1.3.1 South African Product Information

1.3.1.1 Professional Information (PI)

1.3.1.1.1 Professional Information – Approved

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

OFLOXACIN 0,3 % w/v Eye Drops FDC (Eye Drops) 0.3% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

OFLOXACIN 0,3 % w/v Eye Drops FDC, 0.3% w/v 5 mL.

Each vial contains Ofloxacin 0.3% w/v is equivalent to 3mg/mL Ofloxacin

Excipients with known Effect:

Benzalkonium Chloride (NF) 0.005% w/v (As preservative)

For full list of excipients, (See section 6.1)

3. PHARMACEUTICAL FORM

OFLOXACIN 0,3 % w/v Eye Drops FDC is a clear, light yellow solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

OFLOXACIN 0,3 % w/v Eye Drops FDC is indicated for the topical treatment of external ocular infections caused by ofloxacin susceptible bacteria.

4.2. Posology and method of administration

The recommended dosage for the treatment of bacterial conjunctivitis is:

One drop every two to four hours for the first two days, then four times daily in the affected eye(s).

Treatment should not exceed ten days.

The recommended dosage regimen for the treatment of bacterial corneal ulcer is:

Days 1 and 2: Instil one to two drops into the affected eye every 30 minutes, while awake.

Awaken at approximately four and six hours after retiring and instil one to two drops.

Days 3 through 7 to 9: Instil one or two drops hourly, while awake.

Days 7 to 9 through treatment completion: Instil one to two drops, four times daily.

Method of administration: For ocular use

4.3. Contraindications

- **OFLOXACIN 0,3 % w/v Eye Drops FDC** is contraindicated in patients hypersensitive to ofloxacin or any of its components (see section 6.1).
- Since systemic quinolones have been shown to cause arthropathy in immature animals, it is recommended that **OFLOXACIN 0,3 % w/v Eye Drops FDC** not be used by pregnant or lactating women (see section 4.6).
- Safety and effectiveness in infants below the age of one year have not been established (see section 4.4.

4.4. Special warnings and precautions for use

OFLOXACIN 0,3 % w/v Eye Drops FDC is not for injection.

Serious and occasionally fatal hypersensitivity (anaphylactic/anaphylactoid) reactions, some following the first dose, have been reported in patients receiving systemic 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 **OFLOXACIN 0,3 % w/v Eye Drops FDC** occurs, discontinue the product and contact your medical practitioner. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

Use **OFLOXACIN 0,3 % w/v Eye Drops FDC** with caution in patients who have exhibited sensitivities to other quinolone antibacterial medicines.

When using **OFLOXACIN 0,3 % w/v Eye Drops FDC** eye drops the risk of rhinopharyngeal passage, which can contribute the occurrence and the diffusion of bacterial resistance, should be considered.

Prolonged use may result in overgrowth of non-susceptible organisms. If superinfection

occurs, or if clinical improvement is not noted within a reasonable period, discontinue use and institute appropriate therapy.

Stevens-Johnson syndrome, toxic epidermal necrolysis and anaphylactic reaction/shock have been reported in patients receiving ofloxacin as in **OFLOXACIN 0,3 % w/v Eye Drops FDC.**

Corneal precipitates, and corneal perforation in patients with pre-existing corneal epithelial defect or corneal ulcer, have been reported during treatment with ofloxacin as in **OFLOXACIN 0,3 % w/v Eye Drops FDC**. Long-term, high-dose use of fluoroquinolones in experimental animals has caused lenticular opacities. However, this effect has not been reported in human patients.

OFLOXACIN 0,3 % w/v Eye Drops FDC contains the preservative benzalkonium chloride, which may cause eye irritation.

As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmic preparations cannot be excluded, regular ophthalmological examination is required.

Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

The use of **OFLOXACIN 0,3 % w/v Eye Drops FDC** while wearing soft contact lenses is not recommended.

Benzalkonium chloride may be absorbed by soft contact lenses and discolour them.

Contact lenses should be removed prior to installation and may be reinserted 15 minutes following administration.

Elderly use

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

Paediatric use

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

The use of **OFLOXACIN 0,3 % w/v Eye Drops FDC** eye drops in neonates with

ophthalmia neonatorum caused by *Neisseria gonorrhoeae* or *Chlamydia trachomatis* is not recommended as it has not been evaluated in such patients. Neonates with ophthalmia neonatorum should receive appropriate treatment for their condition, e.g. systemic treatment in cases caused by *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.

Ofloxacin have been shown to cause arthropathy in immature animals after oral administration; however, topical ocular administration of **OFLOXACIN 0,3 % w/v Eye Drops FDC** to immature animals has not shown any arthropathy (see section 4.3).

4.5. Interaction with other medicines and other forms of interaction

It has been shown that the systemic administration of some quinolones inhibits the metabolic clearance of caffeine and theophylline. 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 central nervous system toxicity with systemic dosing of fluoroquinolones when used concomitantly with systemic non-steroidal anti-inflammatory drugs (NSAIDs), this has not been reported with the concomitant systemic use of NSAIDs and ofloxacin.

No interaction studies with **OFLOXACIN 0,3 % w/v Eye Drops FDC** have been performed.

4.6. Fertility, pregnancy and lactation

Pregnancy

Since systemic quinolones have been shown to cause arthropathy in immature animals, it is recommended that **OFLOXACIN 0,3 % w/v Eye Drops FDC** not be used in pregnant women (see section 4.3).

Breastfeeding

Ofloxacin and other quinolones are excreted in breast milk, therefore there is a potential for harm to nursing infants. **OFLOXACIN 0,3 % w/v Eye Drops FDC** is not recommended for breastfeeding women and temporary discontinuation of breastfeeding should be considered (see section 4.3).

4.7. Effects on ability to drive and use machines

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

Since a small amount of **OFLOXACIN 0,3 % w/v Eye Drops FDC** is systemically absorbed after topical administration, adverse events reported with systemic use could possibly occur.

Tabulated list of adverse reactions

System Organ Class	**Frequency**
Nervous system disorders	
Dizziness	Frequency unknown
Eye disorders	
Eye irritation, ocular discomfort	Frequent
Keratitis, conjunctivitis, vision blurred, photophobia, eye oedema, foreign body sensation in eyes, lacrimation increased, dry eye, eye pain, eye pruritus, eyelids pruritus, ocular hyperaemia, periorbital oedema (including eyelid oedema)	Frequency unknown
Gastrointestinal disorders	
Nausea	Frequency unknown
Skin and subcutaneous tissue disorders	
Stevens-Johnson syndrome	Frequency unknown
Immune system disorders	
Hypersensitivity reactions, anaphylactic reactions (such as angioedema, dyspnea, anaphylactic shock, oropharyngeal swelling	Frequency unknown

and tongue swollen) and allergic dermatitis	
General disorders and administration site conditions	
Facial oedema	Frequency unknown

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 medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9. Overdose

In the event of accidental ingestion of 10 ml of **OFLOXACIN 0,3 % w/v Eye Drops FDC**, 30 mg of ofloxacin would be ingested. This amount does not appear to be clinically significant in terms of overdosage.

However, there would be an increased potential for systemic reactions (see section 4.4).

In the event of a topical overdosage, flush the eye with a topical ocular irrigant.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: A. 15.1 Ophthalmic preparations with antibiotics.
ATC code: J01MA01

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 is bacteriocidal at concentrations equal to or slightly greater than inhibitory concentrations.

The primary mechanism of action is through inhibition of bacterial DNA gyrase, the enzyme responsible for maintaining the structure of DNA. Ofloxacin possesses an

additional bacteriocidal mechanism, which is not dependent on protein or RNA synthesis. It is bacteriocidal in both replicating and non-replicating stages of bacterial growth.

Cross-resistance has been observed between ofloxacin and other fluoroquinolones.

The safety and effectiveness of ofloxacin in treating ophthalmologic infections due to the following microorganisms have not been established in adequate and well-controlled clinical trials:

Aerobes, Gram-Positive	
Enterococcus faecalis	*Streptococcus mitis*
Listeria monocytogenes	*Staphylococcus simulans*
Staphylococcus capitis	*Staphylococcus hominus*
Streptococcus pyogenes	
Aerobes, Gram-Negative	
Acinetobacter calcoaceticus var. anitratum	*Klebsiella pneumonia*
Acinetobacter calcoaceticus var. wolffii	*Moraxella (branhameila) catarrhalis*
Citrobacter diversus	*Moraxella lacunata*
Citrobacter freundii	*Morganella morganii*
Enterobacter aerogenes	*Neisseria gonorrhoeae*
Enterobacter agglomerans	*Pseudomonas acidovorans*
Escherichia coli	*Pseudomonas fluorescens*
Haemophilus parainfluenzae	*Shigella sonnei*
Klebsiella oxytoca	
Other	
Chlamydia trachomatis	

5.2. Pharmacokinetic properties

Systemic absorption of ofloxacin was detected following ocular administration. In man, the systemic absorption of ofloxacin was in the low ng/mL range.

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 2 µg/g minimum concentration of ofloxacin necessary to inhibit 90 % of most ocular bacterial strains (MIC_{90}) *in vitro*.

5.3. Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium Chloride USP

Benzalkonium Chloride NF

Hydrochloric Acid NF

Sodium Hydroxide NF

Water for Injection USP

6.2. Incompatibilities

Not Applicable

6.3. Shelf life

Shelf-life for unopened LDPE bottle: 24 months and

Opened LDPE bottle: Discard 28 days after first opening.

6.4. Special precautions for storage

Store at temperature below 25°C. Protect from light.

Discard remaining contents 28 days after opening.

6.5. Nature and contents of container

OFLOXACIN 0,3 % w/v Eye Drops FDC 5 mL is a clear, light yellow solution.

It is available in 5.0 ml LDPE labelled bottle with insert cap assembly comprising of white colored, HDPE screw cap over a LDPE nozzle with tamper evident LDPE dust cover, sealing the bottle cap. One such bottle is packed in a carton with pack insert.

6.6. Special precautions for disposal and other handling

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

FDC SA (PTY) LTD
Unit J3,Willows Office Park
Farm Road, The Willows,
Pretoria 0081,
South Africa

8. REGISTRATION NUMBER(S)

57/15.1/0380

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 SEPTEMBER 2025

10. DATE OF REVISION OF TEXT

Not Applicable