1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ophtalon vet 10 mg/g eye ointment for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Chloramphenicol .....10 mg

Excipients:

Qualitative composition of excipients and other constituents
Vitamin A (all-(*E*)-retinol palmitate)
White soft paraffin
Liquid paraffin

White, translucent, homogeneous, water-dispersible ointment.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Treatment of ocular bacterial infections.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Cross-resistance has been shown between chloramphenicol and other phenicols. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to phenicols because its effectiveness may be reduced.
Before starting treatment, it should be ensured that there are no mechanical or physical causes for the eye inflammation e.g. ectopic cilium, entropion, foreign body, deficiency in tear secretion.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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

Chloramphenicol can cause allergic reactions. People with known hypersensitivity to chloramphenicol should only administer the veterinary medicinal product with disposable gloves.

In humans, there is evidence that exposure to chloramphenicol may increase the risk of severe aplastic anaemia.
It is therefore essential to avoid skin and eye contact and wash hands after administration of the veterinary medicinal product. In case of accidental skin or eye contact, flush with plenty of water. In the event of hypersensitivity reactions, seek medical advice and show the package leaflet or the label to the physician.

Chloramphenicol may cause serious harm to the unborn child and children who are breastfed. The veterinary medicinal product should therefore not be administered by pregnant and breastfeeding women.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Conjunctivitis, blepharitis, eye irritation, eye redness, corneal ulcer, blepharospasm, conjunctival oedema

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

Chloramphenicol can cross the placenta and pass into milk. Effects on fetuses or suckling puppies and kittens are unlikely due to the topical ocular route of administration, but the veterinary medicinal product should only be used according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Ocular use.

Apply a small ribbon of ointment along the length of the conjunctival sac of the affected eye twice daily (approximately every 12 hours).

The recommended treatment duration is generally 8 to 10 days. Shorter or longer durations of treatment may be required based on veterinary assessment of the clinical response.
Treatment with the veterinary medicinal product should be re-evaluated by a veterinary professional if symptoms worsen.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Unknown.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QS01AA01

4.2 Pharmacodynamics

Chloramphenicol is a synthetic broad-spectrum antibiotic whose spectrum of activity includes aerobic and anaerobic gram-positive and gram-negative bacteria, as well as *Chlamydia* sp. and *Mycoplasma* sp. Chloramphenicol binds to the 50S subunit of the bacterial ribosome and prevents transpeptidation in bacterial protein synthesis. The effect of chloramphenicol is mainly bacteriostatic. Chloramphenicol shows no significant activity against *Pseudomonas aeruginosa*.

The most commonly described resistance mechanism for chloramphenicol is enzymatic inactivation by chloramphenicol acetyltransferases (CAT). Acetylation prevents chloramphenicol from binding to the 50S subunit of the bacterial ribosome. Genes encoding CAT are often located on moving parts such as plasmids, transposons or gene cassettes. In addition, mechanisms of resistance through efflux systems, inactivation of phosphotransferases and mutations on target structures are described.
There is cross-resistance between substances of the phenicol class. For instance, in gram-negative bacteria the floR gene located on a plasmid promotes efflux of chloramphenicol and florfenicol. In gram-positive cocci, fexA has been found which encodes an efflux pump conferring resistance to florfenicol and chloramphenicol.
Additionally, a multi-resistance genes cfr has been identified that can be located on plasmids or transposons which confers resistance by the rRNA methyltransferase to pleuromutilins, oxazolidinones, phenicols, streptogramin A, and lincosamides.

4.3 Pharmacokinetics

Chloramphenicol is a fat-soluble substance. Chloramphenicol penetrates into cells and remains active during intracellular infections. When applied locally, it is well absorbed into the conjunctiva and it can diffuse into aqueous humour through the cornea, particularly when the corneal epithelium is compromised (e.g., abraded). However, due to its limited corneal penetration under normal conditions, therapeutic concentrations are not reliably achieved in the posterior segment of the eye following topical

administration. Drug distribution into ocular tissues depends on formulation (ointment vs. solution), frequency of dosing, and integrity of the corneal barrier.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 12 days

5.3 Special precautions for storage

Do not store above 25°C. Do not freeze.

5.4 Nature and composition of immediate packaging

Aluminium tube with internal epoxy phenolic varnish
White high-density polyethylene nozzle
White polypropylene cap

Box containing 1 tube of 5 g.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DOMES PHARMA

7. MARKETING AUTHORISATION NUMBER(S)

VPA23340/010/001

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).