

PACKAGE LEAFLET:
Ocil 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

Ocil 5 mg/g eye ointment
Dogs, cats and non-food producing horses
Oxytetracycline hydrochloride

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

The active substance is oxytetracycline hydrochloride.
The other ingredients are lanolin and white soft paraffin.

4. INDICATION(S)

This veterinary medicinal product is indicated in the treatment of external ocular infections of bacterial etiology (blepharitis, conjunctivitis, keratitis, keratoconjunctivitis, blepharoconjunctivitis and meibomianitis) sensitive to oxytetracycline. It is also recommended for local treatment of trachoma and conjunctivitis of *Chlamydia* origin.

This veterinary medicinal product is also used in prophylaxis of pre- and post-surgery and in general in eyeball wounds.

5. CONTRAINDICATIONS

Do not use in case of allergy (hypersensitivity) to oxytetracycline hydrochloride, to tetracyclines and its derivatives, or to any other ingredients of this medicine (indicated in section 3).

Do not use in animals with renal or hepatic pathology.

Do not use in pregnant animals.

Do not use in newborns and young animals.

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.

The use of topical oxytetracycline may lead to serious allergic reactions, mainly in cats.

Burning or stinging sensation in the eye may occur following application of the veterinary medicinal product.

Although these side effects have only been reported following systemic administration of oxytetracycline, its possibility should be considered:

- nausea, vomiting, anorexia, and diarrhoea (in dogs and cats).
- fever, fur loss and depression (in cats).
- diarrhoea (in horses following surgery, anaesthesia, or trauma).

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.

Topically apply on the eye mucosa (in the inner angle) 2 to 4 times per day until symptom resolution. Treatment may last up to 6 weeks, especially in infections by *Chlamydia*.

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

Treatment should be continued for 48 hours after symptoms resolution.

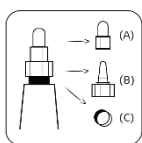
In case of a forgotten dose, this should be applied as soon as possible. Treatment should be continued with the administration of the following dose, as planned.

9. ADVICE ON CORRECT ADMINISTRATION

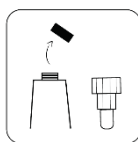
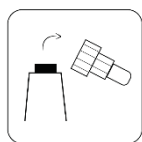
How to use the veterinary medicinal product:

Tube preparation (first administration)

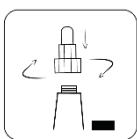
Wash your hands and put on gloves, if necessary.



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.

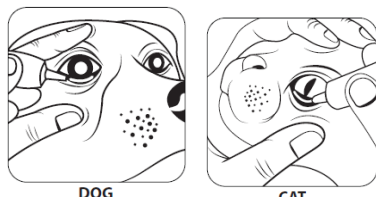
Remove excess of secretion from around the animal's eye(s) with a wet dressing or cloth.



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.

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 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:

Although treatment of external ocular infections is generally empirical, it is recommended the collection of samples to identify the concerned microorganism before administrating the veterinary medicinal product. The continued use of oxytetracycline may favour the appearance of infections by resistant bacteria and opportunistic infections, namely fungal. In these cases, its use should be interrupted, and appropriate treatment should be started.

There is possibility of cross hypersensitivity between tetracyclines when administrated by systemic or topical route, thus existence of any hypersensitivity to tetracyclines should require caution in the administration of the veterinary medicinal product.

It is recommended special care in the administration of the veterinary medicinal product in horses following surgery, anaesthesia, or trauma.

Special precautions for use

Special precautions for use in animals

When an infection is suspected to be the cause of a disease process, 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 oxytetracycline 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.

When starting the use of the eye ointment the first portion should be discarded.

Pregnancy

Do not use during pregnancy.

Lactation

The veterinary medicinal product should not be administrated 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.

Overdose (symptoms, emergency procedures, antidotes)

Not known.

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 as eye ointment packaged in an aluminium tube (coated internally by epoxyphenolic lacquer and externally by white polyester) with white HDPE cap. The tube has capacity of 5 g.