PACKAGE LEAFLET:
Aureodermil
5 mg/g + 5 mg/g + 100 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.

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

Aureodermil 5 mg/g + 5 mg/g + 100 mg/g, eye ointment
Dogs, cats and non-food producing horses
Prednisolone acetate + neomycin sulphate + sulfacetamide sodium

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

The active substances are prednisolone acetate, neomycin sulphate and sulfacetamide sodium.
The other ingredients are lanolin, white soft paraffin and liquid paraffin.

4. INDICATION(S)

The veterinary medicinal product is indicated for the topical treatment of bacterial infections caused by microorganisms sensitive to neomycin and sulfacetamide, namely aerobic gram-positive and gram-negative microorganisms such as *Salmonella, Klebsiella, Enterobacter, Proteus, Acinetobacter spp.*, *Escherichia coli, Staphylococcus aureus, Streptococcus pneumoniae* and *Haemophilus muenzae*, and in inflammatory conditions of the eyeball and annex structures, namely:
- microbial conjunctivitis,
- infected allergic conjunctivitis,
- keratoconjunctivitis,
- eosinophilic keratitis,
- uveitis, scleritis,
- episcleritis,
- blepharitis.

5. CONTRAINDICATIONS

Do not use in case of allergy (hypersensitivity) to the active substances or to any other ingredients of this medicine (indicated in section 3).
Do not use in animals with a history of glaucoma.
Do not administer as a first line in case of conjunctivitis in cats, its use must be conditioned to the demonstration of microbial infection by a sensitive microorganism.

6. ADVERSE REACTIONS

The occurrence of possible allergic hypersensitivity reactions to the active substances or to any of the ingredients 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 (in the inner angle) 3 to 4 times a day.

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

Since the action of sulfacetamide is bacteriostatic, the treatment should be extended until 48 hours after healing.
Do not abruptly discontinue treatment and progressively reduce the dose in case of prolonged therapy.

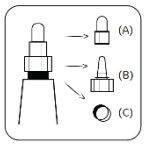
In case of a forgotten dose, this should be applied as soon as possible. Treatment should be continued with the administration of the following dose, as planned.

9. ADVICE ON CORRECT ADMINISTRATION

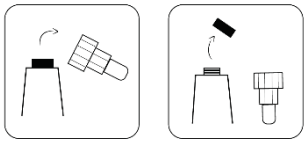
How to use the veterinary medicinal product:

Tube preparation (first administration)

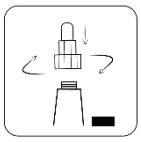
Wash your hands and put on gloves, if necessary.



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.



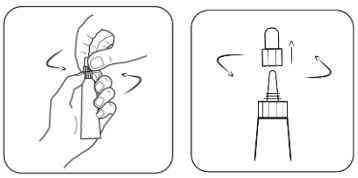
Screw the set composed by the base (tip) and cap back on and ensure that the aluminium film that seals the tube is broken. After this step, do not unscrew the base (tip) of the tube again.

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

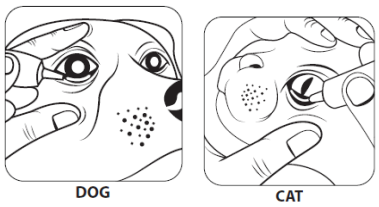
Before each administration

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.



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 30 °C.
Keep the tube in the outer carton tightly closed in order to protect from light and moisture.

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 as a first approach in the treatment of eye conditions in cats.
Prolonged use of ophthalmic ointment can lead to glaucoma, cataracts, and exophthalmos.
Prolonged use of topical neomycin in dogs and cats can trigger an allergic reaction.
Use with caution in case of ulcerative eye lesions.
As with any antibiotic, the appearance of superinfection should be monitored.

Special precautions for use

Special precautions for use in animals
When infection is suspected to be the cause of a disease process, especially in purulent conjunctivitis, sensitivity tests should be performed before applying any ophthalmic preparation to determine which antibiotic is most suitable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to prednisolone, neomycin and/or sulfacetamide 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 substances of this veterinary medicinal product (prednisolone acetate, neomycin sulphate and sulfacetamide sodium) 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.

Overdose (symptoms, emergency procedures, antidotes)
No cases of overdose were observed.

Incompatibilities
Not known.

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 white to yellowish ointment with a soft consistency and apparently homogeneous.
The veterinary medicinal product is packaged in aluminium tubes coated on the inside with varnish, with an HDPE cap, containing 3.5 g or 5 g of ointment.
It is possible that not all presentations are marketed.