SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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 (E131), colouring agent	4.8 mg
Butane (Butan 100)	
Colloidal anhydrous silica (Aerosil 200)	
Isopropyl alcohol	
Sorbitan trioleate (Span 85)	

Blue coloured spray.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

Supportive treatment of infections of superficial traumatic origin or surgical wounds caused by micro-organisms sensitive to chlortetracycline. The veterinary medicinal 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.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

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 the instructions given in the SPC 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.

Special precautions for the protection of the environment:
Not applicable.

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

No data on interactions with other local treatments are available.

3.9 Administration routes and dosage

Cutaneous use.
The 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.

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.

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

3.12 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.

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. In particular, cell division and the formation of the cell wall are impaired. Chlortetracycline binds to the 30S-subunit of the bacterial ribosome where it interferes with the binding of the aminoacyl-transfer RNA (AA-tRNA) to the acceptor site on the messenger RNA ribosome complex. Resistance to tetracyclines can be mediated by different mechanisms: (1) energy-dependent efflux systems; (2) ribosomal protection proteins that dissociate the tetracyclines from their binding site near the ribosomal AA-tRNA docking site; (3) enzymatic hydroxylation of carbon-11a, which disrupts the tetracyclines' β-keto-enol involved in ribosome binding; (4) ribosomal 16S RNA mutation at the primary binding site of tetracyclines; and (5) stress-induced down-regulation of the porins through which the drug crosses the outer Gram-negative wall. The first two mechanisms are by far the most common.

4.3 Pharmacokinetics

Following cutaneous administration of the veterinary medicinal product, 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

None known.

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. 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.

5.4 Nature and composition of immediate packaging

270 ml (containing 130.76 g) or 520 ml (containing 261.52 g) 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

Eurovet Animal Health B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 16849/3006

8. DATE OF FIRST AUTHORISATION

14 December 2015

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

September 2023

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).

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

Approved 26 February 2024