Amended Pages: March 2023

AN: 03327/2022

PARTICULARS TO APPEAR ON THE OUTER PACKAGE = IMMEDIATE PACKAGE = LEAFLET {130.76 g, 261.52 g}

Full text will be printed on the can

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Eurovet Animal Health B.V.

Handelsweg 25, NL-5531 AE Bladel, The Netherlands

Manufacturer responsible for batch release:

Eurovet Animal Health B.V.

Handelsweg 25, NL-5531 AE Bladel, The Netherlands

IGS Aerosols GmbH

Im Hemmet 1 und 2, 79664 Wehr, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclo Spray, Chlortetracycline HCL 2.45% w/w, cutaneous spray, suspension for pigs, sheep and cattle

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

Active substance:

Chlortetracycline HCI: 3.210 g, 6.420 g /container (equivalent to 2.45% w/w/)

Excipients:

Patent Blue V (colouring agent E131)

Butane 100 (propellant)

4. PHARMACEUTICAL FORM

Cutaneous spray.

Suspension.

5. PACKAGE SIZE

130.76 g, 261.52 g

6. INDICATION(S)

Prevention of infections of superficial traumatic or surgical wounds caused by microorganisms sensitive to chlortetracycline.

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The product can be used as part of a treatment for superficial claw/hoof infections, in particular interdigital dermatitis (foot rot) in sheep and digital dermatitis in cattle.

7. CONTRA-INDICATIONS

Do not use in case of hypersensitivity to tetracyclines.

8. ADVERSE REACTIONS

Hypersensitivity reactions may occur rarely.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

9. TARGET SPECIES

Cattle, sheep and pigs.

10-11. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION AND ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

Cyclo Spray is indicated for cutaneous administration. Clean the affected area thoroughly before spraying. Protect the eyes when spraying in the vicinity of the head. Treatment of foot conditions should always be preceded by appropriate paring of the hoof, as this is critical for achieving an adequate response. The animal should be discouraged from licking the treated area, or treated areas on other animals. 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 until the treatment-area is evenly coloured. In case of claw/hoof infections this treatment should be repeated after 30 seconds.

- For prevention of infections after superficial traumatic 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 hoof 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. After spraying the feet, the animal should be kept on dry ground for at least one hour.

12. WITHDRAWAL PERIOD

Meat and offal: 0 days

Milk: 0 hours

Do not use on the udder of lactating animals if milk is intended for human consumption.

Stained part of the pig-skin must be removed prior to the rest of the animal being used for human consumption.

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13. SPECIAL STORAGE PRECAUTIONS

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.

Do not use after the expiry date stated on the bottom of the can.

14. SPECIAL WARNINGS

User warnings:

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 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 product in open air or in a sufficiently ventilated area. Wash hands after use. Do not eat or smoke whilst administering the product.

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

Use during pregnancy and lactation:

Following cutaneous administration of the product, absorption of chlortetracycline is negligible and it is not detectable in the milk.

Overdose:

Not applicable

Interactions:

After cutaneous administration of chlortetracycline spray, absorption of chlortetracycline is negligible. No data on interactions with other local treatments are available.

15. EXPIRY DATE

EXP: {month/year}

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

17. DATE ON WHICH THE TEXT WAS LAST APPROVED

January 2023

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18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. For external use only.

To be supplied only on veterinary prescription

POM- Prescription Only Medicine -

V Veterinarian

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

Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4002

21. MANUFACTURER'S BATCH NUMBER

Lot:

22. OTHER INFORMATION

130.76 g / 261.52 g - Not all pack sizes may be marketed.

Approved: 29 March 2023