13. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

1.1 Strength:

0.5% w/v

1.2 Pharmaceutical form:

For Ophthalmic use only

14. QUALITATIVE AND QUANTITATIVE COMPOSITION

14.1 Qualitative declaration:

1 ml of solution contains 5.46 mg Moxifloxacin hydrochloride equivalent to 5 mg Moxifloxacin base.

14.2 Quantitative declaration:

1 ml of solution contains 5.46 mg Moxifloxacin hydrochloride equivalent to 5 mg Moxifloxacin base.

14.3 Salts and hydrates:

Not Applicable

14.4 Esters and pro-drugs

Not Applicable

14.5 Oral powders for solution or suspension

Not Applicable

14.6 Parenteral excluding powders for reconstitution

Not Applicable

14.7 Powders for reconstitution prior to parenteral administration

Not Applicable

14.8 Concentrates

Not Applicable

14.9 Transdermal patches

Not Applicable

14.10 Multi dose solid or semi-solid products

Not Applicable

14.11 Biological medicinal products

Not Applicable

14.11.1 Expression of strength

Not Applicable

14.11.2 The biological origin of the active substance

Not Applicable

14.11.3 Special provisions for normal immunoglobulin

Not Applicable

14.11.4 Herbal pharmaceutical products

Not Applicable

15. PHARMACEUTICAL FORM

Ophthalmic Sterile Solution

16. CLINICAL PARTICULARS

16.1 Therapeutic indications

16.2 Posology and method of administration

Adults

The usual dosage regimen in adults is as follows:

Initial Supplemental

Spontaneous Respiration

Assisted Ventilation

Paediatric population

No dosage adjustment is necessary

OXCIN Ophthalmic Solution (Moxifloxacin HCl 0.5% w/v)

Follow adult dosage.

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

The usual dosage regimen in children is as follows: No dosage adjustment is necessary

Age Initial Supplemental

Spontaneous

Respiration

Assisted Ventilation

Use in children:

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

Use in elderly and debilitated patients:

16.3 Method of administration

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.

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

16.4 Contraindications

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

16.5 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 OXCIN 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.

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

OXCIN 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.

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.

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

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

16.6 Paediatric population

Not Applicable

16.7 Interaction with other medicinal products and other forms of interaction

No specific interaction studies have been performed with OXCIN 5 mg/ml Eye Drops, Solution.

Given the low systemic concentration of moxifloxacin following topical ocular administration of the medicinal product (see Section 5.2), drug interactions are unlikely to occur

16.8 Additional information on special populations

Not Applicable

16.9 Paediatric population

Not Applicable

16.10 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of OXCIN 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.

Lactation

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

16.10.1 General principles

16.10.2 Women of childbearing potential / Contraception in males and females

Not Applicable

16.10.3 Pregnancy

16.10.5 Fertility

16.11 Effects on ability to drive and use machine

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.

16.12 Undesirable effects

16.13 Overdose

Additional information on special populations

Not Applicable

Paediatric population

Not Applicable

17. PHARMACOLOGICAL PROPERTIES

17.1 Pharmacodynamic properties

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

17.2 Pharmacokinetic properties

Following topical ocular administration of OXCIN, 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.

17.3 Preclinical safety data

Environmental Risk Assessment (ERA)

NA

18. PHARMACEUTICAL PARTICULARS

18.1 List of excipients

18.2 Incompatibilities

Not applicable

18.3 Shelf life

24 Months.

18.4 Special precautions for storage

Protect from light. Store below 25°C

18.5 Nature and contents of container

Primary Packing –

5 ml LDPE Bottle (Sterile)

Secondary Packing

Printed Carton

18.6 Special precautions for disposal and other handling

19. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Marketing Authorisation Holder

Abacus Pharma Limited

B.P 4344, Kigali

Rwanda

Manufacturing Site:

ATCO Laboratories Limited

B-18, S.I.T.E., Karachi-75700, Pakistan

20. MARKETING AUTHORISATION NUMBER

Not Applicable

21. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Not Applicable

22. DATE OF REVISION OF THE TEXT

23. DOSIMETRY (IF APPLICABLE)

Not Applicable

24. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not Applicable