PACKAGE LEAFLET:

Oflex 3 mg/ml eye drops, solution
Dogs, cats and non-food producing horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
VAPP - Produção e Comercialização de Produtos para Veterinária, Lda.
Rua Casal do Canas, 6
2790-204 Carnaxide
Portugal

Manufacturer responsible for batch release:
Laboratório Edol – Produtos Farmacêuticos, S.A.

Av. 25 de Abril, 6-6A
2795-225 Linda-a-Velha
Portugal

Rua Quinta do Salrego 22-22A, Portela de Carnaxide, 2790-144 Carnaxide - Portugal
Rua Casal do Canas 6-6A, 2790-204 Carnaxide - Portugal

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oflex, 3 mg/ml, eye drops, solution
Dogs, cats and non-food producing horses
Ofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

The active substance is ofloxacin.
The other ingredients are: sodium dihydrogen phosphate monohydrate, disodium phosphate dodecahydrate, sodium chloride, benzalkonium chloride (50% solution) and water for injections. May contain hydrochloric acid or sodium hydroxide for pH adjustment.

4. INDICATION(S)

This veterinary medicinal product is indicated for the treatment of external eye infections caused by gram-positive and gram-negative microorganisms that are sensitive to ofloxacin, such as conjunctivitis (inflammations of the conjunctiva), keratitis (corneal ulcers), blepharitis (inflammation of the eyelids), blepharoconjunctivitis (simultaneous inflammation of the eyelids and conjunctiva) and dacryocystitis (infections of the lacrimal sac).
This veterinary medicinal product is also used in the prophylaxis of pre- and post-operative infections and in eyeball wounds in general.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, to other quinolones (ciprofloxacin, levofloxacin and norfloxacin), or to any of the ingredients of this veterinary medicinal product (listed in section 3).

Do not use in young animals and neonates.

6. ADVERSE REACTIONS

This veterinary medicinal product is generally well tolerated after topical application.
The most frequent adverse reactions are rare but may include transient eye irritation characterised by burning or ocular discomfort, stinging sensation or foreign body sensation, redness, pruritus (itching) and photophobia (sensitivity to light), eyelid edema, tearing and nausea.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via National Veterinary Pharmacovigilance System (SNFV):
farmacovigilancia.vet@dgav.pt

7. TARGET SPECIES

Dogs, cats and non-food producing horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Always use this medicine exactly as your veterinary surgeon has told you. Check with your veterinary surgeon if you are not sure.

This veterinary medicinal product is for application to the eye.
The posology as well as the duration of treatment must be established by the veterinary surgeon, on a case-by-case basis.

Dogs, cats and non-food producing horses: on average, it is recommended the application of 1 drop every 6 hours. In more serious cases, it can be applied one drop to the affected eye every 15 minutes, up to 4 applications.

Administer the eye drops to the conjunctival sac (space between the eye and eyelid) of the animal.
Do not let the dropper tip touch the eye or other surfaces in order to avoid contamination of the solution.
Put the cap back on and close the bottle right after use.

Treatment should be maintained for 48 hours after disappearance of the symptoms and for a minimum period of 5 days.

In case of a forgotten dose, this should be applied as soon as possible. Treatment should be continued with the administration of the following dose, as planned.

9. ADVICE ON CORRECT ADMINISTRATION

Wash your hands thoroughly before applying this veterinary medicinal product to the animal.
The eye drops should not be used if its usual colour is not observed or if strange particles are present.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25ºC.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species
Do not use this medicine if the animal has a viral or fungal infection.
Although treatment for external eye infections is generally empirical, a harvest is recommended to identify the causative microorganism before the use of this veterinary medicinal product. Rarely, as with other antibiotics, the continuous use of ofloxacin might facilitate the development of opportunistic infections, namely caused by fungus. In horses it may lead to corneal ulceration caused by fungal infection.
If superinfection occurs or if clinical improvement is not observed after one week of treatment, the use of this medicine should be discontinued, and an appropriate therapy should be instituted. Consult your veterinary surgeon for a better assessment of the clinical situation.
Excessive exposure of the animal to sunlight should be avoided while using this medicine as it may cause photosensitisation.
This medicine contains benzalkonium chloride. It may cause eye irritation.

Special precautions for use
Special precautions for use in animals
The use of this medicine should be reserved for infections in which the culture and sensitivity tests show a clinical response to the topical application of ofloxacin.
Particular caution should be taken during administration to avoid contamination of the content of the dropper-container and direct contact of the dropper tip with the eye.
Do not use the same container to treat different animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Hands should always be washed before applying the eye drops.
The dropper tip should not touch any surface, including the eyes and hands. This way, the contamination of the eye drops is avoided, which could cause an eye infection.
The eye drops should not be used if its usual colour is not observed or if strange particles are present.

Pregnancy
Since it has been shown that the systemic administration of quinolones, including ofloxacin, may cause arthropathies in young animals, this veterinary medicinal product should only be administered during pregnancy if the potential benefit justifies the possible risks.

Lactation
Since ofloxacin may be excreted in maternal milk, it should not be used during lactation and its suspension should be considered in case of treatment necessity.

Interaction with other medicinal products and other forms of interaction
Tell your veterinary surgeon if the animal is using, have recently used or might use any other medicines. There are no drug interaction studies for ofloxacin eye drops; however, given the risk of systemic absorption after topical application, the possibility of drug interactions should be considered, such as those reported with systemic quinolones (for example interactions with theophylline, caffeine, oral anticoagulants, digoxin, cyclosporine, corticoids, etc).

Overdose (symptoms, emergency procedures, antidotes)
There are no known cases of overdose for the pharmaceutical form in question.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

04/2023

15. OTHER INFORMATION

This veterinary medicinal product is presented in a package containing an opaque white low density polyethylene bottle with dropper tip containing 10 ml of solution. The bottle is closed with an opaque white high density polyethylene tamper-proof screw cap (with security seal).