SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Chlortetracycline HCl.
The active ingredient content is 2.45 % w/w

Excipients:

Patent Blue V, colouring agent	0.15 % w/w
Butane 100	68.77 % w/w

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous Spray, suspension
Blue colored

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

- Prevention of infections of superficial traumatic or surgical wounds caused by micro-organisms sensitive to chlortetracycline.
- 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.

4.3 Contraindications

Do not use in case of hypersensitivity to tetracyclines.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

Protect the eyes when spraying in the vicinity of the head. Clean the affected area thoroughly before spraying. Treatment of foot conditions should always be preceded by appropriate paring of the hoof, as this is critical for achieving an adequate response. After spraying the feet, the animal should be kept on dry ground for at least one hour.
The animal should be discouraged from licking the treated area, or treated areas on other animals.

ii. 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur rarely.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interactions with other veterinary medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

CYCLO Spray 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 product or 0.10 g chlortetracycline) 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

4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary

Not applicable

4.11 Withdrawal periods

Meat : zero days
Milk : zero hours
Do not use on the udder of lactating animals if milk is intended for human consumption.
Stained part of the pigskin must be removed prior to the rest of the animal being used for human consumption.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlortetracycline belongs to the pharmacotherapeutic group of tetracycline antibiotics.

ATC vet code: QD06AA02

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.

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V [E 131]
Butane (Butan 100)
Colloidal anhydrous silica (Aerosil 200)
Isopropyl alcohol
Sorbitan trioleate (Span 85)

6.2 Incompatibilities

None known

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

211 ml of suspension in a 270 ml and 422 ml of suspension in a 520 ml pressurised container of coated tin plate with a plastic valve mechanism and spraying nozzle.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 16849/4002

9. DATE OF FIRST AUTHORISATION

14 August 2006

10. DATE OF REVISION OF THE TEXT

May 2017

Approved: 17 May 2017