PACKAGE LEAFLET:

Tropicavet 10 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

Tropicavet 10 mg/ml eye drops, solution for dogs, cats and non-food producing horses
Tropicamide

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

The active substance is tropicamide.
The other ingredients are: boric acid, benzalkonium chloride (50% solution), propylene glycol, water for injections, concentrated hydrochloric acid, sodium chloride (for osmolality adjustment) and hydrochloric acid and/or sodium hydroxide (for pH adjustment).

4. INDICATION(S)

The veterinary medicinal product is indicated as a mydriatic agent in intraocular diagnostic exams, due to its rapid action and short duration of mydriasis. When applied topically, tropicamide promotes pupil dilation allowing the evaluation of the lens, vitreous, retina and optic disc. Tropicamide is also used to induce mydriasis in intraocular surgery, especially cataract surgery.
Tropicamide has a lower cycloplegic effect than other parasympatholytic drugs; however, it is indicated for the treatment of anterior uveitis as a short-acting mydriatic agent to prevent posterior synechiae.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the ingredients.

6. ADVERSE REACTIONS

The occurrence of possible allergic hypersensitivity reactions to the active substance or to any of the excipients of the veterinary medicinal product may happen, which is why therapeutic suspension is recommended in these situations.

Symptoms that require medical attention if persisting after application:
Eye irritation not existing before application of the veterinary medicinal product, eye pain after application, chemosis, conjunctival hyperemia, blepharospasm, protrusion of the nictitating membrane (in cats) and salivation (described in cats).

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

Posology
The veterinary medicinal product should only be used under veterinary prescription and under supervision of the veterinary surgeon, who will indicate the dosage to be followed. The veterinary medicinal product should be applied topically to the ocular mucosa.

The usual dose is: 1 drop in the eye(s); repeat 20-30 minutes after, if necessary.

Method of administration
Open the cap of the dropper-container and apply a slight pressure on it, letting out the liquid drop by drop in the recommended dose. Avoid eye contact with the dropper-container.

9. ADVICE ON CORRECT ADMINISTRATION

Do not use the veterinary medicinal product in case of visible signs of deterioration/change.

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
After application of tropicamide, a transient increase in intraocular pressure may occur, therefore monitoring of intraocular pressure throughout treatment is recommended. As this effect is transient, it is unlikely to cause glaucoma, even in susceptible breeds.
After application of tropicamide, a transient decrease in tear production may occur in cats and horses.
The absence of mydriasis after application of tropicamide may be indicative of intraocular inflammation, posterior synechiae, etc.
Special attention should be given when this veterinary medicinal product is administered together with butorphanol (by systemic route) in dogs predisposed to or with glaucoma due to increased intraocular pressure.

Special precautions for use
Special precautions for use in animals
Particular caution should be taken during administration to avoid contamination of the content of the dropper-container and a direct contact of the dropper tip with the eye.
Do not use the same container to treat different animals.
After opening the bottle, this veterinary medicinal product should not be used beyond 28 days.
In case of accidental self-administration, immediately seek medical attention and show the package leaflet or the label to a doctor.
This medicine contains benzalkonium chloride. It may cause eye irritation.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to tropicamide should avoid contact with the veterinary medicinal product and administer the veterinary medicinal product with caution.
If the veterinary medicinal product is accidentally ingested, contact a physician immediately.
Avoid eye contact. In case of accidental eye contact, wash the eyes with plenty of water.
In case of eye change or eye irritation, seek medical advice.
In case of accidental skin contact, it is advisable to wash with plenty of water.
Wash your hands after application.
Keep out of the sight and reach of children and domestic animals.

Pregnancy
No studies during gestation were conducted, however tropicamide may be systemically absorbed.
Administration of tropicamide should be avoided during gestation. Administer only in accordance with the benefit/risk assessment performed by the veterinary surgeon.

Lactation
Topically applied tropicamide may be systemically absorbed and may cause adverse effects in nursed animals. Administer during lactation only in accordance with the benefit/risk assessment performed by the veterinary surgeon.

Interaction with other medicinal products and other forms of interaction
The effects of tropicamide and other antimuscarinics may be potentiated by the concomitant use of other medicinal products with antimuscarinic properties.
An increase in intraocular pressure has been observed in dogs predisposed to or with glaucoma following topical administration of tropicamide together with systemic butorphanol.

Overdose (symptoms, emergency procedures, antidotes)
Accidental overdose advises veterinary care.

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

The veterinary medicinal product is presented in the pharmaceutical form of eye drops, solution, clear, colourless and odourless. The veterinary medicinal product is presented in a low-density polyethylene dropper bottle containing 10 ml of eye drops, solution.