ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outside Booklet Label (tear open label)
{130.76 g, 261.52 g}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CTC Spray 78.6 mg/g, cutaneous spray, suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Chlortetracycline HCl 78.6 mg/g
(equivalent to chlortetracycline 73.0 mg/g)

3. PACKAGE SIZE

130.76 g
261.52 g

4. TARGET SPECIES

Cattle, sheep and pigs. [pictogram]

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cutaneous spray.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: zero days
Milk: zero hours
Not authorised for use on the udder of lactating animals if milk is intended for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Read the package leaflet before use.
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10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV [logo]

14. MARKETING AUTHORISATION NUMBERS

Vm 16849/3006

15. 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.

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

{130.76 g, 261.52 g}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CTC Spray 78.6 mg/g, cutaneous spray, suspension for pigs, sheep and cattle

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. [pictograms]

5. INDICATIONS FOR USE

Indications for use
Supportive treatment of infections of superficial traumatic origin or surgical wounds caused by micro-organisms sensitive to chlortetracycline.The product can be used as part of a treatment for superficial foot infections, in particular interdigital dermatitis (foot rot) in sheep, and digital dermatitis in cattle.

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

Special precautions for safe use in the target species:

Protect the eyes of the animal when spraying in the vicinity of the head.

The animal should be discouraged from licking the treated area, or treated areas on other animals.

Susceptibility testing and official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal product deviating from these instructions 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:

Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and
possible hypersensitivity reactions to chlortetracycline.

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.

In case of accidental ingestion, or in case of contact with eyes, seek medical advice immediately and show the label to the physician.

Avoid inhaling vapours. Apply the veterinary medicinal product in open air or in a sufficiently ventilated area.

Wash hands after use.

Do not eat or smoke whilst administering the veterinary medicinal product.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction:

No data on interactions with other local treatments are available.

Major incompatibilities:
None known.

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 {national system details}.

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

Dosage for each species, routes and method of administration
Cutaneous use.
This veterinary medicinal product is indicated for cutaneous administration. Shake the container thoroughly before spraying. The container should be held at a distance of 15-20 cm from the area to be sprayed; spray for approximately 3 seconds (equivalent to approximately 3.9 g of veterinary medicinal product or 0.10 g chlortetracycline HCl) until the treatment area is evenly coloured. In case of foot infections this treatment should be repeated after 30 seconds.
For supportive treatment of infections of superficial traumatic origin or surgical wounds , a single administration is recommended.
For treatment of Dermatitis Digitalis, a double administration (with a 30 second interval) is recommended daily for three consecutive days.
For treatment of other foot infections (foot rot), a double administration (with a 30 second interval) 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

Advice on correct administration
Clean the affected area thoroughly before spraying. Treatment of foot conditions should always be preceded by appropriate paring of the foot, as this is critical for achieving an adequate response. After administration to the claw, the animal should be kept on dry ground for at least one hour.

11. WITHDRAWAL PERIODS

Withdrawal periods
Meat and offal: zero days
Milk: zero hours
Not authorised for use on the udder of lactating animals if milk is intended for human consumption.

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 bottom of this can. 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

Pack sizes
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

September 2023

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

For UK(NI) only: Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:>
Eurovet Animal Health BV,
Handelsweg 25,
5531 AE Bladel,
The Netherlands
Tel: +31 (0)348-563434

Marketing authorisation holder:
Eurovet Animal Health BV,
Handelsweg 25,
5531 AE Bladel,
The Netherlands
Tel: +31 (0)348-563434

Manufacturer responsible for batch release:
Eurovet Animal Health BV,
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.

B. PACKAGE LEAFLET

**Inside Booklet Label (tear open label)
can 130.76 g, 261.52 g**

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CTC Spray 78.6 mg/g, cutaneous spray, suspension for pigs, sheep and cattle

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. Target species

Cattle, sheep and pigs.

4. Indications for use

Supportive treatment of infections of superficial traumatic origin or surgical wounds caused by micro-organisms sensitive to chlortetracycline.The product can be used as part of a treatment for superficial foot infections, in particular interdigital dermatitis (foot rot) in sheep, and digital dermatitis in cattle.

5. Contraindications

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

6. Special warnings

Special precautions for safe use in the target species:
Protect the eyes of the animal when spraying in the vicinity of the head.
The animal should be discouraged from licking the treated area, or treated areas on other animals.
Susceptibility testing and official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal product deviating from these instructions 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:
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and
possible hypersensitivity reactions to chlortetracycline.
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.
In case of accidental ingestion, or in case of contact with eyes, seek medical advice immediately and show the label to the physician.
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 a sufficiently ventilated area.
Wash hands after use.
Do not eat or smoke whilst administering the veterinary medicinal product.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
No data on interactions with other local treatments are available.

Major incompatibilities:
None known.

7. 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 in this package leaflet, 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 at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Cutaneous use.
This veterinary medicinal product is indicated for cutaneous administration. Shake the container thoroughly before spraying. The container should be held at a distance of 15-20 cm from the area to be sprayed; spray for approximately 3 seconds (equivalent to approximately 3.9 g of veterinary medicinal product or 0.10 g chlortetracycline HCl) until the treatment area is evenly coloured. In case of foot infections this treatment should be repeated after 30 seconds.
For supportive treatment of infections of superficial traumatic origin or surgical wounds , a single administration is recommended.
For treatment of Dermatitis Digitalis, a double administration (with a 30 second

interval) is recommended daily for three consecutive days.
For treatment of other foot infections (foot rot), a double administration (with a 30 second interval) is recommended. Dependent on the seriousness of the injury and the rate of improvement, treatment should be repeated within 1 to 3 days.

9. Advice on correct administration

Clean the affected area thoroughly before spraying. Treatment of foot conditions should always be preceded by appropriate paring of the foot, as this is critical for achieving an adequate response. After administration to the claw, the animal should be kept on dry ground for at least one hour.

10. Withdrawal periods

Meat and offal: zero days
Milk: zero hours
Not authorised for use on the udder of lactating animals if milk is intended for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

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 use this veterinary medicinal product after the expiry date which is stated on the bottom of this can. The expiry date refers to the last day of that month.

12. 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.>

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 16849/3006

Pack sizes: 130.76 g, 261.52 g.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

September 2023

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

For UK(NI) only: Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
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5531 AE Bladel,
The Netherlands
Tel: +31 (0)348-563434

Marketing authorisation holder:
Eurovet Animal Health BV,
Handelsweg 25,
5531 AE Bladel,
The Netherlands
Tel: +31 (0)348-563434

Manufacturer responsible for batch release:
Eurovet Animal Health BV,
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.>

17. Other information

Approved 26 February 2024