# PARTICULARS TO APPEAR ON THE OUTER PACKAGE Outside Booklet Label (tear open label)

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CTC Spray 78.6 mg/g, cutaneous spray, suspension

#### 2. STATEMENT OF ACTIVE AND OTHER 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. INDICATION(S)

# **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.

#### 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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV[logo]

#### 14. MARKETING AUTHORISATION NUMBERS

Vm 16849/5006

#### **15. BATCH NUMBER**

Lot {number}

# 16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

# 17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS. IF ANY

Disposal: Read package leaflet

# 18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

Veterinary medicinal product subject to prescription.



#### 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 PACKAGE LEAFLET:

Inside Booklet Label (tear open label)

### 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 WARNING(S)

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.

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals:</u>

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, ROUTE(S) 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 HCI) 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 PERIOD(S)

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. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. 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 16849/5006

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

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

# **16. CONTACT DETAILS**

<u>Marketing authorisation holder and contact details to report suspected adverse</u> reactions:

Eurovet Animal Health BV,

Handelsweg 25, 5531 AE Bladel.

The Netherlands

Tel: +44 (0) 1939 211200

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 representative and contact details to report suspected adverse reactions:

**Dechra Veterinary Products Limited** 

Sansaw Business Park

Hadnall

Shrewsbury

Shropshire

SY4 4AS

Tel: +44 (0) 1939 211200

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

17. OTHER INFORMATIC
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# MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet {NATURE/TYPE}

[This template should only be used when all printed information is directly visible on the immediate container and cannot be used if a fold-out or concertina format is proposed.]

#### 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.

Interaction 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 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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

# 9. DOSAGE FOR EACH 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 PERIOD

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

Vm 16849/5006

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

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

#### 17. CONTACT DETAILS

### **Contact details**

<u>Marketing authorisation holder and contact details to report suspected adverse</u> reactions:

Eurovet Animal Health BV,

Handelsweg 25,

5531 AE Bladel.

The Netherlands

# 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 representative and contact details to report suspected adverse reactions:

**Dechra Veterinary Products Limited** 

Sansaw Business Park

Hadnall

Shrewsbury

Shropshire

**SY4 4AS** 

Tel: +44 (0) 1939 211200

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

18. OTHER INFORMATIO	)N
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# 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.

Approved 26 February 2024