

PACKAGE LEAFLET:
Cortcil 5 mg/g eye ointment
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

Cortcil 5 mg/g eye ointment
Dogs, cats and non-food producing horses
Prednisolone acetate

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

The active substance is prednisolone acetate.
The other ingredients are lanolin and white soft paraffin.

4. INDICATION(S)

This veterinary medicinal product is indicated for the topical treatment of inflammatory conditions of the eyeball and annex structures, namely in case of conjunctivitis, anterior uveitis (in the absence of corneal ulcers) and in the reduction of inflammation after eye surgeries.

It is indicated in allergic manifestations in immune-mediated ocular diseases that respond to corticosteroid therapy, such as eosinophilic keratitis, chronic superficial keratitis, equine recurrent uveitis.

Due to its high penetration into the cornea, this veterinary medicinal product is indicated for the treatment of inflammatory and immune-mediated conditions of the anterior segment.

5. CONTRAINDICATIONS

Do not use in case of allergy (hypersensitivity) to prednisolone acetate or to any other ingredients of this medicine (indicated in section 3).

Do not use in animals with history of glaucoma.

Do not use in cats with conjunctivitis of unknown origin.

Do not use in case of ocular viral infections

The veterinary medicinal product has properties that affect liver function (hepatotoxic).

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.

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 posology as well as the duration of treatment should be established by the veterinary surgeon, on a case-by-case basis.

Topically apply on the eye mucosa (in the inner angle) 1 to 4 times per day until symptom resolution. After symptom resolution, treatment should be discontinued gradually over a period of 5 to 10 days. During the first administration, discard the small amount of ointment in contact with the cap.

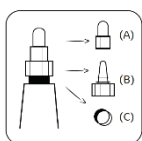
In case of a forgotten dose, this should be applied as soon as possible. Treatment should be continued with the administration of the following dose, as planned.

9. ADVICE ON CORRECT ADMINISTRATION

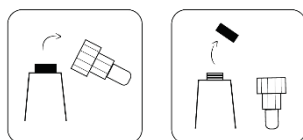
How to use the veterinary medicinal product:

Tube preparation (first administration)

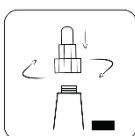
Wash your hands and put on gloves, if necessary.



When preparing the tube, always check that it has a cap (A), base (tip) (B) and ring (C). If it does not have a ring, do not use the veterinary medicinal product and talk to your veterinary surgeon or pharmacist.



Carefully unscrew the set constituted by the base (tip) and cap. Remove the ring and throw it away.



Screw the set composed by the base (tip) and cap back on and ensure that the aluminium film that seals the tube is broken. After this step, do not unscrew the base (tip) of the tube again.

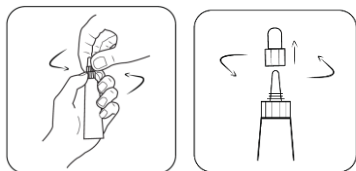
Whenever you need to administer the veterinary medicinal product, just remove the cap.

Before each administration

After the preparation of the tube (in case it is the first administration), or in the following administrations, follow the instructions below whenever you need to administer the veterinary medicinal product:

Wash your hands and put on gloves, if necessary.

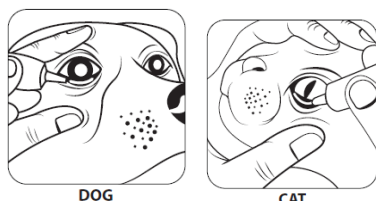
Remove excess of secretion from around the animal's eye(s) with a wet dressing or cloth.



Hold the base (tip) of the tube with one hand and with the other unscrew and remove the cap.

When first administering the eye ointment, the first portion should be discarded.

Avoid touching the tip of the tube with your hands or any other surface, so as not to contaminate the ointment.



DOG

CAT

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 tip of the tube close to the eye, but not touching it.

Make sure that the tip of the tube does not point directly to the eye and that it does not touch the animal's eye, eyelid, or eyelashes.



NON-FOOD PRODUCING HORSE

Holding the tube parallel to the eyelid, apply the correct amount to the inner edge of the lower eyelid.

Approximately 0.5 cm of ointment should be applied to the conjunctival sac.

Gently press the closed eyelids and massage to disperse the medicine.

If necessary, repeat the application in the other eye.

At the end of administration, screw the cap back onto the base (tip) of the tube, remove the gloves, if applicable, and wash your hands.

You should always praise and reward the animal to encourage cooperation.

After each administration of the ointment in the eye, and even without pressing the tube, it is normal for the ointment to continue to flow out of the tube. Discard that portion before closing the tube again.

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 25°C.

Keep the tube tightly closed in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Shelf life after first opening the tube: 28 days.

12. SPECIAL WARNING(S)

Special warnings

This veterinary medicinal product should not be used as first line in the treatment of eye disorders in cats.

Prolonged use of this veterinary medicinal product may lead to the development of glaucoma, cataracts, and exophthalmos.

Special precautions for use

Special precautions for use in animals

When it is suspected that the infection is caused by a disease process, especially in purulent conjunctivitis, sensitivity tests should be performed to determine which antibiotic is the most appropriate, before using any ophthalmic preparation.

Particular attention should be given during the administration to avoid contamination of the content and the direct contact of the tip of the tube with the eye.

Do not use the same tube to treat different animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to prednisolone 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 ointment. The tip of the tube should not touch any surface, including the eyes and hands. This way, the contamination of the eye ointment is avoided, which could cause an eye infection.

Pregnancy

There are no studies on the use of the veterinary medicinal product in pregnant animals. As such, this veterinary medicinal product should only be used if the potential benefits for pregnant animals outweigh the potential risk for the fetus and embryo.

Lactation

It is not known whether a topical ocular application of the active substance of this veterinary medicinal product (prednisolone acetate) can result in sufficient systemic absorption to cause detectable amounts in milk. However, since prednisolone acetate crosses to the maternal milk, the use of this veterinary medicinal product should be avoided during lactation, unless the veterinary surgeon considers that the benefit outweighs the risk.

Interaction with other medicinal products and other forms of interaction

Tell your veterinary surgeon if the animal is using, have recently used or might use any other medicines.

Antiglaucoma agents (chronic or intensive use of this veterinary medicinal product may increase intraocular pressure and reduce the efficacy of antiglaucoma agents).

Anticholinergics, particularly atropine and related compounds (prolonged use of this veterinary medicinal products may increase the risk of intraocular hypertension).

Overdose (symptoms, emergency procedures, antidotes)

Not known for the pharmaceutical form in question.

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

This veterinary medicinal product is presented in the dosage form of eye ointment, supplied in an aluminium tube, (epoxiphenolic varnish inner coating and white polyester outer coating) with a white HDPE cap. The tube contains 3.5 g or 5 g of eye ointment.