PACKAGE LEAFLET:
Dorzoglau 20 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

Dorzoglau 20 mg/ml eye drops, solution for dogs, cats and non-food producing horses
Dorzolamide

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

The active substance is dorzolamide, as hydrochloride. Each ml of eye drops, solution contains 20 mg of dorzolamide.
The other ingredients are: hypromellose, mannitol, sodium citrate dihydrate, benzalkonium chloride, water for injections, sodium hydroxide and/ or hydrochloric acid (for pH adjustment).

4. INDICATION(S)

The veterinary medicinal product is indicated in the

- Treatment of diseases involving increased intraocular pressure (IOP), namely in situations of glaucoma.
- Treatment of acute situations of increased IOP resulting from primary or secondary glaucoma and in the treatment of chronic conditions of glaucoma.
- IOP control in short- and long-term treatments.
- Treatment of glaucoma in emergency situations, namely in glaucoma associated with lens dislocation, uveitis-induced glaucoma, and hyphema-associated glaucoma.
- IOP control before and after eye surgery.
- Treatment of glaucoma in cats, as it does not contribute to pupillary blockage or intensify pre-existing uveitis.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to dorzolamide or any of the other 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.

Some eye discomfort may occur after administration of the veterinary medicinal product.

Corneal edema may occur in animals with changes in the corneal endothelium.

The veterinary medicinal product may cause blepharitis in dogs (rare).

In some cats, conjunctivitis, hypersialia and inappetence associated with treatment with the veterinary medicinal product may occur.

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

Dosage:
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 recommended dose is: dogs and cats 1 drop in the affected eye(s) 2-3 times a day and horses 1 drop in the affected eye(s) every 12 hours.

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 if you notice visible signs of deterioration.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25º C.
Keep the container tightly closed.

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.

12. SPECIAL WARNING(S)

Special warnings
Administer with caution to animals with alterations on corneal endothelium.
After opening the bottle, this veterinary medicinal product should not be used beyond 28 days.
This veterinary medicinal product contains benzalkonium chloride. 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 dorzolamide should avoid contact with the veterinary medicinal product and administer the veterinary medicinal product with caution.
If the veterinary medicinal product is accidentally swallowed, contact a doctor immediately.

Pregnancy
There are no laboratory studies demonstrating that topically applied dorzolamide has teratogenic, fetotoxic, or maternal toxic effects. The veterinary medicinal product should only be administered in accordance with the benefit/risk assessment carried out by the responsible veterinary surgeon.

Lactation
There are no laboratory studies demonstrating that topically applied dorzolamide reaches concentrations in breast milk. The veterinary medicinal product should only be administered in accordance with the benefit/risk assessment carried out by the responsible veterinary surgeon.

Interaction with other medicinal products and other forms of interaction
In horses, the combination of dorzolamide 2% with other antiglaucoma drugs to reduce intraocular pressure is beneficial.

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

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 a clear, colorless or practically colorless, slightly viscous solution. The veterinary medicinal product is presented in the pharmaceutical form of eye drops, solution in dropper containers with 5 ml of solution.