

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Adrocil 5 mg/ml Eye drops, solution  
Dogs, cats and non-food producing horses

### 2. Composition

The active substance is ketorolac tromethamine.  
The other ingredients are: sodium chloride, disodium edetate, benzalkonium chloride, water for injections and hydrochloric acid and/or sodium hydroxide for pH adjustment.

### 3. Target species

Dogs, cats and non-food producing horses

### 4. Indications for use

This veterinary medicinal product is indicated in postoperative and post-traumatic pain and inflammatory reaction control, in intraoperative miosis inhibition and in the treatment of postsurgical uveitis. It is also indicated in the symptomatic treatment of allergic conjunctivitis due to its anti-inflammatory effect. This veterinary medicinal product is also indicated in the treatment of anterior uveitis and ulcerative keratitis, in eye inflammations in animals with diabetes mellitus, when the use of corticosteroids is contraindicated.

### 5. Contraindications

Hypersensitive to ketorolac tromethamine or to any of the other ingredients of this medicine (listed in section 2).  
Hypersensitivity to other nonsteroidal anti-inflammatory drugs.  
During pregnancy and lactation.  
Cats under 1 year of age or with a body weight of less than 1 kg.

### 6. Special warnings

#### Special warnings:

Talk to your veterinary surgeon before using this veterinary medicinal product if the animal suffers from a haemorrhagic, kidney or liver disease.

This veterinary medicinal product can cause changes on the kidney function in cats, so its administration in this target species must be based on a careful benefit/risk assessment carried out by the responsible veterinary surgeon. Therefore, it is recommended to use this veterinary medicinal product with special caution in cats, always keeping a close monitoring of the treated animal. If there is any change in the kidney function in cats, it is recommended to discontinue the therapy immediately.

This veterinary medicinal product contains benzalkonium chloride. It may cause eye irritation.

Special precautions for safe use in the target species:

This veterinary medicinal product is for ocular use. Keep this veterinary medicinal product out of the reach of animals. Special precautions must be taken to prevent the veterinary medicinal product from being ingested by animals, particularly cats, and from coming into contact with the mouth of the treated animal and/or other animals. In case of ingestion by the animal, the veterinary surgeon should be contacted.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to ketorolac should avoid contact with the veterinary medicinal product and administer the veterinary medicinal product with caution.

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.

After opening, this veterinary medicinal product has a shelf life of 28 days.

Pregnancy:

The use of this veterinary medicinal product during pregnancy is contraindicated.

Lactation:

The use of this veterinary medicinal product during lactation is not recommended.

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.

Talk to your veterinary surgeon if the animal is using the following medicines:

- medicines that turn the blood more fluid such as warfarin;
- antibiotics belonging to the group of aminoglycosides;
- angiotensin converting enzyme inhibitors;
- corticosteroids.

Overdose:

There are no known cases of overdose for the pharmaceutical form in question.

Major incompatibilities:

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

**7. Adverse events**

Uncommon (1 to 10 animals / 1,000 animals treated)	stinging sensation or burning in eyes and eyelids.
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The occurrence of possible allergic hypersensitivity reactions to the active substance or to any of the excipients of this veterinary medicinal product may happen, which is why therapeutic suspension is recommended in these situations.

Acute kidney injury (AKI) in cats under 1 year of age or weighing less than 1 kg.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse

events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: [farmacovigilancia.vet@dgav.pt](mailto:farmacovigilancia.vet@dgav.pt)

## **8. Dosage for each species, routes and method of administration**

Posology as well as treatment duration should be instituted by the veterinary surgeon, on a case-by-case basis. In cats, the veterinary medicinal product should not be used for more than 5 consecutive days.

### **The recommended dose is:**

- before eye surgery: 1 drop in the affected eye(s) four times with a 20-minute interval.
- after eye surgery: 1 drop in the affected eye(s), 6-8 times a day.
- other indications: 1 drop in the affected eye(s), up to 4 times a day.

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 and put on gloves, if necessary.
- Remove excess of secretion from around the animal's eye(s) with a wet dressing or cloth.
- Take off the cap and avoid contact of the dropper tip with your hands or any other surface.
- Tilt the animal's head back so it is looking at the ceiling.
- Slightly pull down the lower eyelid of the affected eye and place the dropper tip close to the eye, but not touching it.
- Make sure that the dropper tip does not point directly to the eye and that it does not touch the animal's eye, eyelid or eyelashes.
- Holding the container parallel to the eyelid, apply the correct amount in the inner corner of the lower eyelid.
- Gently press the closed eyelids and massage to disperse the medicine.
- Put the cap back on the container avoiding touching the inside of the cap with your hands.
- Remove the gloves, if applicable, and wash your hands.
- You should always praise and reward the animal to encourage cooperation.

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 25°C.

Keep the dropper container tightly closed.

Keep the dropper container in the outer carton in order to protect from light and moisture.

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 precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

To be supplied only on veterinary prescription.

## **14. Marketing authorisation numbers and pack sizes**

1023/01/16NFVPT

This veterinary medicinal product is presented as an eye drops, solution in a sterile dropper container with the capacity of 10 ml.

## **15. Date on which the package leaflet was last revised**

06/2023

## **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

VAPP - Produção e Comercialização de Produtos para Veterinária, Lda.

Rua Casal do Canas, 6

2790-204 Carnaxide

Portugal

Email: farmacovigilancia@vapp.pt

Telephone: +351 21 415 59 70

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