ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 gram contains:

Active substances:
Chlortetracycline hydrochloride 10.0 mg

3. PHARMACEUTICAL FORM

Eye ointment.

4. PACKAGE SIZE

5 g

5. TARGET SPECIES

Dogs, cats and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Ocular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 1 day
Not authorised for use in horses producing milk intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 14 days. Use by…….

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4043

17. MANUFACTURER'S BATCH NUMBER

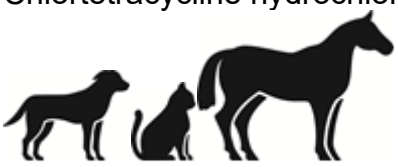
Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Tube 5 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ophtocycline 10 mg/g eye ointment
Chlortetracycline hydrochloride



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Chlortetracycline hydrochloride 10.0 mg/g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 g

4. ROUTE(S) OF ADMINISTRATION

Ocular use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 1 day
Not authorised for use in horses producing milk intended for human consumption.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP{month/year}
Once broached, use within 14 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Ophtocyclin 10 mg/g eye ointment for dogs, cats and 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
Le Vet. Beheer B.V.
Wilgenweg 7
3421 TV Oudewater,
The Netherlands

Manufacturer responsible for the batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ophtocyclin 10 mg/g eye ointment for dogs, cats and horses
Chlortetracycline hydrochloride

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

Each gram contains:

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

Yellowish to yellow homogenous ointment

4. INDICATION(S)

Treatment of bacterial infections in the eye (keratitis, conjunctivitis and blepharitis) caused by *Staphylococcus* spp., *Streptococcus* spp*., Proteus* spp. and/or *Pseudomonas* spp.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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).

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 your national reporting system {national system details}.

7. TARGET SPECIES

Dogs, cats and horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25ºC.
Shelf-life after first opening the tube: 14 days
Do not use this veterinary medicinal product after the expiry date which is stated on the container after EXP.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Use of the 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 product deviating from the instructions given in the package leaflet 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 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.

Pregnancy and lactation:
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.

Interaction with other medicinal products and other forms of interaction
No data available.

Overdose (symptoms, emergency procedures, antidotes)
No data available.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

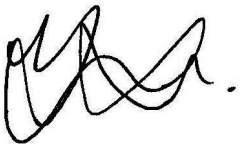
Dispose of waste material in accordance with local requirements.
Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2022

15. OTHER INFORMATION

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



Approved: 08 September 2022