[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CTC Spray, 2.45 % w/w cutaneous spray, suspension for cattle, sheep and pigs (NL)
Cyclospray, 2.45 % w/w cutaneous spray, suspension for cattle, sheep and pigs
(AT, DE, DK, EL, ES, FR, IE, IT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Chlortetracycline HCl	78.6 mg
(equivalent to chlortetracycline	73.0 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Patent Blue V (E 131)	4.8 mg
Butane 100	
Colloidal anhydrous silica	
Isopropyl alcohol	
Sorbitan triolate	

Blue coloured spray.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

- Treatment of superficial traumatic or surgical wounds contaminated with chlortetracycline-sensitive agents.
- The veterinary medicinal product can be used as part of a treatment for superficial skin and claw/hoof infections, in particular interdigital dermatitis (foot rot and foul in the foot) and digital dermatitis caused by micro-organisms sensitive to chlortetracycline.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use on the udder of lactating animals if milk is intended for human consumption.

3.4 Special warnings

Cross-resistance has been shown between chlortetracyclin and others tetracyclins antibiotics. Use of the product should be carefully considered when susceptibility testing has shown resistance to tetracyclins antibiotics because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Protect the eyes when spraying in the vicinity of the head. Clean the affected area thoroughly before spraying. After administration on the claw/hoof the animal should be kept on a dry ground at least for an hour's time. 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.

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

- Because of the risk of sensitisation and contact dermatitis, skin contact should be avoided.
- Wear appropriate impermeable gloves whilst handling the veterinary medicinal product.
- Because of risk of eye irritation, contact with the eyes should be avoided. Protect the eyes and face.
- Do not spray on an open flame or other ignition source.
- Do not pierce or burn, even after use.
- Avoid inhaling vapours. Apply the veterinary medicinal product in open air or in sufficiently ventilated area.
- Wash hands after use.
- Do not eat or smoke whilst administering the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

3.6 Adverse events

Cattle, sheep and pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction

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 label for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Following cutaneous administration of the veterinary medicinal product, chlortetracycline is not absorbed, nor excreted with the milk. Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

After cutaneous administration of chlortetracycline spray, chlortetracycline is not absorbed. Parenteral or oral administered antibiotics will not penetrate the dermis. Therefore no interactions are to be expected.
No data on interactions with other local treatments are available.

3.9 Administration routes and dosage

Cutaneous use.
Shake the container thoroughly before spraying. The container should be held at a distance of approximately 15-20 cm from the area to be sprayed; spray for 3 seconds until the treatment-area is evenly coloured.
In case of claw/hoof infections this treatment should be repeated after 30 seconds.

- For treatment of superficial traumatic or surgical wounds contaminated with chlortetracycline-sensitive agents a single administration is recommended.
- For treatment of Dermatitis Digitalis administration twice with a 30 second interval during three consecutive days once or twice daily is recommended.
- For treatment of other claw/hoof infections (foot rot and foul in the foot), administration twice with a 30 second interval once or twice daily is recommended. Dependent on the seriousness of the injury and the rate of improvement treatment should be repeated within 1 to 3 days.

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

Not applicable.

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

To be completed nationally.

3.12 Withdrawal periods

Meat and offal: zero days
Milk: zero days
See also 3.3 contraindications

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QD06AA02

4.2 Pharmacodynamics
In vitro, chlortetracycline is primarily bacteriostatic. Chlortetracycline exerts its action by inhibiting the protein synthesis of the bacterial cell. Especially cell-division and the formation of the cell wall are impaired. Chlortetracycline binds to receptors on the 30S-subunit of the bacterial ribosome where they interfere with the binding of the aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex.
Chlortetracycline belongs to the group of the tetracycline antibiotics.
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). Cross-resistance between tetracyclines has also been described.

4.3 Pharmacokinetics

Following cutaneous administration of chlortetracycline spray, chlortetracycline absorption is negligible. Therefore the veterinary medicinal product will only have a local effect, no systemic effects are to be anticipated.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Extremely flammable aerosol. Pressurised container: May burst if heated.
Protect from sunlight. Do not expose to temperatures exceeding 50°C.
Keep away from heat/hot surfaces/sparks/open flames and other ignition sources. No smoking.

5.4 Nature and composition of immediate packaging

270 ml (containing 130,76 g of veterinary medicinal product, equivalent with 40,84 g suspension without propellant) pressurised container of coated tin plate with a plastic valve mechanism and spraying nozzle.
520 ml (containing 261,52 g of veterinary medicinal product, equivalent with 81,68 g suspension without propellant) pressurised container of coated tin plate with a plastic valve mechanism and spraying nozzle.

Not all pack sizes may be marketed.

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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.>

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

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Coated tin plate can 130,76 g ; 261,52 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CTC SPRAY, 2.45 % w/w cutaneous spray, suspension for cattle, sheep and pigs (NL)
Cyclospray, 2.45 % w/w cutaneous spray, suspension for cattle, sheep and pigs
(AT, DE, DK, Elm, ES, FR, IE, IT)

2. COMPOSITION

Each gram contains:

Active substance:

Chlortetracycline HCl	78.6 mg
(equivalent to chlortetracycline	73.0 mg)

Excipients:

Patent Blue V (E131), colouring agent	4.8 mg

Blue coloured spray.

3. PACKAGE SIZE

130,76 g;
261,52 g.

4. TARGET SPECIES

Cattle, sheep and pigs.

5. INDICATIONS FOR USE

Indications for use

- Treatment of superficial traumatic or surgical wounds contaminated with chlortetracycline-sensitive agents.
- The veterinary medicinal product can be used as part of a treatment for superficial skin and claw/hoof infections, in particular interdigital dermatitis (foot rot and foul in the foot) and digital dermatitis caused by micro-organisms sensitive to chlortetracycline.

6. CONTRAINDICATIONS

Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients. Do not use on the udder of lactating animals if milk is intended for human consumption.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
Cross-resistance has been shown between chlortetracyclin and others tetracyclins antibiotics. Use of the product should be carefully considered when susceptibility testing has shown resistance to tetracyclins antibiotics because its effectiveness may be reduced.

Special precautions for safe use in the target species:
Protect the eyes when spraying in the vicinity of the head. Clean the affected area thoroughly before spraying. After administration on the claw/hoof the animal should be kept on a dry ground at least for an hours time. 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Because of the risk of sensitisation and contact dermatitis, skin contact should be avoided.
Wear appropriate impermeable gloves whilst handling the veterinary medicinal product.
Because of risk of eye irritation, contact with the eyes should be avoided. Protect the eyes and face.
Avoid inhaling vapours. Apply the veterinary medicinal product in open air or in sufficiently ventilated area.
Wash hands after use.
Do not eat or smoke whilst administering the veterinary medicinal product.

Pregnancy and lactation:
Following cutaneous administration of the veterinary medicinal product, chlortetracycline is not absorbed, nor excreted with the milk. Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
After cutaneous administration of chlortetracycline spray, chlortetracycline is not absorbed. Parenteral or oral administered antibiotics will not penetrate the dermis. Therefore no interactions are to be expected.
No data on interactions with other local treatments are available.

<Special restrictions for use and special conditions for use:>

8. ADVERSE EVENTS

Adverse events
Cattle, sheep and pigs:
Rare (1 to 10 animals / 10,000 animals treated): Hypersensitivity reaction.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system: .

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
Cutaneous use.
Shake the container thoroughly before spraying. The container should be held at a distance of approximately 15-20 cm from the area to be sprayed; spray for 3 seconds until the treatment-area is evenly coloured.
In case of claw/hoof infections this treatment should be repeated after 30 seconds.

- For treatment of superficial traumatic or surgical wounds contaminated with chlortetracycline-sensitive agents a single administration is recommended.
- For treatment of Dermatitis Digitalis administration twice with a 30 second interval during three consecutive days once or twice daily is recommended.
- For treatment of other claw/hoof infections (foot rot and foul in the foot), administration twice with a 30 second interval once or twice daily is recommended. Dependent on the seriousness of the injury and the rate of improvement treatment should be repeated within 1 to 3 days.

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

Withdrawal periods
Meat and offal: zero days
Milk: zero days
See also contraindications.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions
Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal
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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

To be completed nationally.

Pack sizes
Can 130,76 g; 261.52 g.
Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

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

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Eurovet Animal Health B.V.
Handelsweg 25, 5531 AE Bladel
The Netherlands

IGS Aerosols GmbH
Im Hemmet 1 und 2
79664 Wehr
Germany

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

18. OTHER INFORMATION

Other information

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

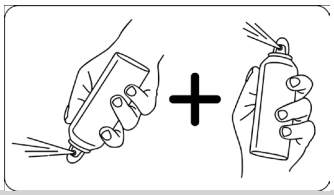
20. EXPIRY DATE

Exp {mm/yyyy}

21. BATCH NUMBER

Lot {number}

Danger
Extremely flammable aerosol. Pressurized container: May burst if heated.
Protect from sunlight. Do not expose to temperatures exceeding 50°C.
Keep away from heat/hot surfaces/sparks/open flames and other ignition sources. No smoking.
Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use.



Symbols will be placed on the label text presented on the can