OXCIN-D OPHTHALMIC SOLUTION
Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT
Oxcin-D Ophthalmic Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Moxifloxacin (as HCl) BP..... 0.5%w/v
Dexamethasone Sodium Phosphate USP equivalent to
Dexamethasone Phosphate.....0.1%w/v

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM
Eye drops (solution)
Yellow coloured clear solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Oxcin-D Ophthalmic Solution is indicated for steroid responsive inflammatory ocular conditions for which a corticosteroid is indicated and where Bacterial infection or a risk of bacterial ocular infection exists. The combination can also be use for post-operative inflammation associated with infection.

4.2 Posology and method of administration
Instill one drop in the affected eye 3 times a day for 7 days or as directed by Physician

4.3 Contraindications
Oxcin-D 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. Prolong use of steroid may result in Ocular hypertension and /or glaucoma, with damage to the optic nerve, defects in visual acuity and field of vision, and posterior subcapsular cataract formation. Prolong use may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

4.4 Special warnings and precautions for use

WARNINGS
Not for injection.
Oxcin-D Ophthalmic Solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.
In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions are reported, some following the first dose. Some reactions are accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

PRECAUTIONS
General
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. 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.
Information for Patients
Avoid contaminating the applicator tip with material from the eye, fingers or other source.
Systemically administered quinolones including moxifloxacin have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

4.5 Interaction with other medicinal products and other forms of interaction

Moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2 indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isozymes.

4.6 Pregnancy and lactation

Pregnancy
Teratogenic Effects.
Pregnancy Category C
Since there are no adequate information available about the safety of moxifloxacin in pregnant women, Oxcin solution
should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
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.

Pediatric Use
The safety and effectiveness of moxifloxacin solution in infants below 1 year of age is not known.

Geriatric Use
No overall differences in safety and effectiveness are observed between elderly and younger patients.

4.7 Effects on ability to drive and use machines

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 Side effects

The most frequently reported ocular adverse events are conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing.
Other nonocular adverse events include fever, increased cough, infection, otitis media, pharyngitis, rash, and rhinitis.

4.9 Overdose

No case of overdose with OXCIN has been reported. The limited holding capacity of the conjunctival sac for ophthalmic products practically precludes any overdosing of the medicinal product.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mode of Action:
The mechanism of action for quinolones, including moxifloxacin, is different from that of macrolides, aminoglycosides, or tetracyclines. Therefore, moxifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to moxifloxacin. There is no cross-resistance between moxifloxacin and the aforementioned classes of antibiotics.

Mechanisms of Resistance:
Resistance to moxifloxacin develops via multiple-step mutations. Resistance to moxifloxacin occurs at a general frequency of between 1.8 x 10-9 to < 1 x 10-11 for Gram-positive bacteria.

Moxifloxacin has been shown to be active against most strains of the following microorganisms.

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:
Acinetobacter lwoffii*
Haemophilus influenzae
Haemophilus parainfluenzae*

Other microorganisms:
Chlamydia trachomatis
*The efficacy of moxifloxacin for this organism is studied in fewer than 10 infections.

The following organisms are considered susceptible when evaluated using systemic breakpoints. However, a correlation between the systemic breakpoint and ophthalmological efficacy has not been established. The list of organisms is provided as guidance only in assessing the potential treatment of conjunctival infections. Moxifloxacin exhibits minimal inhibitory concentrations (MICs) of 2 µg/ml or less (systemic susceptible breakpoint) against most (>90%) of strains of the following ocular pathogens.

Aerobic Gram-positive microorganisms:
Listeria monocytogenes
Staphylococcus saprophyticus
Streptococcus agalactiae
Streptococcus mitis
Streptococcus pyogenes
Streptococcus Group C, G and F
Aerobic Gram-negative microorganisms:
Acinetobacter baumannii
Acinetobacter calcoaceticus
Citrobacter freundii
Citrobacter koseri
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Klebsiella oxytoca

Klebsiella pneumoniae
Moraxella catarrhalis
Morganella morganii
Neisseria gonorrhoeae
Proteus mirabilis
Proteus vulgaris
Pseudomonas stutzeri
Anaerobic microorganisms:
Clostridium perfringens
Fusobacterium species
Prevotella species
Propionibacterium acnes

Other microorganisms:
Chlamydia pneumoniae
Legionella pneumophila
Mycobacterium avium
Mycobacterium marinum
Mycoplasma pneumoniae

5.2 Pharmacokinetic properties
The mean steady-state Cmax (2.7 ng/mL) and estimated daily exposure AUC (45 ng·hr/mL) values are 1,600 and 1,000 times lower than the mean Cmax and AUC reported after therapeutic 400 mg oral doses of moxifloxacin. The plasma half-life of moxifloxacin is estimated to be 13 hours.
Dexamethasone suppresses the inflammatory response to a variety of agents and it probably delays or slows healing.

Oxcin-D Ophthalmic Solution is a combination of Moxifloxacin 0.5% and Dexamethasone 0.1%. Moxifloxacin is a fourth generation fluoroquinolone controls infection by inhibiting the DNA gyrase and topoisomerase iv.Dexamethasone a potent corticosteroid effectively controls the inflammation by inhabiting the release inflammatory mediators.

5.3 Preclinical safety data
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
- Benzalkonium Chloride Solution (50%)
- Hypromellose
- Sodium Chloride
- Sodium Hydroxide
- Disodium Edetate
- Tyloxapol
- Anhydrous Sodium Sulphite
- Water for Injection

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
02 years.
Discard 4 weeks after first opening.

6.4 Special precautions for storage
Keep out of the reach of children.
Protect from light. & heat.

Store below 25°C.
Shake well before use.
Replace cap securely after use.

6.5 Nature and contents of container

01 Plastic labeled bottle of 5ml packed in a printed carton of Bleach board with UV Coated

6.6 Special precautions for disposal and other handling

The contents should not be used more than four weeks after first opening the bottle.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

067249

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07-12-2010 / Nil

LEGAL CATEGORY

Prescription Only Medicine