# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Croatia, Cyprus, Czech Republic, Estonia, Latvia, Portugal, Romania, Slovakia, Slovenia, Iceland:
Cyclospray 78.6 mg/g, cutaneous spray, suspension for pigs, sheep and cattle

Sweden:
Cyclospray vet 78.6 mg/g, cutaneous spray, suspension for pigs, sheep and cattle

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of the suspension contains :

**Active substance:**

| | |
|---|---|
| Chlortetracycline HCl | 78.6 mg |
| (equivalent to chlortetracycline | 73.0 mg) |

**Excipients:**

| | |
|---|---|
| Patent Blue V, colouring agent | 4.8 mg |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Cutaneous spray, suspension.
Blue coloured spray.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle, sheep and pigs.

### 4.2 Indications for use, specifying the 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.

## 4.3 Contraindications

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

## 4.4 Special warnings for each target species

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.

## 4.5 Special precautions for use

Special precautions for use in animals

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

## 4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur rarely (more than 1 but less than 10 animals in 10,000 animals treated).

## 4.7 Use during pregnancy, lactation or lay

Following cutaneous administration of the veterinary medicinal product, absorption of chlortetracycline is negligible and it is not detectable in the milk. Therefore, the veterinary medicinal product is safe during pregnancy and lactation.

## 4.8 Interaction with other medicinal products and other forms of interaction

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

## 4.9 Amounts to be administered and administration route

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 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

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

Not applicable.

## 4.11 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..

# 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibiotics for topical use, tetracycline and derivates
ATCvet code: QD06AA02

## 5.1 Pharmacodynamic properties

*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 receptors on the

30S-subunit of the bacterial ribosome where they interfere 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.

### 5.2 Pharmacokinetic particulars

Following cutaneous administration of the veterinary medicinal product, chlortetracycline absorption is negligible. Therefore the product will only have a local effect, no systemic effects are to be anticipated.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Patent Blue V (E131)
Butane (Butan 100)
Colloidal anhydrous silica (Aerosil 200)
Isopropyl alcohol
Sorbitan trioleate (Span 85)

### 6.2 Major 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. 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.

### 6.5 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.

## 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 16849/4053

## 9. DATE OF FIRST AUTHORISATION

14 December 2015

## 10. DATE OF REVISION OF THE TEXT

August 2020

Approved 26 August 2020