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 hydrochloride 10.0 mg
(equivalent to 9.3 mg chlortetracycline)

Excipient(s):

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment.
Yellowish to yellow homogenous ointment

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats and horses.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 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 a known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
Avoid contact with the skin and eyes.
Wear impermeable gloves when handling the 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.

4.6 Adverse reactions (frequency and seriousness)

Application site reactions and eye disorders like irritation, pruritus, oedema and reddening have been very rarely reported after administration of the veterinary medicinal product in isolated cases in spontaneous reports.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

For ocular use only.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No data available.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ophthalmologicals: antibiotics
ATCvet code: QS01AA02

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, light liquid
Wool fat
Paraffin, white soft

6.2 Major incompatibilities

Not applicable

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Le Vet. Beheer. B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

8. MARKETING AUTHORISATION NUMBER

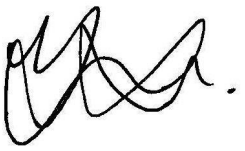
Vm 41821/4043

9. DATE OF FIRST AUTHORISATION

09 August 2017

10. DATE OF REVISION OF THE TEXT

September 2022



Approved: 08 September 2022