Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Onaflox (ofloxacin ophthalmic solution usp 0.3% w/v)

2. Qualitative and quantitative composition

Composition:

Ofloxacin usp 0.3%w/v

Benzalkonium chloride solution usp 0.02%w/v

(as preservative)

Sterile aqueous base..... q.s.

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Ophthalmic solution

4. Clinical particulars

4.1 Therapeutic indications

It is indicated for the topical treatment of external ocular infections (such as conjunctivitis and

keratoconjunctivitis) in adults and children caused by ofloxacin - sensitive organisms.

4.2 Posology and method of administration

Topical ocular instillation.

For all ages: one to two drops in the affected eye(s) every two to four hours for the first two days and then four times daily. The length of treatment should not exceed ten days.

4.3 Contraindications

ONAFLOX (Ofloxacin Ophthalmic Solution USP 0.3% w/v) is contra-indicated in individuals who have shown hypersensitivity to ofloxacin, any of its excipients or any other quinolones.

4.4 Special warnings and precautions for use

ONAFLOX (Ofloxacin Ophthalmic Solution USP 0.3% w/v) is not for injection.

Safety and effectiveness in infants below the age of one year have not been established.

Serious and occasionally fatal hypersensitivity (anaphylactic/anaphylactoid) reactions, some following the first dose, have been reported in patients receiving systemic quinolones, including ofloxacin. 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 ONAFLOX occurs, discontinue the drug. Use ONAFLOX (Ofloxacin Ophthalmic

Solution USP 0.3% w/v) with caution in patients who have exhibited sensitivities to other quinolones antibacterial agents.

When using ONAFLOX (Ofloxacin Ophthalmic Solution USP 0.3% w/v) the risk of rhinopharyngeal passage which can contribute to the occurrence and the diffusion of bacterial resistance should be

considered. As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms.

If worsening infection occurs, or if clinical improvement is not noted within a reasonable period, discontinue use and institute alternative therapy.

Stevens-Johnson syndrome has been reported in patients receiving topical ophthalmic ofloxacin, however, a causal relationship has not been established.

Cardiac disorders

Caution should be taken when using fluoroquinolones, including ONAFLOX in patients with known risk factors for prolongation of the QT interval such as, for example:

- congenital long QT syndrome
- concomitant use of drugs that are known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics)
- uncorrected electrolyte imbalance (e.g. hypokalaemia, hypomagnesaemia)
- cardiac disease (e.g. heart failure, myocardial infarction, bradycardia)

Elderly patients and women may be more sensitive to QTc-prolonging medications. Therefore, caution

should be taken when using fluoroquinolones, including ONAFLOX, in these populations.

Use ONAFLOX (Ofloxacin Ophthalmic Solution USP 0.3% w/v) with caution in patients who have

exhibited sensitivities to other quinolone antibacterial agents.

Data are very limited to establish efficacy and safety of ONAFLOX (Ofloxacin Ophthalmic Solution USP 0.3% w/v) in the treatment of conjunctivitis in neonates.

The use of ONAFLOX (Ofloxacin Ophthalmic Solution USP 0.3% w/v) in neonates with ophthalmianeonatorum caused by Neisseria gonorrhoeae or Chlamydia trachomatis is not recommended as it has not been evaluated in such patients.

Use in elderly: No comparative data are available with topical dosing in elderly versus other age groups.

Clinical and non-clinical publications have reported the occurrence of corneal perforation in patients with pre-existing corneal epithelial defect or corneal ulcer, when treated with topical fluoroquinolone antibiotics.

However, significant confounding factors were involved in many of these reports, including advanced age, presence of large ulcers, concomitant ocular conditions (e.g. severe dry eye), systemic inflammatory diseases (e.g. rheumatoid arthritis), and concomitant use of ocular steroids or non-steroidal anti-inflammatory drugs.

Nevertheless, it is necessary to advise caution regarding the risk of corneal perforation when using product to treat patients with corneal epithelial defects or corneal ulcers.

Corneal precipitates have been reported during treatment with topical ophthalmic ofloxacin. However, a causal relationship has not been established.

Long-term, high-dose use of other fluoroquinolones in experimental animals has caused lenticular opacities.

However, this effect has not been reported in human patients, nor has it been noted following topical ophthalmic treatment with ofloxacin for up to six months in animal studies including studies in monkeys.

ONAFLOX (Ofloxacin Ophthalmic Solution USP 0.3% w/v) contains the preservative benzalkonium chloride which may cause ocular irritation and discolour soft contact lenses.

Sun or UV-exposition should be avoided during use of ofloxacin due to the potential for photosensitivity.

Use of contact lenses is not recommended in patients receiving treatment for an eye infection.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

It has been shown that the systemic administration of some quinolones inhibits the metabolic clearance of

caffeine and theophylline. Drug interaction studies conducted with systemic ofloxacin have demonstrated that metabolic clearance of caffeine and theophylline are not significantly affected by ofloxacin.

Although there have been reports of an increased prevalence of CNS toxicity with systemic dosing of fluoroquinolones when used concomitantly with systemic nonsteroidal anti-inflammatory drugs (NSAIDs),

this has not been reported with the concomitant systemic use of NSAIDs and ofloxacin.

ONAFLOX (Ofloxacin Ophthalmic Solution USP 0.3% w/v), like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III anti-

arrhythmics, tricyclic antidepressants, macrolides, antipsychotics)

4.6 Pregnancy and Lactation

Use in pregnancy: There have been no adequate and well-controlled studies performed in pregnant women.

Since systemic quinolones have been shown to cause arthropathy in immature animals, it is recommended that ONAFLOX (Ofloxacin Ophthalmic Solution USP 0.3% w/v) not be used in pregnant women.

Use during lactation: Because ofloxacin and other quinolones taken systemically are excreted in breast milk, and there is potential for harm to nursing infants, a decision should be made whether to temporarily

discontinue nursing or not to administer the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Transient blurring of vision may occur on instillation of eye drops. Do not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

General: Serious reactions after use of systemic ofloxacin are rare and most symptoms are reversible. Since a small amount of ofloxacin is systemically absorbed after topical administration, side-effects reported with

systemic use could possibly occur.

Frequency categories: 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):

Immune System Disorders:

Very rare: Hypersensitivity* (including angioedema, dyspnea, anaphylactic reaction/shock, oropharyngeal

swelling and tongue swollen).

- Serious and occasionally fatal hypersensitivity (anaphylactic/anaphylactoid) reactions, some following the

first dose have been reported in patients receiving systemic quinolones, including ofloxacin.

Nervous System Disorders

Not known: Dizziness

Eye Disorders

Common: Eye irritation; Ocular discomfort

Not known: Keratitis; Conjunctivitis; Vision blurred; Photophobia; Eye oedema; Foreign body sensation in

eyes; Lacrimation increased; Dry eye; Eye pain; Ocular hyperaemia; Hypersensitivity (including Eye

pruritus and Eyelid pruritus).

Cardiac disorders

Not known: ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk

factors for QT prolongation), ECG QT prolonged

Gastrointestinal Disorders

Not known: Nausea

Skin and Subcutaneous Tissue Disorders

Not Known: Periorbital oedema, Facial oedema

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.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via the pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS): https://pv.pharmacyboardkenya.org

4.9 Overdose

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals, anti-infectives, fluoroquinolones

ATC code: S01AE01.

Ofloxacin is a synthetic fluorinated 4-quinolone antibacterial agent with activity against a broad spectrum of Gram negative and to a lesser degree Gram positive organisms.

Ofloxacin has been shown to be active against most strains of the following organisms both in vitro and clinically in ophthalmic infections. Clinical trial evidence of the efficacy of ONAFLOX (Ofloxacin

Ophthalmic Solution USP 0.3% w/v) against S. pneumoniae was based on a limited number of isolates.

Gram-negative bacteria: Acinetobacter calcoaceticus var. anitratum, and A. calcoaceticus var. iwoffi;

Enterobacter Sp. including E. cloacae; Haemophilis Sp, including H. influenza and H. aegyptius; Klebsiella

Sp., including K. Pneumoniae; Moraxella Sp., Morganella morganii; Proteus Sp., including P. Mirabilis;

Pseudomonas Sp.; including P. Aeruginosa, P. cepacia, and P. fluoroscens; and Serratia Sp., including S. marcescens.

Gram-positive bacteria: Bacillus Sp.; Corynebacterium Sp.; Micrococcus Sp.; Staphylococcus Sp., including

S. aureus and S. epidermidis; Streptococcus Sp., including S. Pneumoniae, S. viridans and Beta-haemolytic.

The primary mechanisms of action is through inhibition of bacterial DNA gyrase, the enzyme responsible for maintaining the structure of DNA.

Ofloxacin is not subject to degradation by beta-lactamase enzymes nor is it modified by enzymes such as aminoglycoside adenylases or phosphorylases, or chloramphenicol acetyltransferase.

5.2 pharmacokinetics properties

After ophthalmic instillation, ofloxacin is well maintained in the tear-film.

In a healthy volunteer study, mean tear film concentrations of ofloxacin measured four hours after topical dosing (9.2 µg/g) were higher than the 2µg/ml minimum concentration of ofloxacin necessary to inhibit 90%

of most ocular bacterial strains (MIC90) in-vitro.

Maximum serum ofloxacin concentrations after ten days of topical dosing were about 1000 times lower than those reported after standard oral doses of ofloxacin, and no systemic side-effects attributable to topical

ofloxacin were observed.

5.3 Preclinical safety data

There are no toxicological safety issues with this product in man as the level of systemic absorption from topical ocular administration of ofloxacin is minimal.

Animal studies in the dog have found cases of arthropathy in weight bearing joints of juvenile animals after high oral doses of certain quinolones. However, these findings have not been seen in clinical studies and

their relevance to man is unknown.

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium Chloride Solution USP

Sodium Chloride BP

Disodium Edetate BP

Glacial Acetic Acid USP

Polysorbate (Tween 80) USP

Sodium Hydroxide BP

Water for Injection

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months from the date of Manufacturing (unopened).

Discard after 1 month (30 days) after first opening.

6.4 Special precautions for storage

Do not store above 30°C. Protect from direct sunlight.

6.5 Nature and contents of container

5 ml LDPE dropper bottle with white cap and nozzle packed in a carton along with leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

DAWA LIMITED
P.O BOX 16633-00620 NAIROBI

8. Marketing authorisation number

H2025/CTD11917/26009

9. Date of first authorisation/renewal of the authorisation

2025 July 17

10.Date of revision of the text

2025 July 17