Summary of Product Characteristics
MOXINAL
(Moxifloxacin 0.5% w/v Eye Drops, Solution)

1 Name of the medicinal product

MOXINAL – Moxifloxacin 0.5% w/v Eye Drops, Solution

2 Qualitative and quantitative composition

Each ml of solution contains moxifloxacin hydrochloride equivalent to moxifloxacin 5 mg (0.5% w/v).

Excipient(s) with known effect
Each ml contains benzalkonium chloride 0.2 mg (0.02% w/v).

For the full list of excipients, see section 6.1.

3 Pharmaceutical form

Eye drops, solution.

A pale yellow solution.

4 Clinical particulars

4.1 Therapeutic indications

MOXINAL is indicated for the topical treatment of purulent bacterial conjunctivitis caused by moxifloxacin-susceptible strains (see sections 4.4 and 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

Adults, including the elderly
Instil one drop into the affected eye(s) three times a day. The infection normally improves within 5 days, and treatment should then be continued for a further 2 to 3 days. If no improvement is observed within 5 days of initiating therapy, the diagnosis and/or the treatment should be reconsidered. The duration of treatment depends on the severity of the disorder and on the clinical and bacteriological course of the infection.

Renal and hepatic impairment
No dose adjustment is considered necessary, as systemic exposure following topical ocular administration is negligible.

Paediatric population
No dose adjustment is necessary. Data are very limited to establish the efficacy and safety of moxifloxacin eye drops in the treatment of conjunctivitis in neonates.

Method of administration

For ocular use only. Not for injection: the solution must not be injected subconjunctivally or introduced directly into the anterior chamber of the eye.

To prevent contamination of the dropper tip and the solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip. Patients should be instructed to keep the bottle tightly closed when not in use.

Nasolacrimal occlusion, or gently closing the eyelid, for 2 to 3 minutes after instillation is recommended, as this may reduce systemic absorption and the risk of systemic adverse reactions. If more than one topical ophthalmic medicinal product is being used, the products should be administered at least 5 minutes apart; eye ointments should be administered last.

4.3 Contraindications

- Hypersensitivity to the active substance, to other quinolones, or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For topical ocular use only. Not for injection.

Hypersensitivity reactions

In patients receiving systemically administered quinolones, including moxifloxacin, 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 pruritus. If an allergic reaction to moxifloxacin occurs, use of the medicinal product should be discontinued. Serious acute hypersensitivity reactions may require immediate emergency treatment, with oxygen and airway management administered as clinically indicated.

Growth of resistant organisms with prolonged use

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, treatment should be discontinued and alternative therapy instituted. Whenever clinical judgement dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, with fluorescein staining.

Gonococcal conjunctivitis

MOXINAL should not be used for the prophylaxis or empirical 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.

Tendon disorders

Following ophthalmic administration, plasma concentrations of moxifloxacin are much lower than after therapeutic oral doses (see sections 4.5 and 5.2). Nevertheless, caution should be exercised, and treatment should be discontinued at the first sign of tendon inflammation.

Contact lenses
Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis. This medicinal product contains benzalkonium chloride, which is known to discolour soft contact lenses; contact with soft contact lenses must be avoided. If contact lens wear is permitted by the prescriber, lenses should be removed prior to instillation and not reinserted for at least 15 minutes.

Excipients
This medicinal product contains benzalkonium chloride, which may cause eye irritation, symptoms of dry eye, and effects on the tear film and corneal surface. It should be used with caution in patients with dry eye and in patients where the cornea may be compromised. Patients should be monitored in the event of prolonged use.

4.5 Interaction with other medicinal products and other forms of interaction

No specific interaction studies have been conducted with moxifloxacin eye drops. 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 medicinal products metabolised by these cytochrome P450 isozymes.

Given the low systemic concentrations of moxifloxacin following topical ocular administration, systemic drug interactions are unlikely to occur.

If more than one topical ophthalmic medicinal product is being used, the products should be administered at least 5 minutes apart (see section 4.2).

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate and well-controlled studies of moxifloxacin eye drops in pregnant women. Animal studies with systemic administration of moxifloxacin have shown reproductive toxicity at maternally toxic doses. Since the systemic exposure following ocular administration of moxifloxacin is negligible, no effects on pregnancy are anticipated. However, as a precautionary measure, use during pregnancy should be avoided unless the expected benefit outweighs any potential risk to the foetus.

Breast-feeding
It is unknown whether moxifloxacin is excreted in human milk following topical ocular administration. Systemically administered moxifloxacin is excreted in breast milk in animals. Because systemic exposure following ocular

administration is low, no effects on the breast-fed infant are anticipated. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

No studies have been conducted to evaluate the effect of topical ocular administration of moxifloxacin on human fertility. Systemic exposure after topical ocular administration is negligible, and no effects on fertility are anticipated.

4.7 Effects on ability to drive and use machines

MOXINAL has a minor influence on the ability to drive and use machines. Temporary blurred vision or other visual disturbances may occur after instillation. If blurred vision occurs, the patient should wait until vision is clear before driving or operating machinery.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions are eye pain and eye irritation, generally of mild intensity and transient. In clinical studies, the most common ocular reactions also included conjunctival haemorrhage, dry eye, ocular hyperaemia, eye pruritus and punctate keratitis.

Tabulated list of adverse reactions

Adverse reactions are listed below by System Organ Class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Immune system disorders	Not known	Hypersensitivity, anaphylactic reaction
Nervous system disorders	Uncommon	Headache
	Not known	Dizziness, dysgeusia
Eye disorders	Common	Eye pain, eye irritation
	Uncommon	Punctate keratitis, dry eye, conjunctival haemorrhage, ocular hyperaemia, eye pruritus, eyelid oedema, ocular discomfort
	Not known	Endophthalmitis, ulcerative keratitis, corneal erosion, corneal abrasion, corneal opacity, corneal infiltrates, corneal deposits, eye allergy, keratitis, conjunctivitis, blepharitis, eye swelling, conjunctival oedema, blurred vision, decreased visual acuity, asthenopia, photophobia, eyelid erythema, increased lacrimation, increased intraocular pressure
Cardiac disorders	Not known	Palpitations

System Organ Class	Frequency	Adverse reaction
Respiratory, thoracic and mediastinal disorders	Uncommon	Dyspnoea (reported in paediatric patients)
	Not known	Laryngeal oedema, airway obstruction (quinolone class effect)
Gastrointestinal disorders	Not known	Vomiting
Skin and subcutaneous tissue disorders	Not known	Erythema, rash, pruritus, urticaria

Description of selected adverse reactions

Serious and occasionally fatal hypersensitivity reactions, including anaphylaxis, have been reported with systemically administered quinolones, some following the first dose. If an allergic reaction occurs, treatment should be discontinued immediately (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority.

4.9 Overdose

No cases of overdose have been reported. The total amount of moxifloxacin in a single container is too small to induce systemic adverse effects after accidental ingestion.

A topical overdose may be flushed from the eye(s) with lukewarm water. In the event of accidental ingestion, treatment should be symptomatic and supportive according to the patient's clinical condition.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals; anti-infectives, other anti-infectives.

ATC code: S01AE07

Mechanism of action

Moxifloxacin is a fourth-generation fluoroquinolone antibacterial agent with broad-spectrum activity against Gram-positive and Gram-negative ocular pathogens. It exerts its bactericidal activity by inhibiting bacterial DNA gyrase (topoisomerase II) and topoisomerase IV, enzymes essential for bacterial DNA replication, transcription, repair and recombination.

Resistance

Resistance to fluoroquinolones, including moxifloxacin, generally occurs by chromosomal mutations in the genes encoding DNA gyrase and topoisomerase IV.

In Gram-negative bacteria, moxifloxacin resistance can be due to mutations in the mar (multiple antibiotic resistance) and qnr (quinolone resistance) gene systems. Resistance is also associated with expression of bacterial efflux proteins and inactivating enzymes. Cross-resistance with other fluoroquinolones may occur. Cross-resistance with beta-lactams, macrolides and aminoglycosides is not expected, owing to differences in mode of action.

Susceptibility
The prevalence of acquired resistance may vary geographically and with time for selected species, and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infection is questionable.

Moxifloxacin has been shown to be active against most isolates of the following organisms, both in vitro and in bacterial conjunctivitis:

- Gram-positive organisms: Corynebacterium species*, Micrococcus luteus*, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri*, Streptococcus pneumoniae, Streptococcus viridans group.
- Gram-negative organisms: Acinetobacter lwoffii*, Haemophilus influenzae, Haemophilus parainfluenzae*.
- Other organisms: Chlamydia trachomatis.

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

There are no pharmacodynamic data correlated with clinical outcome for moxifloxacin administered as a topical ophthalmic agent.

5.2 Pharmacokinetic properties

Plasma concentrations were studied in 21 healthy male and female subjects who were administered moxifloxacin hydrochloride eye drops to both eyes every 8 hours for a total of 13 doses. Measurable plasma concentrations of moxifloxacin (≥ 0.75 ng/ml) were observed in 16 of 21 subjects 4 hours following the first dose, and in all subjects following the last dose.

The mean steady-state estimates for Cmax and AUC were 2.7 ng/ml and 41.9 ng·h/ml respectively. These steady-state parameter estimates were at least 1,600-fold and 1,000-fold lower than the mean Cmax and AUC values reported after therapeutic 400 mg oral doses of moxifloxacin. The steady-state plasma half-life of moxifloxacin was estimated to be 13 hours.

Subgroup analysis by race (Caucasian, Asian) showed no meaningful differences in the mean steady-state pharmacokinetic parameters of moxifloxacin. Gender differences in the steady-state Cmax and AUC were observed; however, when adjusted for body weight, the differences were minimised and were not clinically relevant.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans at the exposures achieved following topical ocular administration, based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity and toxicity to reproduction and development.

As with other quinolones, moxifloxacin has been shown to cause articular cartilage lesions in immature animals following systemic administration at exposures substantially in excess of those achieved by the topical ophthalmic route. There is no further information of relevance to the prescriber other than that which is included in other sections of this Summary of Product Characteristics.

6 Pharmaceutical particulars

6.1 List of excipients

- Benzalkonium chloride
- Sodium chloride
- Glycerol
- Sodium hydroxide (for pH adjustment)
- Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a dry, dark place below 30°C.

Keep out of the sight and reach of children.

6.5 Nature and contents of container

White plastic LDPE vial containing 5 ml of solution, sealed and packed in a carton with a package insert.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

For single-patient use only. The container should be discarded after the completion of treatment.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 Marketing authorisation holder

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8 Marketing authorisation number

CTD13204

9 Date of first authorisation/renewal of the authorisation

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10 Date of revision of the text

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