SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adrocil 5 mg/ml Eye drops, solution
Dogs, cats and sport horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Ketorolac tromethamine at 5 mg/ml.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzalkonium chloride	0,1 mg/ml (solution at 50%)
Sodium chloride	
Disodium edetate	
Water for injections	
Hydrochloric acid or sodium hydroxide for pH adjustment	

Clear, colourless and odourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats and sport horses

3.2 Indications for use for each target species

This veterinary medicinal product is indicated in pain control and control of the preoperative and post-traumatic inflammatory reaction, in the inhibition of intraoperative miosis and in the treatment of post-surgical 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 animals with diabetes mellitus suffering from ocular inflammations, when the use of corticosteroids is contraindicated.

3.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in case of hypersensitivity to others nonsteroidal anti-inflammatory drugs.
Do not use during pregnancy and lactation.
Do not use in cats under 1 year of age.

Do not use in cats weighing less than 1,5 kg.

3.4 Special warnings

This veterinary medicinal product should be used with special precaution in animals with 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.

3.5 Special precautions for use

Special precautions for use in animals for safe use in 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 veterinarian 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, the veterinary medicinal product has a shelf life of 28 days.
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.

3.6 Adverse events

Uncommon (1 to 10 animals / 1,000 animals treated)	stinging sensation or burning in eyes and eyelids.

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.
Acute kidney injury (AKI) in cats weighing less than 1,5 kg.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Ketorolac tromethamine crosses the placental barrier with the potential to cause malformations in foetuses, therefore its use is contraindicated during pregnancy. The occurrence of dystocia (with neonatal death) is a common effect in rodents exposed to systemic non-steroidal anti-inflammatory drugs.

Lactation:
Ketorolac tromethamine is secreted in milk after systemic administration. The administration of this veterinary medicinal product during lactation is not recommended.

3.8 Interaction with other medicinal products and other forms of interaction

Administer under surveillance in animals presenting haemorrhagic tendencies or who are taking anticoagulant therapy (heparin, warfarin, aspirin).
Avoid the simultaneous administration with aminoglycosides and angiotensin-converting-enzyme inhibitors.
Do not administer simultaneously with corticosteroids.

3.9 Administration routes and dosage

Posology as well as the duration of treatment should be instituted by the veterinarian, case by case.

Pre-surgery administration: apply 1 drop four times with a 20-minute interval.

Post-surgery administration: apply 1 drop to the affected eye(s), 6-8 times a day.

Other indications: topically apply on the eye mucosa (in the internal angle) 1 drop up to 4 times a day.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not known for the pharmaceutical form in question.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QS01BC05

4.2 Pharmacodynamics

Ketorolac tromethamine is a non-steroidal anti-inflammatory, which demonstrates analgesic, anti-inflammatory and antipyretic activity when systemically administered. The mechanism leading to these actions is due to the ability to inhibit the prostaglandin biosynthesis. Ocular administration of ketorolac tromethamine decreases prostaglandin E2 levels in the aqueous humour.

Prostaglandins promote a certain type of ocular inflammation since its presence is responsible for vasodilation and increased vascular permeability, leukotaxis, increased intraocular tone and rupture of the blood-aqueous barrier. Prostaglandins while promoting the constriction of iris sphincter, they are responsible for the miotic response of the pupil during eye surgery.

4.3 Pharmacokinetics

Absorption
The systemic absorption of ketorolac tromethamine after topical application is not clear.

Distribution
Binding to plasmatic proteins is 99%. The volume of distribution in dogs is approximately 0,33-0,42 L/kg (similar to that of humans).
Ketorolac tromethamine crosses the placental barrier. In addition, ketorolac tromethamine is distributed in maternal milk.

Biotransformation
Ketorolac is primarily metabolised in the liver by glucuronidation and hydroxylation.

Elimination
Ketorolac and its metabolites are mostly excreted in urine.
Half life period: dogs: 4-8 hours; cats: 3-6 hours; horses: 30 minutes - 1 hour.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25ºC.
Keep the dropper container tightly closed.
Keep the dropper container in the outer carton in order to protect from light and moisture.

5.4 Nature and composition of immediate packaging

This veterinary medicinal product is an eye drops, solution supplied in opaque white LD-polyethylene bottles, with the capacity of 10 ml, with a LD-polyethylene dropper tip and a HD-polyethylene cap with tamper-proof closure.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

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

7. MARKETING AUTHORISATION NUMBER(S)

1023/01/16NFVPT

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 30 June 2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.