SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ophtocycline 10 mg/g eye ointment for dogs, cats and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:
Chlortetracycline 9.3 mg
(equivalent to 10.0 mg chlortetracycline hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents
Paraffin, light liquid
Wool fat
Paraffin, white soft

Yellowish to yellow homogenous ointment.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats and horses.

3.2 Indications for use for each target species

Treatment of keratitis, conjunctivitis and blepharitis caused by *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp. and/or *Pseudomonas* spp.

3.3 Contraindications

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

3.4 Special warnings

None.

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 farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to chlortetracycline and may decrease the effectiveness of treatment with other tetracyclines due to the potential for cross-resistance.

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

This veterinary medicinal product may cause skin sensitisation, hypersensitivity reactions and/or eye irritation.
People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
Avoid contact with the skin and eyes.
Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product.
In case of contact with the skin, wash exposed skin with water and soap. If you develop symptoms following exposure such as a skin rash, seek medical advice immediately and show the package leaflet or label to the physician.
In case of contact with the eyes, wash immediately with clean water. If irritation persists, seek medical advice immediately and show the package leaflet or label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dog, cat, horse:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Application site reaction Eye disorder (e.g. Eye irritation, Eye itching, Swollen eye, Eye redness)

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:
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

Ocular use.

Horses: Apply 2-3 cm of ointment (depending on the size of the animal) in the conjunctival sac 4 times a day for 5 days. If after 3 days of treatment no clinical improvement has occurred, alternative therapy should be considered.
Dogs and cats: Apply 0.5-2 cm of ointment (depending on the size of the animal) in the conjunctival sac 4 times a day for 5 days. If after 3 days of treatment no clinical improvement has occurred, alternative therapy should be considered.

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

No data available.

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

Meat and offal: 1 day.
Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QS01AA02

4.2 Pharmacodynamics

Chlortetracycline hydrochloride is a first-generation tetracycline. It is a predominantly bacteriostatic antibiotic that inhibits bacterial protein synthesis by binding to the 30S subunit of the bacterial ribosome. Chlortetracycline has time-dependent as well as concentration-dependent effects with AUC/MIC being the main PK/PD parameter. Chlortetracycline has a broad spectrum including both aerobic and anaerobic Gram-positive and Gram-negative bacteria.

Four resistance mechanisms acquired by microorganisms against tetracyclines in general have been reported: decreased accumulation of tetracyclines (decreased permeability of the bacterial cell wall and active efflux), protein protection of the bacterial ribosome, enzymatic inactivation of the antibiotic and rRNA mutations (preventing the tetracycline binding to ribosome).

Tetracycline resistance is usually acquired by means of plasmids or other mobile elements (e.g. conjugative transposons).

Resistance to tetracyclines is common and has been identified in target bacterial pathogens; however, the prevalence of resistance is likely to vary widely between different locations.

Cross-resistance among tetracyclines is common.

4.3 Pharmacokinetics

Chlortetracycline is a non-lipophilic molecule. After topical administration in the eye, systemic absorption is expected to be minimal.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 14 days.

5.3 Special precautions for storage

Do not store above 25 ºC.

5.4 Nature and composition of immediate packaging

Epoxy resin lacquered aluminium tube with a content of 5 g, with a HDPE cannula and screw cap. One tube in a cardboard box.

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

Medicines should not be disposed of via wastewater.

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

Le Vet. Beheer. B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 41821/4043

8. DATE OF FIRST AUTHORISATION

09 August 2017

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

June 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall

Approved: 16 October 2025