SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name	:	**MOXIGEN EYE DROPS 5ML**
Generic Name	:	Moxifloxacin (as Hydrochloride)
Pharmaceutical Dosage Form	:	Eye Drops (sterile)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL sterile solution contains Moxifloxacin Hydrochloride 27.25 mg equivalent to 25 mg of Moxifloxacin.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Eye Drops (sterile)

Clear solution in 5 mL round ivory color plastic dropper bottle with plug and cap.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The ophthalmic solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: Aerobic Gram-positive microorganisms: Corynebacterium species, Micrococcus luteus, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri, Streptococcus pneumoniae, Streptococcus viridans group. Aerobic Gram-negative microorganisms: Acinetobacterlwoffii, Haemophilus influenzae, Haemophilus parainfluenzae. Other microorganisms: Chlamydia trachomatis.

4.2 Posology and method of administration

Eye Drops: One drop in the affected eye 3 times per day for 7 days.

4.3 Contraindications

Moxifloxacin Hydrochloride ophthalmic solution is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

4.4 Special warnings and special precautions for use

As with other anti-infectives, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

4.5 Interaction with other FPPs and other forms of interaction

Drug-drug interaction studies have not been conducted with Moxigen ophthalmic solution. In vitro studies indicate that Moxigen does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2 indicating that Moxigen is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isozymes.

4.6 Fertility, pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women. Moxifloxacin ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when Moxifloxacin is administered to a nursing mother.

4.7 Effects on ability to drive and use machines

It is suggested to consult with the doctor or pharmacist.

4.8 Undesirable effects

The most frequently reported ocular adverse events were decreased visual acuity, dry eye, ocular discomfort, ocular hyperemia ocular pain ocular pruritus, subconjunctival hemorrhage and tearing. These events occurred in approximately 1-6% of patients.

4.9 Overdose

There is practically no risk of adverse effects due to accidental ingestion, since a bottle of 5 ml eye drops solution contains only 25 mg Moxifloxacin that is much lower than recommended daily oral dose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

ATC-code: S01A E07

Mechanism of action

The antimicrobial action of Moxigen results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division.

5.2 Pharmacokinetic properties

Moxifloxacin steady-state plasma pharmacokinetics were evaluated in healthy adult male and female subjects who were administered multiple, bilateral, topical ocular doses of MOXEZA™ solution two times daily for four days with a final dose on day 5. The average steady-state AUC0-12 was 8.17 ± 5.31 ng*h/mL. Moxifloxacin Cmax following twice-daily bilateral ophthalmic administration of moxifloxacin AF 0.5% for 5 days is approximately 0.02% of that achieved with the oral formulation of moxifloxacin hydrochloride (Cmax following oral dosing of 400 mg AVELOX*, 4.5 ± 0.5 mcg/mL).

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 photo genotoxic properties in extensive in vitro and in vivo studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride

Boric Acid

Sodium Hydroxide

Water for Injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years (24 Months from the date of manufacturing)

6.4 Special precautions for storage

Store in a cool and dry place away from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of the opening do not use the medicine of dropper.

6.5 Nature and contents of container

5 ml round Ivory color plastic dropper bottle with plug & cap.

The packaging material i.e container & plug material is Low Density Polyethylene(LDPE) and cap material is the combination of Low Density Polyethylene (LDPE) & High Density Polyethylene (HDPE).

6.6 Special precautions for disposal and other handling

During use of the dropper, do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of opening do not use the medicine of dropper. Dispose the empty container in waste bin.

7. MARKETING AUTHORISATION HOLDER

7.1 Name and address of manufacturer

Name	:	**GENERAL Pharmaceuticals Ltd. (Unit: 2)**
Address	:	Karolshurichala, Kaliakair, Gazipur, Bangladesh
E-mail	:	gplfactoryu2@generalpharma.com

8. MARKETING AUTHORISATION NUMBER(S)

05567/07704/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16-12-2020

10. DATE OF REVISION OF THE TEXT

17-06-2022