1.5 Product Information

1.5.1 Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Floxsol® 0.3 % eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For 5 ml:
Norfloxacin 15 mg

Excipients: benzalkonium chloride solution (preservative)
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Local antibacterial treatment of severe ocular infections (severe conjunctivitis, keratitis and corneal ulcers) caused by organisms sensitive to norfloxacin. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2. Posology and method of administration

The usual posology is one to two drops 4 times a day in the infected eye(s). Depending on the infection severity, one or two drops can be prescribed every 2 hours during the first day of treatment.
For the bottle opening instructions, see section 6.6.

4.3. Contraindications

This medicine should not be used in the following cases:

- Hypersensitivity to one of the components,
- Hypersensitivity to quinolones.

In general, this medicine should not be used during lactation.

4.4. Special warnings and precautions for use

Do not inject nor swallow.

- The eye drops should not be injected in peri- nor intra-ocular routes.
- The appearance of a resistance or selection of some resistant strains is possible, especially in long term treatment.
- A cross-resistance between quinolones might occur.
- Treatment should be stopped as soon as first signs of skin rash or hypersensitivity reaction appear.
- When instilling, do not touch the eye with the nozzle,
- During the treatment, wearing contact lenses is not recommended: because lenses could absorb some components of the eye drops, due to benzalkonium chloride.

- In case of simultaneous administration of other eye drops, an interval of 15 minutes should be respected.

4.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been conducted with eye drops solution containing norfloxacin.

4.6. Pregnancy and lactation

Pregnancy

Taking into account the small administered doses, the use of these eye drops can be considered during pregnancy, if needed.
With norfloxacin administered by systemic route, studies performed on the animal have not shown any teratogenic effect, and clinical data are still insufficient.
Articular disorders have been described in children treated with quinolones but no case of secondary arthropathy after *in utero* exposure has been reported.

Lactation

Norfloxacin, when administered by general route, is secreted into mother's milk. As a consequence, with the lack of data after ocular administration, it is advised not to use these eye drops during the lactation period.
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4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

After ocular application:

Most frequently:

- Burning sensation
- Eye itching

More rarely:

- Conjunctival hyperaemia
- Chemosis
- Photophobia
- Bitter taste after instillation

Very rarely:

- corneal staining.

Due to benzalkonium chloride, risk of contact eczema and of irritation.

<u>Reporting of suspected adverse reactions</u>

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 via the national reporting system.

4.9. Overdose

No overdose has been reported with eye drops solution containing norfloxacine.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Antibiotic – quinolone ATC code: S01AX12

Norfloxacin is a quinolone antibiotic, it inhibits the bacterial DNA synthesis and has a bacteriostatic activity.

SUSPECTIBILITY

The prevalence of acquired resistance may vary geographically and with time for some species. Local information on resistance, particularly when treating severe infections, is therefore helpful.

The critical concentrations discriminate the sensitive strains from the strains of intermediate sensitivity, and the latter from the resistant strains.

Categories	**Frequency of acquired resistance in Europe, as indication**
SENSITIVES SPECIES	
Gram positive Aerobics	
Staphylococcus meti-S	0 - 16 %
Gram negative Aerobics	
Acinetobacter baumannii	50 - 88 %
Citrobacter freundii	0 - 36 %
Citrobacter koseri	0 - 12 %
Enterobacter aerogenes	0 - 65 %
Enterobacter cloacae	0 - 27 %
Escherichia coli	0 - 15 %
Klebsiella oxytoca	0 - 13 %
Klebsiella pneumoniae	0 - 15 %
Morganella morganii	0 - 15 %
Neisseria gonorrhoeae	
Proteus mirabilis	0 - 17 %
Proteus vulgaris	
Providencia rettgeri	
Providencia stuartii	0 - 71 %
Pseudomonas aeruginosa	0 - 45 %
Serratia marcescens	0 - 30 %
RESISTANT SPECIES	
Gram positive Anaerobics	
Enterococcus	

Staphylococcus meti-R *	
Anaerobics	
Gram positive anaerobic bacteria except some *Clostridium perfringens* strains	
All Gram negative anaerobic bacteria	

5.2. Pharmacokinetic properties

In animal models, the lachrymal concentration has been shown to be greater than the MIC after instillation of one drop.
After unique or repeated administrations, it has not been possible to detect norfloxacine in the blood 3 hours after administration.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium chloride, disodium edetate, benzalkonium chloride solution, glacial acetic acid, water for injections.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Store at room temperature (below 30°C). Protect from light. Do not use after one month after the bottle opening.

6.5. Nature and contents of container

The bottle is made of clear low density polyethylene.
Plastic cap of white low density polyethylene.
Bottle of 5 ml.

6.6. Special precautions for disposal and other handling

Bottle opening:

1. With the spike: tighten the cap on the nozzle.
2. The spike in the cap will pierce the tip of the bottle.
3. Dispense drops with gentle pressure. Replace the cap after every use.

7. CATEGORY OF DISTRIBUTION:

☐ Over-the counter medicine ☒ Prescription only medicine

8. MARKETING AUTHORISATION HOLDER:

Exphar sa
Zoning Industriel de Nivelles Sud, zone II – Av. Thomas Edison 105 – 1402 Thines (Belgium)

Phone +32 (0)67 68 84 05
Fax +32 (0)67 68 84 19

9. MANUFACTURER:

AHLCON PARENTERALS (INDIA) LIMITED
SP-918, Phase-III, Bhiwadi-301019,
Dist.: Alwar (Rajasthan), India

10. UPDATE DATE:

January 2019

1.5.2 Container labelling

Information to appear on the immediate packaging (label on LPDE bottle)
Name of drug product: present
Pharmaceutical form and Statement of the active substances: present
Name and address of the manufacturer: present
Name and address of the marketing authorization holder (applicant): present
Batch number: present
Manufacturing date: present
Expiry date: present

Information to appear on the outer packaging
Name of drug product: present
Pharmaceutical form and Statement of the active substances: present
Statement "*Read the package leaflet before use*." present
Special warnings that the drug product must be stored out of the reach and sight of children: present
Storage conditions: present
Name and address of the manufacturer: present
Name and address of the marketing authorization holder (applicant): present
Batch number: present
Manufacturing date: present
Expiry date: present
Advice on general classification for distribution: present (Prescription Only Medicines)