

# OFTAVET® Ophthalmic solution

## OPHTHALMIC TOPICAL ANTIBIOTIC.



Oftavet® Ophthalmic Solution is an antibiotic for topical use indicated to treat superficial and deep ocular infections of the eye and its annexes, including corneal ulcers infected with bacteria sensitive to the drug.

## Technical Specification

### SPECIES

Dogs, cats and horses.

### DOSAGE FORM

Ophthalmic solution

### THERAPEUTIC ACTION

Ophthalmic topical antibiotic.

### COMPOSITION

Each 1 mL of product contains:

Ciprofloxacin Hydrochloride Monohydrate ..... 3.49 mg  
(Equivalent to 0.3% of Ciprofloxacin base)

Anhydrous Disodium EDTA ..... 2.33 mg

Excipients q.s.p ..... 1 mL

### PROPERTIES

Ciprofloxacin is a Fluoroquinolone with bactericidal action. Its action is based on the inhibition of bacterial DNA gyrase or topoisomerase IV (a type of topoisomerase II), thereby preventing DNA supercoiling and replication. Respiration and cell division are terminated, and other processes are disrupted, including membrane integrity. Ciprofloxacin has a wide spectrum of activity, being highly effective against the most commonly found ocular pathogens, both Gram positive and Gram negative, such as: Staphylococcus spp., Streptococcus spp., Pseudomonas aeruginosa, Pasteurella multocida, E. coli, etc.

EDTA inhibits metalloproteinases by chelation of Zinc and Calcium that the enzyme requires as a cofactor and a stabilizing ion, respectively. By chelating the calcium ion, EDTA interferes with the stability of metalloproteinases and thus decreases the stimulation for the migration of polymorphonuclear leukocytes to the corneal ulcer site. EDTA also interferes with the adhesion of

metalloproteinases to the polymorphonuclear cell membrane, leading the cell membrane to an inactivated state. EDTA exhibits a high rate of anti-metalloproteinase activity in vitro (99.4%).

#### INDICATIONS

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Oftavet® Ophthalmic Solution is an antibiotic for topical use indicated to treat superficial and deep ocular infections of the eye and its annexes, including corneal ulcers infected with bacteria sensitive to the drug.

#### ROUTE OF ADMINISTRATION AND DOSAGE

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Topical administration by instillation into the lower ocular sac. Administer aseptically. Wash your hands before handling and avoid the bottle coming into contact with the patient's eyes.

- **Horses:** 2 drops every 6 hours for 7 days.
- **Dogs and cats:** 1 drop every 6 hours for 7 days.

#### DRUG INTERACTIONS

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Synergism can occur with aminoglycosides, 3rd generation cephalosporins, and broad spectrum penicillins.

#### CONTRAINDICATIONS

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Oftavet® Ophthalmic Solution is contraindicated in patients with hypersensitivity to active ingredients or other quinolones.

Do not use in pregnant or lactating females.

#### **Use during pregnancy and lactation:**

Because there is no history about the use of Ciprofloxacin via the eye in pregnant females, it is recommended not to use in this state, nor during lactation.

#### PRECAUTIONS

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- For ophthalmic use only.
- Fluoroquinolones, such as Ciprofloxacin, should not be used as the first line of treatment, unless there is no therapeutic alternative available. When used as a second treatment, it should be based on susceptibility studies.

#### SPECIAL PRECAUTIONS FOR THE OPERATOR

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- To reduce the risk of contact, people who are hypersensitive to quinolones should wear rubber gloves to avoid contact.
- In case of skin contact, immediately wash the affected area with plenty of water. If irritation persists, consult a doctor.
- In case of eye contact, wash immediately with plenty of water, if vision is blurred, immediately take to a medical center.

#### WARNINGS

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Keep out of the reach of children.

#### ADVERSE EFFECTS

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A hypersensitivity could cause erythema, itching, swelling, tearing. In the event of any hypersensitivity reaction, discontinue use and consult a Veterinarian.

**Security:**

The use of ophthalmic Ciprofloxacin administered in concentrations of 0.3% and 0.75% for one month in Beagle puppies does not produce any local or systemic adverse effects.

**GUARD PERIOD**

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Do not administer to horses intended for human consumption.

**OBSERVATIONS**

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**Special precautions for disposal of unused product or waste material:**

Discard any unused product remains in its original container. Do not dump the empty container or with product remains in rivers, lakes or streams of natural water. Dispose of this product waste carefully with household waste. Contact the manufacturing company or companies specialized in the elimination of waste, to receive recommendations on the disposal of expired or unused products.

**CONSERVATION**

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Keep at a temperature between 2 and 30 ° C and protected from light.

**Uruguay:** The validity period once the container is opened is 4 weeks.

**CONDITION OF SALE**

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Sale with veterinary prescription.

**PRESENTATION**

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Dropper bottle with 5 mL

**PREPARED BY**

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Laboratorio Drag Pharma Chile Invetec S.A.

**RECORDS**

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**Chile:** Reg. SAG N° 2105

**Bolivia:** Reg. SENASAG PUV-F-N° 005509/13

**Uruguay:** Reg. MGAP N° 2018A00614

**COUNTRIES WHERE IT IS MARKETED**

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Imported and distributed in Bolivia by:

ZOOFARMA

TEL: +(591)222-3357

Street Díaz Romero 1339, La Paz.

Importer in Uruguay:

VIVAFIL S.A.

RIO NEGRO 1107 Montevideo - Uruguay, TEL 29001112

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Technical Director: DMTV Diego Cuadrado.

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Drag Pharma Lab is not responsible for the consequences of misuse of the products, and the use of this information without consulting a veterinarian