

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10989/049/001**

Case No: 7005618

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Eurovet Animal Health B.V.

Handelsweg 25, 5531 AE Bladel, Netherlands

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

CTC SPRAY, 2.45 % w/w for cattle, sheep and pigs

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **26/08/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CTC SPRAY, 2.45 % w/w for cattle, sheep and pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per container:

Active Substance:

Chlortetracycline HCl.

The active ingredient content is 2.45 % w/w (equivalent to 3.210 g)

Excipients:

| | |
|-----------------------|--------------------------------------|
| Patent Blue V (E 131) | 0.15 % w/w (equivalent to 0.196 g) |
| Butane 100 | 68.77 % w/w (equivalent to 89.920 g) |

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Spray, Suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

- Treatment of superficial traumatic or surgical wounds contaminated with chlortetracycline-sensitive agents.
- The product can be used as part of a treatment for superficial skin and claw/hoof infections, in particular interdigital dermatitis (foot rot and foul in the foot) and digital dermatitis caused by micro-organisms sensitive to chlortetracycline.

4.3 Contraindications

Do not use in case of hypersensitivity to tetracyclines or to other ingredients of the product. Do not use on the udder of lactating animals if milk is intended for human consumption.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Protect the eyes when spraying in the vicinity of the head. Clean the affected area thoroughly before spraying. After administration on the claw/hoof the animal should be kept on a dry ground at least for an hours time. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. 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

- Because of the risk of sensitisation and contact dermatitis, skin contact should be avoided.
- 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 a naked flame or any incandescent material.
- 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.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur rarely.

4.7 Use during pregnancy, lactation or lay

Following cutaneous administration of the product, chlortetracycline is not absorbed, nor excreted with the milk. Therefore, the product is safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

After cutaneous administration of chlortetracycline spray, chlortetracycline is not absorbed. Parenteral or oral administered antibiotics will not penetrate the dermis. Therefore no interactions are to be expected. No data on interactions with other local treatments are available.

4.9 Amounts to be administered and administration route

The product is indicated for cutaneous administration. Shake the container thoroughly before spraying. The container should be held at a distance of approximately 15-20 cm from the area to be sprayed; spray for 3 seconds until the treatment-area is evenly coloured.

In case of claw/hoof infections this treatment should be repeated after 30 seconds.

- For treatment of superficial traumatic or surgical wounds contaminated with chlortetracycline-sensitive agents a single administration is recommended.
- For treatment of Dermatitis Digitalis administration twice with a 30 second interval during three consecutive days once or twice daily is recommended.

For treatment of other claw/hoof infections (foot rot and foul in the foot), administration twice with a 30 second interval once or twice daily 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 Period(s)

Meat : zero days

Milk : zero days

See also 4.3 contraindications

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: tetracycline antibiotics.

ATCvet code: QD06A

5.1 Pharmacodynamic properties

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 properties

Following cutaneous administration of chlortetracycline spray, 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

Colloidal anhydrous silica

Isopropyl alcohol

Patent blue V (*E-131*)

Sorbitan trioleate

Butane 100

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. Protect from frost. Pressurized container. Do not expose the container to direct sunlight or to temperatures higher than 50°. Keep away from sources of ignition.

6.5 Nature and composition of immediate packaging

270 ml pressurised container of coated tin plate with a plastic valve mechanism and spraying nozzle.

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, PO Box 179, 5530 AD Bladel
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10989/049/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th August 2009

10 DATE OF REVISION OF THE TEXT