PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

[Pr]OCUFLOX®

Ofloxacin ophthalmic solution

Solution, 0.3% w/v, for ophthalmic use

USP

Antibacterial Agent (ATC code: S01AE01)

AbbVie Corporation

8401 Trans-Canada Highway

St-Laurent, Quebec

H4S 1Z1

Date of Initial Authorization:
NOV 25, 1994

Date of Revision:
AUG 15, 2022

Submission Control Number: 266079

RECENT MAJOR LABEL CHANGES

None at the time of the most recent authorization.	

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

OCUFLOX® (ofloxacin) is indicated for the treatment of conjunctivitis when caused by susceptible strains of the following bacteria:

Gram Positive Bacteria

- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Streptococcus pneumoniae*

Gram Negative Bacteria

- *Haemophilus influenza*

To reduce the development of drug-resistant bacteria and maintain the effectiveness of OCUFLOX and other antibacterial drugs, OCUFLOX should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

1.1 Pediatrics

Pediatrics (< 18 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of OCUFLOX in pediatric patients has not been established. Therefore, Health Canada has not authorized an indication for pediatric use. See 7.1.3 Pediatrics.

1.2 Geriatrics

Geriatrics (> 65 years of age): No comparative data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

2 CONTRAINDICATIONS

OCUFLOX is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING. A history of hypersensitivity to other quinolones also contraindicates use of ofloxacin.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

Prolonged use of OCUFLOX may result in overgrowth of nonsusceptible organisms, including fungi. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. If the infection is not improved within 7 days, cultures should be obtained to guide further treatment. If such infections occur, discontinue use and institute alternative therapy.

4.2 Recommended Dose and Dosage Adjustment

One to two drops every two to four hours for the first two days, and then four times daily in the affected eye(s) for 8 days.

Health Canada has not authorized an indication for pediatric use.

4.4 Administration

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures to avoid eye injury and contamination of the eye drops.

The preservative in OCUFLOX, benzalkonium chloride, may be absorbed by and cause discoloration of soft contact lenses. OCUFLOX should not be administered while wearing soft contact lenses. Contact lenses should be removed prior to instillation of OCUFLOX and may be reinserted 15 minutes following its administration.

4.5 Missed Dose

Patients should be instructed to instill the drops as soon as they remember, and then to return to their regular routine.

5 OVERDOSAGE

In the event of accidental ingestion of 10 mL of OCUFLOX, 30 mg of ofloxacin would be ingested. Although this amount may not be clinically significant in terms of overdosage, there could be an increased potential for systemic reactions.

A topical overdosage of OCUFLOX is considered a remote possibility. Discontinue medication if heavy or protracted use is suspected. In the event of a topical overdose, flush the eye with a topical ocular irrigant.

For management of a suspected drug overdose, including accidental ingestion, contact your regional Poison Control Centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
ophthalmic	solution, 0.3% w/v	benzalkonium chloride 0.005% w/v (as preservative), hydrochloric acid and/or sodium hydroxide to adjust the pH, purified water and sodium chloride

OCUFLOX is available for topical ophthalmic administration as a 0.3% w/v sterile solution in the unopened package and is supplied in plastic dropper bottles of 5 mL.

7 WARNINGS AND PRECAUTIONS

General

OCUFLOX is not for injection into the eye.

Contact of the tip of the dispensing container with the eye or surrounding structures may lead to eye injury and contamination of eye drops.

The use of ofloxacin with other products may lead to drug interactions. For established or potential drug interactions. See 9 DRUG INTERACTIONS.

Driving and Operating Machinery

As with any ocular medication, if transient blurred vision occurs at instillation, the patient should wait until the vision clears before driving or using machinery.

Immune

Hypersensitivity

Use OCUFLOX with caution in patients who have exhibited sensitivities to other quinolone antibacterial agents. Only a few patients had a history of hypersensitivity reactions. Serious anaphylactic reactions may require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids and airway management, including intubation, should be administered as clinically indicated. OCUFLOX should be discontinued if an allergic reaction occurs.

Hypersensitivity reactions including angioedema, dyspnea, anaphylactic reaction/shock, oropharyngeal swelling, Stevens-Johnson syndrome, tongue swollen and toxic epidermal necrolysis have been reported with OCUFLOX. See 8.5 Post-Market Adverse Reactions.

In patients receiving systemic quinolone therapy, serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching.

Musculoskeletal

Tendon inflammation and rupture may occur with systemic fluoroquinolone therapy including ofloxacin, particularly in elderly patients and in those treated concurrently with corticosteroids. Treatment with OCUFLOX should be discontinued at the first sign of tendon inflammation.

The systemic administration of quinolones has led to lesions or erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species. Ofloxacin, administered systemically at 10 mg/kg/day in young dogs (equivalent to 150 times the maximum recommended daily adult ophthalmic dose), has been associated with these types of effects.

Ophthalmologic

Corneal precipitates, and corneal perforation in patients with pre-existing corneal epithelial defect/corneal ulcer, have been reported during treatment with topical ophthalmic ofloxacin. However, a causal relationship has not been established.

Sensitivity/Resistance

Prescribing OCUFLOX in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant organisms. See 4.1 Dosing Considerations.

7.1 Special Populations

7.1.1 Pregnant Women

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, OCUFLOX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

7.1.2 Breastfeeding

Because ofloxacin taken systemically is excreted in breast milk, and there is potential for harm to nursing infants, a decision should be made whether to temporarily discontinue nursing during therapy or not to administer the drug, taking into account the importance of the drug to the mother.

7.1.3 Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4 Geriatrics

Geriatrics (> 65 years of age): No comparative data are available with topical ofloxacin therapy in this age category versus other age groups.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Since a small amount of ofloxacin is systemically absorbed after topical administration, adverse reactions reported with systemic use could possibly occur.

Ophthalmic Use of Ofloxacin:

The most frequently reported drug-related adverse reaction was transient ocular burning or discomfort. Other reported reactions were ocular irritation, redness, stinging, itching, photophobia, tearing and dryness. One report of dizziness, one report of headache and one spontaneous report of toxic epidermal necrolysis have also been received.

Systemic Effects of Ofloxacin:

As with all topical ophthalmic drugs, the potential exists for systemic effects. Ofloxacin used systemically has rarely been associated with serious side effects. Serious reactions reported for systemic dosing of ofloxacin include convulsions and increased intracranial pressure. For the oral dosage form of ofloxacin, gastrointestinal symptoms, mainly nausea/vomiting, pain/discomfort, diarrhea and anorexia, were reported most frequently, followed by central nervous system events (such as dizziness and headaches) and dermatological or hypersensitivity reactions. Additional effects

seen with systemic dosing of ofloxacin and other fluoroquinolones are QT prolongation, exacerbation of myasthenia gravis symptoms, tendinitis and tendon rupture. Photophobia was reported rarely in clinical trials with systemic ofloxacin and phototoxicity has been reported with other drugs in this class.

8.5 Post-Market Adverse Reactions

The following adverse reactions have been identified during post marketing use of OCUFLOX in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made.

Eye disorders: Conjunctivitis, dry eye, eye edema, eye pain, foreign body sensation in eyes, hypersensitivity (including eye pruritus, eyelids pruritus), keratitis, lacrimation increased, ocular hyperemia, periorbital edema (including eyelid edema), photophobia, vision blurred.

Gastrointestinal disorders: Nausea

Immune system disorders: Hypersensitivity (including angioedema, dyspnea, anaphylactic reaction/shock, oropharyngeal swelling, facial edema, Stevens-Johnson syndrome, tongue swollen, and toxic epidermal necrolysis).

Nervous system disorders: Dizziness

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

Specific drug interaction studies have not been conducted with OCUFLOX.

9.3 Drug-Behavioural Interactions

No formal drug-behavioural interaction studies were conducted with OCUFLOX.

9.4 Drug-Drug Interactions

No formal drug-drug interaction studies were conducted with OCUFLOX.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

The primary mechanism of action of ofloxacin appears to be the specific inhibition of DNA gyrase (topoisomerase II). This enzyme is responsible for the negative supercoiling of bacterial DNA and

consequently for its topological configuration, governing functions such as RNA transcription, protein synthesis, DNA replication and repair functions.

10.2 Pharmacodynamics

The general pharmacological activities of ofloxacin have been studied in several mammalian species. At the maximum therapeutic dose levels, no effects on the central nervous system, cardiovascular and respiratory system, autonomic response or smooth and skeletal muscle were observed. These results are consistent with the infrequent occurrence of serious adverse effects with systemic clinical use of ofloxacin. Any pharmacological effects observed were frequently associated with doses at least 1000 times the anticipated maximal daily ocular dose.

10.3 Pharmacokinetics

Human

Systemic Pharmacokinetics:
Absorption

In systemic pharmacokinetic studies following oral dosing, ofloxacin was rapidly absorbed into the blood stream, with peak serum concentrations (C_{max}) increasing in a dose-related manner. There was no significant increase in peak serum ofloxacin concentration following multiple oral administrations.

Following administration of 0.3% ofloxacin topically 4 times daily to the eyes of 30 normal healthy adults, mean serum plateau levels of 0.97 ng/mL after the first dose (day 1) and 1.66 ng/mL after the 41st dose (day 11) were achieved. The maximum serum level from multiple topical dosing (1.9 ng/mL) was approximately 2000-fold less than the maximum serum level achieved from treatment with a single 300 mg oral dose (4620 ng/mL). Time to reach 90% of the plateau serum concentration was 0.9 hours after the initial dose on Day 1 compared with 0.5 hours on Day 11, indicating a change in the rate of systemic absorption from ophthalmic dosing.

Metabolism and Elimination

The metabolism of ofloxacin was studied in five healthy adult male volunteers receiving a single oral dose of a 600 mg mixture of ofloxacin and deuterium-labeled ofloxacin. Ofloxacin and its metabolites were identified, confirmed and quantified using thin layer chromatography, UV spectrophotometry, high pressure liquid chromatography, fluorometry and other methods. Urinary concentration of ofloxacin increased to a maximum of 686.6 mcg/mL at 2-4 hours after dosing and was maintained above 273.9 mcg/mL 4-24 hours after dosing.

Cumulative urinary excretion of ofloxacin was 79.5% at 48 hours after dosing. Urinary concentrations of desmethyl ofloxacin were 10.4 and 6.6 mcg/mL at 2-4 and 12-24 hours after dosing, concentrations of ofloxacin N-oxide were 7.8 and 2.7 mcg/mL at 2-4 and 12-24 hours after dosing. Urinary concentrations of these metabolites were less than 2.5% of the excreted concentration of ofloxacin at each time interval.

The results of this study indicate that ofloxacin exists mainly as parent drug in vivo, and is excreted mainly unchanged in the urine in humans.

Ocular Pharmacokinetics:

Absorption

Administering 0.3% ofloxacin topically 4 times daily to the eyes of 30 normal healthy adults resulted in tear ofloxacin concentrations ranging from 1.2 to 22 mcg/g (mean 9.2 mcg/g) four hours after the first dose on the eleventh day of treatment. The mean tear concentration varied between 5.7 and 31 mcg/g during the time period between 5 and 40 minutes after instillation of the second dose on day 11.

11 STORAGE, STABILITY AND DISPOSAL

OCUFLOX is sterile in the unopened package, and is stable for 24 months when stored at 15 to 25°C. Keep bottle tightly closed when not in use.

Keep out of reach and sight of children.

12 SPECIAL HANDLING INSTRUCTIONS

There are no special handling instructions.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

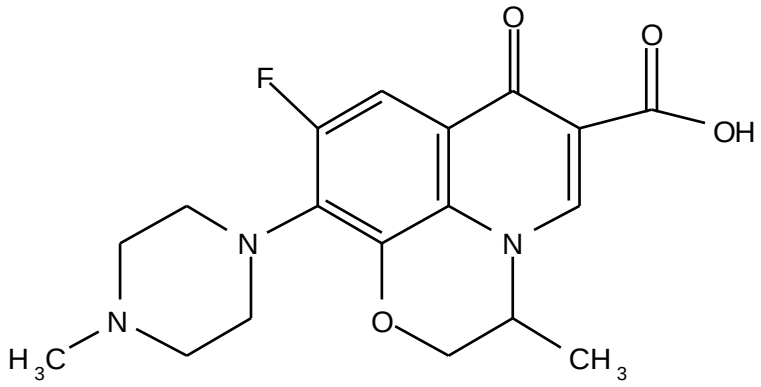
Drug Substance

Proper name: Ofloxacin (INN, USAN, BAN)

Chemical name: (+)-9-Fluoro-2,3-dihydro-3-methyl-10- (4-methyl-l-piperazinyl)-7-oxo-7H-pyrido [1,2,3-de]-1,4 benzoxazine-6-carboxylic acid. CAS-82419-36-1

Molecular formula and molecular mass: $C_{18}H_{20}FN_3O_4$ and 361.37 g/mol

Structural formula:



Physicochemical properties: Cream to pale yellow crystalline powder. Melting point of 260-270°C (with decomposition). Soluble in glacial acetic acid, sparingly soluble in chloroform, slightly soluble in water, methanol, ethanol or acetone.

14 CLINICAL TRIALS

14.1 Clinical Trials by Indication

No clinical trial information is available for this product.

15 MICROBIOLOGY

Ofloxacin has in vitro activity against both gram-positive and gram-negative organisms. The primary mechanism of action of ofloxacin appears to be the specific inhibition of DNA gyrase (topoisomerase II). This enzyme is responsible for the negative supercoiling of bacterial DNA and consequently for its topological configuration, governing functions such as RNA transcription, protein synthesis, DNA replication and repair functions.

In a four-site study using a modified tube-dilution procedure, the in vitro activity of ofloxacin was evaluated against 419 ocular bacterial isolates of 55 species, in media supplemented with Ca++ and Mg++. Table 2 includes MIC values for five major ocular pathogens.

Table 2 – In Vitro Antibacterial Activity of Ofloxacin Against Five Major Ocular Pathogens in Studies Conducted in the USA

Minimum Inhibitory Concentration Range (mcg /mL)			
ORGANISMS (Number)	MINIMUM	MAXIMUM	MIC_{90}
Staphylococcus aureus (79)[1]	0.125	4	0.5
Staphylococcus epidermidis (68)	0.125	16	0.5
Pseudomonas aeruginosa (68)	0.25	8	4
Streptococcus pneumoniae (21)	0.125	2	2
Haemophilus influenzae (18)	0.25	4	4

1 Number of isolates in parentheses.

In Vitro Study of Ocular Isolates from Japanese Clinical Studies: An in vitro evaluation of the activity (MIC) of ofloxacin was conducted using a broth dilution technique, with 2,678 organisms cultured from the infected eyes of subjects enrolled in three clinical trials conducted in the clinics of public hospitals in Japan. The minimum concentrations necessary to inhibit 90% of the strains (MIC_{90}) was 3.13 mcg/mL or less for all species tested except various *Pseudomonas species* and for *Streptococcus sanguis* isolates. MIC_{90} values for ocular isolates are listed in Table 3.

Table 3 – Ocular Isolates from Japanese Clinical Studies (Ofloxacin MIC_{90} Values)

Bacterial species	**N**	**MIC_{90} (mcg/mL)**
Acinetobacter var. anitratum	44	0.39
Acinetobacter var. lwoffii	33	0.39
Alcaligenes denitrificans	10	1.56
Alcaligenes faecalis	24	0.78
Bacillus species	111	0.20
Corynebacterium species	379	3.13
Enterobacter species (3: cloacae, aerogenes and *agglomerans)*	44	0.20
Escherichia coli	8	0.10
Flavobacterium species	22	3.13
Haemophilus aegyptius	59	0.20
Haemophilus influenzae	44	0.20
Klebsiella species (3: oxytoca, pneumoniae and *ozaenae)*	21	0.10
Micrococcus species	73	1.56
Moraxella species	25	0.20
Propionibacterium acnes	66	1.56

Bacterial species	**N**	**MIC_{90} (mcg/mL)**
Proteus species (5: including mirabilis, vulgaris and *morganii)*	30	0.20
Pseudomonas acidovorans	21	1.56
Pseudomonas aeruginosa	11	1.56
Pseudomonas alcaligenes	32	3.13
Pseudomonas cepacia	75	1.56
Pseudomonas fluorescens	44	0.78
Pseudomonas maltophilia	36	3.13
Pseudomonas paucimobilis	31	0.39
Pseudomonas putida	29	0.78
Pseudomonas species (6: including vescularis and *diminuta)*	16	50.5
Pseudomonas stutzeri	20	0.78
Serratia marcescens	46	0.39
Staphylococcus aureus	335	0.39
Staphylococcus epidermidis	735	0.39
Streptococcus beta-hemolytic	17	1.56
Streptococcus faecalis (Enterococcus faecalis)	14	1.56
Streptococcus pneumoniae	101	3.13
Streptococcus sanguis	96	6.25
Streptococcus species (inc. pyogenes)	35	3.13

Ofloxacin is bactericidal (3 log reduction in 1-2 hours) at 1 to 4 times the MIC.

Susceptibility Testing: Laboratory results from standard single disc susceptibility tests with a 5 mcg ofloxacin disc should be interpreted according to the following criteria:

Zone Diameter (mm)	**Interpretation**
≥ 16	Susceptible
13-15	Moderately susceptible
≤ 12	Resistant

Bacterial Resistance: The development of resistance to ofloxacin appears to be related to modification of bacterial DNA gyrase or to permeability changes in the bacterial outer cell membrane. Resistance to ofloxacin in vitro usually develops slowly (multiple-step mutation). Plasmid-mediated resistance or enzymatic inactivation have not been reported. Cross resistance among the fluoroquinolones has been observed, but development of clinically significant cross resistance to nonquinolone drugs appears to be uncommon.

16 NON-CLINICAL TOXICOLOGY

General Toxicology: Ofloxacin was administered in repeated doses in rats, dogs and monkeys for periods of up to 52 weeks. The most notable effect seen in these studies was the effect of ofloxacin on articular cartilage in immature animals. Several special studies of the effects of ofloxacin on articular cartilage were conducted. Orally administered ofloxacin had no effect on articular cartilage in mature rats and dogs. However, in immature animals, daily treatment for 7 days with ofloxacin at 300 mg/kg (but not at 100 mg/kg) in rats and at 10 mg/kg (but not at 5 mg/kg) in dogs produced arthropathic effects.

Studies were conducted to elucidate the mechanism of action, onset, recovery and effects of age and dosage on arthropathy associated with ofloxacin and other quinolones. The studies indicate that toxicity to weight-bearing joints is dose-related at oral dosages far higher than topical ophthalmic dosages and that toxic effects are seen only in growing animals. Damage to joints was partially repairable, although some damage appeared to be permanent. Damage such as erosion of the cartilage occurs in weight-bearing joints where "bubbles" (inconsistencies in growth) have developed in the cartilage.

Carcinogenicity: Because ophthalmic ofloxacin solution is not intended for chronic use, specific carcinogenicity studies were not carried out. Chronic ophthalmic toxicity studies showed no evidence of carcinogenic potential.

Genotoxicity: Predictive tests included: Ames test, REC-Assay, micronucleus test, sister chromatid exchange in cultured Chinese hamster cells and in human peripheral blood lymphocytes, unscheduled DNA repair synthesis test, dominant lethal assay, and in vitro and in vivo cytogenetic tests.

Extensive tests for mutagenicity showed no mutagenic potential. Mutagenicity tests were conducted with ofloxacin by a number of techniques, both in vitro and in vivo. Dose-related damage to the DNA of *Bacillus subtilis* was seen in tests using the REC assay technique. The damage to *B. subtilis* DNA is consistent with the mechanism of action of the drug in bacteria and is not predictive of mutagenic potential in eukaryotic cells. No evidence of significant mutagenic effects was seen in other tests in a variety of eukaryotic somatic or germ cells.

Human blood samples were examined after oral dosing with 200 mg/day of ofloxacin for 1 to 10 weeks (equivalent to 50 times the maximum recommended daily ophthalmic dose). No chromosome-damaging effect was seen in the peripheral blood leukocytes.

Reproductive and Developmental Toxicology: The effects of ofloxacin on fertility, reproduction and fetal toxicity were studied in rats and rabbits. No adverse effects on fertility and general reproductive performance were seen in male or female rats from administration of ofloxacin in dosages of 10 mg/kg/day to 360 mg/kg/day, beginning well before mating and continuing through the seventh day of gestation in females.

Ofloxacin has not been shown to be teratogenic at doses as high as 810 mg/kg/day (equivalent to 13500 times the maximum recommended daily ophthalmic dose) and 160 mg/kg/day (equivalent to 2600 times the daily ophthalmic dose) when administered to pregnant rats and rabbits, respectively. Additional studies in rats with doses up to 360 mg/kg/day during late gestation showed no adverse effect on late fetal development, labor, delivery, lactation, neonatal viability, or growth of the newborn. Doses of 810 mg/kg/day and 160 mg/kg/day resulted in decreased fetal body weight and increased fetal mortality in rats and rabbits, respectively. Minor fetal skeletal variations were reported in rats receiving doses of 810 mg/kg/day.

Special Toxicity Studies

Ocular Toxicity: Ocular toxicity studies were conducted in rabbits and monkeys with ofloxacin ophthalmic solutions. Results indicate that ofloxacin ophthalmic solutions are not toxic to the eyes under the conditions tested, including dosing up to 16 times per day. No local or systemic toxicity was observed as a result of ocular administration of ofloxacin for up to six months in rabbits or monkeys.

Other Special Toxicity Studies: No evidence of ototoxicity, antigenicity or skin sensitization was seen in guinea pigs. Studies in rabbits revealed no evidence of nephrotoxicity.

Special Studies of Tissue Distribution and Accumulation: Special studies of tissue distribution and accumulation, with special reference to the eye tissues, were conducted due to the tendency of ofloxacin to bind to the pigment melanin, which is present in some ocular structures. Studies with the topical solution showed definite binding to melanin which decreased slowly after withdrawal of the drug. In vitro studies with bovine melanin showed the affinity of ofloxacin for melanin to be greater than that of timolol and pilocarpine, but less than that of chloroquine and befunolol. The binding was reversible. A four-week study in pigmented rats revealed no evidence of ocular toxicity after daily oral doses of 100 mg/kg/day. Results of this study were consistent with the lack of ocular toxicity seen in multi-dose ocular and systemic toxicity studies in dogs and monkeys.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]OCUFLOX®

Ofloxacin ophthalmic solution

Read this carefully before you start taking **OCUFLOX** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **OCUFLOX**.

What is OCUFLOX used for?

- OCUFLOX is a treatment for outer eye infections such as conjunctivitis (pink eye).

Antibacterial drugs like OCUFLOX treat only bacterial infections. They do not treat viral infections.

How does OCUFLOX work?

OCUFLOX interferes with the bacterial growth and division. This helps stop the infection.

What are the ingredients in OCUFLOX?

Medicinal ingredient: Ofloxacin

Non-medicinal ingredients: Benzalkonium chloride 0.005% w/v (as preservative), hydrochloric acid and/or sodium hydroxide (to adjust the pH), purified water, sodium chloride.

OCUFLOX comes in the following dosage forms:

Ophthalmic solution, 0.3% w/v

Do not use OCUFLOX if:

- You have a history of allergy to ofloxacin or to any of the ingredients of this drug. (See section **What are the ingredients in OCUFLOX?**).
- You have a history of allergy to other quinolones.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take OCUFLOX. Talk about any health conditions or problems you may have, including if you:

- wear soft contact lenses.
- are pregnant or planning to become pregnant.
- are breastfeeding or planning to breastfeed.
- have a defect or damage to the surface of the eye.

Other warnings you should know about:

If you develop pain or swelling in your tendons, stop using OCUFLOX and get immediate medical help. This is more likely to happen if you are elderly or taking corticosteroids at the same time as OCUFLOX.

Changes in Vision:

Using OCUFLOX may temporarily blur your vision. Do not drive or use machines until your vision has cleared.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

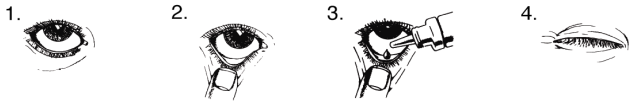
There are no known relevant interactions at this time.

How to take OCUFLOX:

- OCUFLOX contains a preservative called benzalkonium chloride which may discolor soft contact lenses. If you wear contact lenses, remove them before using OCUFLOX. Wait 15 minutes after using the drops before you put your lenses back in.
- To help prevent infections and eye injury, do not let the tip of the bottle touch your eye or anything else. Put the cap back on and close the bottle immediately after you have used it.
- Always use OCUFLOX exactly as your healthcare professional has instructed you.
- Although you may feel better early in treatment, OCUFLOX should be used exactly as directed.
- Misuse or overuse of OCUFLOX could lead to the growth of bacteria that will not be killed by OCUFLOX (resistance). This means that OCUFLOX may not work for you in the future.
- Do not share your medicine.

Follow these steps to use OCUFLOX properly:

- Wash your hands. Tilt your head back and look at the ceiling. (See Illustration 1)
- Gently pull down the lower eyelid to create a small pocket. (See Illustration 2)
- Turn the bottle upside down and squeeze it gently to release one drop into the eyelid pocket. If a drop misses your eye, try again. (See Illustration 3)
- Let go of the lower lid, and close your eye for 30 seconds. (See Illustration 4)



- Repeat steps 1 – 4 in the other eye if both eyes need treatment.

Usual dose:

One to two drops every two to four hours for the first two days. Then four times daily in the affected eye(s) for 8 days.

Overdose:

If you have placed too many drops in your eye(s), wash the eye(s) with clean water. Apply your next dose at the normal time.

If you think you, or a person you are caring for, have taken too much OCUFLOX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you forget to apply your eye drops at your normal time, simply apply them as soon as you remember. Then go back to the original schedule as directed by your healthcare professional. Don't try to catch up on missed drops by applying more than one dose at a time.

What are possible side effects from using OCUFLOX?

These are not all the possible side effects you may have when taking OCUFLOX. If you experience any side effects not listed here, tell your healthcare professional.

You should talk to your healthcare professional if any of the following side effects that affect the eye(s) prove troublesome or if they are long lasting:

- a feeling that something is in your eye
- blurred vision
- dryness
- eye pain
- eye/eyelid swelling
- irritation
- itchy eye/eyelid
- light sensitivity
- redness
- stinging
- tearing
- temporary burning or discomfort

You should talk to your healthcare professional if any of the following side effects that affect the body prove troublesome or if they are long-lasting:

- dizziness
- nausea
- swelling of the face

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
UNKNOWN			
Severe allergic reaction: swelling of the mouth, throat, tongue or hands and feet, difficulty in breathing, skin reactions (redness, irritation, blistering, peeling), loss of consciousness or collapse			√
Toxic epidermal necrolysis (severe skin reaction): redness, blistering and/or peeling of large areas of the skin			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

OCUFLOX should be stored between 15 to 25°C. The bottle should be tightly closed when not in use.

Keep out of reach and sight of children.

If you want more information about OCUFLOX:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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