PACKAGE LEAFLET:

Midria 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.
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

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

Cyclopentolate hydrochloride

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

The active substance is cyclopentolate hydrochloride.
The other ingredients are: boric acid, potassium chloride, disodium edetate, sodium carbonate anhydrous, benzalkonium chloride (50% solution), water for injections, hydrochloric acid at 10% or sodium hydroxide at 40% (for pH adjustment) and sodium chloride (for osmolality adjustment).

4. INDICATION(S)

The veterinary medicinal product is indicated as a mydriatic and cycloplegic agent for the treatment of eye pain associated with corneal ulcer and/or anterior uveitis. Cyclopentolate hydrochloride blocks pupillary spasm (miosis) associated with anterior uveitis.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the ingredients.
Do not use in cats with increased intraocular pressure.

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 (described in dogs) and salivation (described in cats).

Systemic absorption may occur after topical ocular administration of cyclopentolate, which may cause vomiting, tremor, confusional state, abnormal behaviour, weakness (very rare).

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

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), 1-2 times in the first 24 hours and, if necessary to maintain the effect, apply 1 drop every other day.

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.

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.
Store in the original package.
Keep the container tightly closed 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 WARNING(S)

Special warnings
Cyclopentolate hydrochloride increases intraocular pressure in cats, therefore intraocular pressure monitoring during treatment is recommended.
Cyclopentolate hydrochloride does not appear to change tear production or intraocular pressure in dogs and therefore can be administered, under surveillance, to dogs with changes in intraocular pressure and tear production.
In animals with changes in intraocular pressure and/or tear production, treatment with cyclopentolate should be monitored through the measurement of these parameters.
Cyclopentolate is an anticholinergic drug. Although colic pathology is not associated with the administration of cyclopentolate, this veterinary medicinal product should be used with special caution in horses with a history of colic.
After opening the bottle, this veterinary medicinal product should not be used beyond 28 days.
This medicine contains benzalkonium chloride. It may cause eye irritation.

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 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
People with known hypersensitivity to cyclopentolate 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 doctor immediately.

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

Lactation
Topically applied cyclopentolate 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 cyclopentolate and other antimuscarinics may be potentiated by the concomitant use of other medicinal products with antimuscarinic properties.

Overdose (symptoms, emergency procedures, antidotes)
Accidental overdose advises hospital care. In case of overdose or accidental ingestion, cyclopentolate toxic systemic effects are characteristic of other anticholinergic agents and may include hypotension and respiratory depression. An anticholinergic agent (neostigmine, physostigmine) should be administered to reverse toxic effects in case of overdose.

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

07/2025

15. OTHER INFORMATION

The veterinary medicinal product is presented in the pharmaceutical form of eye drops, solution, in a sterile dropper container containing 5 ml of solution. The solution is clear and colourless.