

PACKAGE LEAFLET:

Crotax 10 mg/g eye ointment for 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

Crotax 10 mg/g eye ointment for dogs, cats and non-food producing horses
Chloramphenicol

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

The active substance is chloramphenicol.

The other ingredients are: lanolin and white soft paraffin.

4. INDICATION(S)

The veterinary medicinal product is indicated for the topical treatment of bacterial infections of the eyeball and associated structures caused by microorganisms sensitive to chloramphenicol, namely: conjunctivitis, blepharitis, dacryocystitis, corneal ulcers and keratitis. Indicated in the prophylactic treatment of corneal ulcers.

5. CONTRAINDICATIONS

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

Do not use in food-producing animals.

The veterinary medicinal product should not be administered in animals with bone marrow disorders, anaemia, or immunosuppression.

Do not use in pregnant and/or lactating female animals or in new-born animals.

Do not use in animals that have been vaccinated or will be vaccinated soon.

6. ADVERSE REACTIONS

After the use of this veterinary medicinal product local irritation, transient burning and stinging sensation in the eye, edema and conjunctival erythema may occur.

This veterinary medicinal product may cause bone marrow depression and blood dyscrasias (aplastic anaemia, hypoplastic anaemia, thrombocytopenia and granulocytopenia).

Continued use of chloramphenicol may cause changes to the conjunctiva, as a result of secondary infections by *Pseudomonas* spp.

Superinfections caused by non-sensitive microorganisms, including fungus, may occur in prolonged treatments.

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 must be established by the veterinary surgeon, on a case-by-case basis.

Apply topically on the ocular mucosa (inner angle) every 8-12 hours.

During the first administration, discard the small amount of ointment in contact with the cap.

Considering the main bacteriostatic antibiotic's activity, the treatment should be extended until 48 hours after healing.

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.

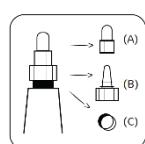
9. ADVICE ON CORRECT ADMINISTRATION

People with known hypersensitivity to chloramphenicol should avoid contact with the veterinary medicinal product and administer the veterinary medicinal product with caution.

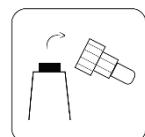
How to use the veterinary medicinal product:

Tube preparation (first administration)

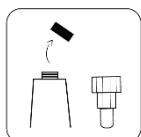
Wash your hands and put on gloves, if necessary.

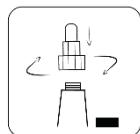


When preparing the tube, always check that it has a cap (A), base (tip) (B) and ring (C). If it does not have a ring, do not use the veterinary medicinal product and talk to your veterinary surgeon or pharmacist.



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.

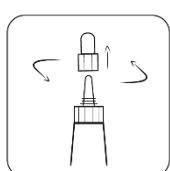
Whenever you need to administer the veterinary medicinal product, just remove the cap.

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.

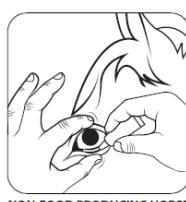
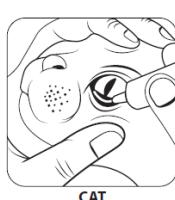
Remove excess of secretion from around the animal's eye(s) with a wet dressing or cloth.



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.



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.

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.

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.

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 for each target species

The veterinary medicinal product should not be used for an extended period or in repeated and frequent treatments since in these conditions it may cause bone marrow aplasia and/or blood dyscrasias (aplastic anaemia, hypoplastic anaemia, thrombocytopenia and granulocytopenia).

In cats, the veterinary medicinal product should not be used for more than 5 consecutive days, as blood dyscrasias may occur.

Chloramphenicol should not be used in common situations, and its use is only justified if there is no alternative therapy with lesser risks.

Like with all antibiotics, the onset of superinfection and gastrointestinal disturbances should be monitored.

The veterinary medicinal product should be used with caution in animals with renal or hepatic failure.

Special precautions for use

Special precautions for use in animals:

Most sensitive bacteria will respond to chloramphenicol treatment within a few days. If no improvement is observed in this period, a therapeutic alternative should be considered.

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.

The administration of the veterinary medicinal product should be based on the identification and sensitivity testing of bacteria that cause the bacterial infection. The inappropriate use of medicinal products that contain antimicrobial agents may increase the occurrence of bacterial resistance.

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

People with known hypersensitivity to chloramphenicol 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

Do not use during pregnancy.

Lactation

Do not use during lactation.

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.

Interactions with other antibiotics have been described, for example, with tetracyclines, with the occurrence of antagonistic effects.

Chloramphenicol may prolong the effect of several medicinal products simultaneously administered. The concomitant therapy with other medicinal products causing bone marrow depression must be avoided.

Overdose (symptoms, emergency procedures, antidotes)

Overdose cases are not known for the pharmaceutical form in question.

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

09/2025

15. OTHER INFORMATION

The veterinary medicinal product is presented as a yellowish, odorless or almost odorless ointment, with a soft consistency, in 5 g aluminium tubes plastic cap.