

PACKAGE LEAFLET:
Aleon, 10 mg/ml eye drop, 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

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

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

The active substance is atropine sulfate at 10 mg/ml.

The other ingredients are: sodium dihydrogen phosphate monohydrate, disodium phosphate dodecahydrate, sodium chloride, benzalkonium chloride, water for injections, hydrochloric acid solution or sodium hydroxide solution (for pH adjustment).

4. INDICATION(S)

The veterinary medicinal product is available in drops for the administration into the eye.

The veterinary medicinal product is indicated as a mydriatic and cycloplegic agent in:

- Iritis;
- Iridocyclitis;
- Uveitis;
- Scleritis;
- As a preventive of postoperative inflammation of the iris and ciliary body;
- Some eye exams.

5. CONTRAINDICATIONS

Hypersensitivity to atropine sulfate or to any of the other ingredients of this medicine (listed in section 3).

It is also contraindicated in cases of ocular hypertonia and glaucoma.

It is contraindicated in horses with colic and a history of chronic colic.

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 only if they persist:

Eye irritation non-existent before the use of the veterinary medicinal product, photophobia, eyelid swelling.

Symptoms that require medical attention (consequence of systemic absorption):

Tremors, confusional state, unusual behavior, fever, tachycardia, weakness.

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

Always use this medicine exactly as your veterinary surgeon has told you. Check with your veterinary surgeon if you are not sure.

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 recommended dose is: 1 drop in the eye(s) 2 to 3 times a day. The veterinary medicinal product should be applied topically to the ocular mucosa.

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.

Treatment duration:

The duration of the treatment must be determined by the veterinary surgeon based on the clinical situation of the animal.

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

How to use the veterinary medicinal product:

- 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.
- Remove 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 PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.

Keep the container tightly closed.

Keep the 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 WARNING(S)

Special warnings for each target species

Hypersialia may occur in dogs and cats.

There may be a decrease in tear production in dogs.

It should not be used in combination with other medicinal products containing mydriatic agents in their composition. It must not be administered together with amitraz and metoclopramide.

Prolonged use of this medicine without supervision by a veterinary surgeon may have harmful effects on health.

Atropine, like all parasympatholytic drugs, increases intraocular pressure. In predisposed animals, an acute attack of glaucoma may occur. It is advisable to determine the intraocular pressure before use.

Caution is recommended for use in animals with:

- cardiac insufficiency;
- difficulty coordinating movements;
- temporary paralysis of the intestine.

Protection of the eyes from the action of ultraviolet rays is recommended as the veterinary medicinal product increases the sensitivity of the eye to light.

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 the active substance 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 prevents contamination of the eye drops, which could cause an eye infection.

Pregnancy

Studies during pregnancy have not been performed, however atropine sulfate may be absorbed systemically.

Lactation

The veterinary medicinal product is contraindicated in lactation. Systemic atropine passes into breast milk. Ophthalmic atropine may be absorbed systemically and may cause adverse effects in suckling animals.

Interaction with other medicinal products and other forms of interaction

Tell your veterinary surgeon if the animal is using, has recently used or might use any other medicines. The effects of atropine and other antimuscarinics may be potentiated by the concomitant use of other medicinal products with antimuscarinic properties such as amantadine, certain antihistamines, phenothiazine antipsychotics and tricyclic antidepressants. Atropine may potentiate signs of amitraz toxicity. Atropine may antagonize the effects of metoclopramide.

Overdose (symptoms, emergency procedures, antidotes)

Accidental overdose advises hospital care.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must 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, with a capacity of 10 ml. The solution is clear and colorless.