Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Moxigen EYE DROPS 5ml(Moxifloxacin Hydrochloride 0.5% w/v)

2. Qualitative and quantitative composition
Each ml of sterile eye drops contains Moxifloxacin 5 mg (as Moxifloxacin Hydrochloride BP).

Excipients with known effects
Sodium chloride- 3.2mg in 5ml
Boric acid-75mg in 5ml

For a full list of excipients, see section 6.1

3. Pharmaceutical form
Yellow coloured transparent sterile eye drops

4. Clinical particulars

4.1 Therapeutic indications
Moxigen ophthalmic solution is indicated for the treatment of bacterial infections including bacterial conjunctivitis, blepharitis, and blepharo-conjunctlvitis which are caused to moxifloxacin susceptible bacteria. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration
Dosage and application: Instill one drop in the affected eye(s) 3 times daily for 7 days.

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.

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

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 (see section 4.8).

If an allergic reaction to Moxifloxacin 5 mg/ml (MOXIGEN 0.5% w/v) eye drops, solution 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 corticosteroid. Following ophthalmic administration of Moxifloxacin 0.5 % w/v eye drops, solution 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 0.5 % w/v eye drops, solution should be discontinued at the first sign of tendon inflammation (see section 4.8).

Moxifloxacin 5 mg/ml eye drops, solution 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 the efficacy and safety of moxifloxacin 0.5 % w/v eye drops, solution, 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 MOXIGEN EYE DROPS 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 0.5 % w/v eye drops, solution 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 0.5 % w/v eye drops, solution no effects on the suckling child are anticipated. The medicinal product can be used during breast-feeding.

Fertility

Studies have not been conducted to evaluate the effect of ocular administration of Moxifloxacin 0.5% w/v eye drops solution on fertility.

4.7 Effects on ability to drive and use machines

MOXIGEN (moxifloxacin 0.5%w/v) EYE DROPS 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

In clinical studies involving 2,252 patients, Moxifloxacin 0.5 % w/v eye drops, solution was administered up to 8 times a day, with over 1,900 of these patients receiving treatment 3 times daily. The overall safety population that received the medicinal product consisted of 1,389 patients from the United States and Canada, 586 patients from Japan and 277 patients from India. No serious ophthalmic or systemic undesirable effects related to the medicinal product were reported in any of the clinical studies. The most frequently reported treatment-related undesirable effects with the medicinal product were eye irritation and eye pain, occurring at an overall incidence of 1 to 2%. These reactions were mild in 96% of those patients who experienced them, with only 1 patient discontinuing therapy as a result.

The following adverse reactions are classified according to the following convention: 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) or not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in decreasing order of seriousness.

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, ocularhyperaemia, eye pruritus, eyelidoedema, 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, urticaria

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 (see section 4.4).

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 the Achilles tendon (see section 4.4).

Paediatric population

In clinical trials, Moxifloxacin 0.5 % w/v eye drops, solution 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of benefit/risk balance of the medicinal product. Health care professionals are asked to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

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

Pharmacotherapeutic group: Ophthalmologicals; anti-infectives, other anti-infectives.
ATC code: J01MA14

Mode of Action

Moxifloxacin, a fourth-generation fluoroquinolone, inhibits the DNA gyrase and topoisomerase IV required for bacterial DNA replication, repair, and recombination.

Resistance

Resistance to fluoroquinolones, including moxifloxacin generally occurs by chromosomal mutations in genes encoding DNA gyrase and topoisomerase IV. In Gram-negative bacteria, moxifloxacin resistance can be due to mutations in mar (multiple antibiotic resistance) and the qnr (quinolone resistance) gene systems. Resistance is also associated with expression of bacteria efflux proteins and inactivating enzymes. Cross-resistance with beta-lactams, macrolides and aminoglycosides is not expected due to differences in mode of action.

Susceptibility Testing Breakpoints

There are no pharmacological data correlated with clinical outcome for moxifloxacin administered as a topical agent. As a result, the European Committee on Antimicrobial Susceptibility Testing (EUCAST) suggests the following epidemiological cut-off values (ECOFF mg/l) derived from MIC distribution curves to indicate susceptibility to topical moxifloxacin:

Corynebacterium	ND
Staphylococcus aureus	0.25 mg/l
Staphylococcus, coag-neg.	0.25 mg/l
Streptococcus pneumoniae	0.5 mg/l
Streptococcus pyogenes	0.5 mg/l
Streptococcus, viridans group	0.5 mg/l
Enterobacter spp.	0.25 mg/l
Haemophilus influenzae	0.125 mg/l
Klebsiella spp.	0.25 mg/l
Moraxella catarrhalis	0.25 mg/l
Morganella morganii	0.25 mg/l
Neisseria gonorrhoeae	0.032 mg/l
Pseudomonas aeruginosa	4 mg/l
Serratia marcescens	1 mg/l

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 moxifloxacin in at least some types of infections is questionable.

COMMONLY SUSCEPTIBLE SPECIES
Aerobic Gram-positive micro-organisms: *Corynebacterium* species including *Corynebacterium diphtheria* *Staphylococcus aureus* (methicillin susceptible) *Streptococcus pneumonia* *Streptococcus pyogenes* *Streptococcus viridans* Group **Aerobic Gram-negative micro-organisms*:*** *Enterobacter cloacae* *Haemophilus influenzae* *Klebsiella oxytoca* *Moraxella catarrhalis* *Serratia marcescens* **Anaerobic micro-organisms:** *Proprionibacterium acnes* **Other micro-organisms:** *Chlamydia trachomatis*
SPECIES FOR WHICH ACQUIRED RESISTANCE MAY BE A PROBLEM
Aerobic Gram-positive micro-organisms: *Staphylococcus aureus* (methicillin resistant)

Staphylococcus, coagulase-negative species (methicillin resistant) **Aerobic Gram-negative micro-organisms*:*** *Neisseria gonorrhoeae* **Other micro-organisms:** None
INHERENTLY RESISTANT ORGANISMS
Aerobic Gram-negative micro-organisms*:* *Pseudomonas aeruginosa* **Other micro-organisms:** None

5.2 Pharmacokinetic properties

Following topical ocular administration of Moxifloxacin 0.5 % w/v eye drops, solution, moxifloxacin was absorbed into the systemic circulation. Plasma concentrations of moxifloxacin were measured in 21 male and female subjects who received bilateral topical ocular doses of the medicinal product 3 times a day for 4 days. The mean steady-state Cmax and AUC were 2.7 ng/ml and 41.9 ng· hr/ml, respectively. These exposure values are approximately 1,600 and 1,200 times lower than the mean Cmax and AUC reported after therapeutic 400 mg oral doses of moxifloxacin. The plasma half-life of moxifloxacin was estimated to be 13 hours.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure following administration to the eye indicating little relevance to clinical use.

As with other quinolones, moxifloxacin was also genotoxic in vitro in bacteria and mammalian cells. As these effects can be traced to the interaction with bacterial gyrase and in considerably higher concentrations to the interaction with topoisomerase II in mammalian cells, a threshold level for genotoxicity can be assumed. In in vivo tests, no evidence of genotoxicity was found, despite high doses of moxifloxacin. The therapeutic doses for human use therefore provide adequate safety margin. No indication of a carcinogenic effect was observed in an initiation promotion model in rats.

Unlike other quinolones, moxifloxacin showed no phototoxic or photogenotoxic properties in extensive in vitro and in vivo studies.

6. Pharmaceutical Particulars

6.1 List of Excipients

Sodium Chloride (For sterile)
Boric Acid
Sodium Hydroxide (For Sterile)
Water for Injection

6.2 Incompatibilities

None

6.3 Shelf-Life

24 months.
Discard 4 weeks after first opening.

6.4 Special Precautions for storage

Store in cool (below 30°C) and dry place, away from light.

6.5 Nature and Content of container

5 ml round white ivory coloured plastic dropper bottle
with plug and cap, packed in a carton of Swedish paper with pack insert.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of per local requirements.

7. Marketing Authorization Holder

General Pharmaceuticals Limited,
Bangladesh

8. Marketing Authorization Number

CTD10781

9. Date of first authorization/renewal of the authorization

8/11/2023

10. Date of revision of the text

11/05/2025