6 Product Information

1.6.1 Summary of Product characteristics.
M-FLOX (Moxifloxacin (0.5% w/v))

1. Name of the medicinal product
MFLOX

2. Qualitative and quantitative composition
Moxifloxacin 0.5%w/v
For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Eye drops, solution.
Clear, yellow color aqueous solution, practically free from visible particles.

4. Clinical particulars
4.1 Therapeutic indications

Topical treatment of purulent bacterial conjunctivitis, caused by moxifloxacin susceptible strains. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Use in adults including the elderly (≥ 65 years)

The dose is one drop in the affected eye(s) 3 times a day.

The infection normally improves within 5 days and treatment should then be continued for a further 2-3 days. If no improvement is observed within 5 days of initiating therapy, the diagnosis and/or treatment should be reconsidered. The duration of treatment depends on the severity of the disorder and on the clinical and bacteriological course of infection.

Paediatric patients

No dosage adjustment is necessary.

Use in hepatic and renal impairment

No dosage adjustment is necessary.

Method of administration

For ocular use only. Not for injection. Moxifloxacin 0.5%w/v eye drops, solution should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye.

To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle.

In order to prevent the drops from being absorbed via the nasal mucosa, particularly in new-born infants or children, the nasolacrimal ducts should be held closed for 2 to 3 minutes with the fingers after administering the drops. After cap is removed, if tamper evident snap collar is loose, remove before using the product.

If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

Duration of treatment:
For a transient treatment in the paediatric population.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

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, dyspnoea, urticaria, and itching.

If an allergic reaction to Moxifloxacin occurs, discontinue use of the medicinal product. Serious acute hypersensitivity reactions to moxifloxacin or any other product ingredient may require immediate emergency treatment. Oxygen and airway management should be administered where clinically indicated.

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.

Tendon inflammation and rupture may occur with systemic fluoroquinolone therapy including Moxifloxacin, particularly in older patients and those treated concurrently with corticosteroids. Following ophthalmic administration of Moxifloxacin plasma concentrations of Moxifloxacin are much lower than after therapeutic oral doses of Moxifloxacin (see section 4.5 and 5.2), however, caution should be exercised and treatment with Moxifloxacin should be discontinued at the first sign of tendon inflammation.

Moxifloxacin should not be used for the prophylaxis or empiric treatment of gonococcal conjunctivitis, including gonococcal ophthalmia neonatorum, because of the prevalence of fluoroquinolone-resistant Neisseria gonorrhoeae. Patients with eye infections caused by Neisseria gonorrhoeae should receive appropriate systemic treatment.

Patients should be advised not to wear contact lenses if they have signs and symptoms of a bacterial ocular infection.

Paediatric population

Data are very limited to establish efficacy and safety of Moxifloxacin in the treatment of conjunctivitis in neonates. Therefore use of this medicinal product to treat conjunctivitis in neonates is not recommended.

Neonates with ophthalmia neonatorum should receive appropriate treatment for their condition, e.g. systemic treatment in cases caused by Chlamydia trachomitis or Neisseria gonorrhoeae.

The medicinal product is not recommended for the treatment of Chlamydia trachomatis in patients less than 2 years of age as it has not been evaluated in such patients. Patients older than 2 years of age with eye infections caused by Chlamydia trachomitis should receive appropriate systemic treatment.

4.5 Interaction with other medicinal products and other forms of interaction

No specific interaction studies have been performed with Moxifloxacin 0.5%w/v eye drops, solution. Given the low systemic concentration of Moxifloxacin following topical ocular administration of the medicinal product, drug interactions are unlikely to occur.

4.6 Pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Moxifloxacin in pregnant women. However, no effects on pregnancy are anticipated since the systemic exposure to Moxifloxacin is negligible. The medicinal product can be used during pregnancy.

Breastfeeding

It is unknown whether Moxifloxacin/metabolites are excreted in human milk. Animal studies have shown excretion of low levels in breast milk after oral administration of Moxifloxacin. However, at therapeutic doses of Moxifloxacin no effects on the suckling child are anticipated. The medicinal product can be used during breast-feeding.

Fertility

Studies have not been performed to evaluate the effect of ocular administration of Moxifloxacin on fertility.

4.7 Effects on ability to drive and use machines

Moxifloxacin has no or negligible influence on the ability to drive and use machines, however, as with any eye drops, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient should wait until their vision clears before driving or using machinery.

4.8 Undesirable effects

System Organ Classification	Frequency	Adverse reactions
Blood and lymphatic system disorders	Rare	haemoglobin decreased
Immune system disorders	Not known	Hypersensitivity
Nervous system disorders	Uncommon Rare Not known	headache paresthesia dizziness
Eye disorders	Common Uncommon Rare Not known	eye pain, eye irritation punctate keratitis, dry eye, conjunctival haemorrhage, ocular hyperaemia, eye pruritus, eyelid oedema, ocular discomfort, corneal epithelium defect, corneal disorder, conjunctivitis, blepharitis, eye swelling, conjunctival oedema, vision blurred, visual acuity reduced, asthenopia, erythema of eyelid endophthalmitis, ulcerative keratitis, corneal erosion, corneal abrasion, intraocular pressure increased, corneal opacity, corneal infiltrates, corneal deposits, eye allergy, keratitis, corneal oedema, photophobia, eyelid oedema, lacrimation increased, eye discharge, foreign body sensation in eyes
Cardiac disorders	Not known	Palpitations
Respiratory, thoracic and mediastinal disorders	Rare Not known	nasal discomfort, pharyngolaryngeal pain, sensation of foreign body (throat) dyspnoea
Gastrointestional disorders	Uncommon Rare Not known	dysgeusia vomiting nausea
Hepatobiliary disorders	Rare	alanine aminotransferase increased, gamma-glutamyltransferase increased
Skin and subcutaneous tissue disorders	Not known	erythema, rash, pruritus, urticarial

Description of selected adverse reactions

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following first dose, have been reported in patients receiving systemic quinolone therapy. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnoea, urticaria and itching.

Ruptures of the shoulder, hand, Achilles, or other tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving systemic fluoroquinolones. Studies and post marketing experience with systemic quinolones indicate that a risk of these ruptures may be increased in patients receiving corticosteroids, especially geriatric patients and in tendons under high stress, including Achilles tendon.

Pediatric population

In clinical trials, Moxifloxacin has shown to be safe in paediatric patients, including neonates. In patients under 18 years old, the two most frequent adverse reactions were eye irritation and eye pain, both occurring at an incidence rate of 0.9%.

Based on data from clinical trials involving paediatric patients, including neonates (see section 5.1), the type and severity of adverse reactions in the paediatric population are similar to those in adults.

4.9 Overdose

The limited holding capacity of the conjunctival sac for ophthalmic products practically precludes any overdosing of the medicinal product.

The total amount of Moxifloxacin in a single container is too small to induce adverse effects after accidental ingestion.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Moxifloxacin is a quinolone/fluoroquinolone antibiotic. Moxifloxacin can be used to treat infections caused by the following bacteria: Aerobic Gram-positive microorganisms: Corynebacterium species, Micrococcus luteus, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri, Streptococcus pneumoniae, and Streptococcus viridans group. Aerobic Gram-negative microorganisms: Acinetobacter lwoffii, Haemophilus influenzae, and Haemophilus parainfluenzae. Other microorganisms: Chlamydia trachomatis.

Moxifloxacin is bactericidal and its mode of action depends on blocking of bacterial DNA replication by binding itself to an enzyme called DNA gyrase, which allows the untwisting required replicating one DNA double helix into two. Notably the drug has 100 times higher affinity for bacterial DNA gyrase than for mammalian. Moxifloxacin is a broad-spectrum antibiotic that is active against both Gram-positive and Gram-negative bacteria.

5.2 Pharmacokinetic properties

- Moxifloxacin is readily absorbed from the gastrointestinal tract after oral doses with an absolute bioavailability of about 90%. It is widely distributed throughout the body tissues and is about 30 to 50% bound to plasma proteins. Moxifloxacin has an elimination half-life of about 12 hours,

allowing once-daily dosing. It is metabolised mainly via sulphate and glucuronide conjugation, and is excreted in the urine and the faeces as unchanged drug and as metabolites, the sulphate conjugate primarily in the faeces and the glucuronide exclusively in the urine. Distribution into milk has been found in animals.

Paediatric Population:
As already confirmed by adult data, 80% of each eye drop passes through the nasolacrimal system where it may be rapidly absorbed into the systemic circulation via the nasal mucosa, conjunctiva, nasolacrimal duct, oropharynx and gut, or the skin from tear overflow.
Due to the fact that the blood volume in children is smaller than that in adults a higher circulation concentration has to be taken into account. In addition, neonates have immature metabolic enzyme pathways and it may result in an increase in elimination half-life and potentiating adverse events.
Limited data show that plasma Timolol levels in children after 2.5 mg/ml greatly exceed those in adults after 5 mg/ml, especially in infants and are presumed to increase the risk of side effects such as bronchospasm and bradycardia.

5.3 Preclinical safety data

No adverse ocular effects were observed in rabbits and dogs administered Timolol topically in studies lasting one and twelve months.
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. Pharmaceutical particulars
6.1 List of excipients
Boric acid BP

Sodium chloride BP

Tween 80 BP

Disodium Edetate BP

Purified water QS BP

6.2 Incompatibilities
None known.

6.3 Shelf life
24months unopened.
Discard 28 days after first opening.

6.4 Special precautions for storage
Do not store above 30°C.

6.5 Nature and contents of container
Packed in 5ml low density polyethylene container with HDPE cap and nozzle. Such 5ml is packed in a monocarton with package insert.

6.6 Special precautions for disposal and other handling

There is no special requirement for disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Aurolab, No.1,
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Madurai - 625020,
India.

8. Marketing authorisation number(s)

TN00002387

9. Date of first authorisation/renewal of the authorisation

11.07.2022

10. Date of revision of the text

Not Applicable