SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taf Spray 28.5 mg/g Cutaneous spray, solution

Denmark, Sweden, Finland:
Taf vet. 28.5 mg/g Cutaneous spray, solution

Italy:
Denicol Spray 28.5 mg/g Cutaneous spray, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Thiamphenicol	28.5 mg

Excipients:

Curcumine (E100)	0.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle, goats, sheep, pigs, mink, rabbits.

4.2 Indications for use, specifying the target species

In all target species:
- Treatment of superficial wound infections caused by micro-organisms susceptible to thiamphenicol.

In cattle, goats and sheep:
- Treatment of infections of the claw and hoof such as foot rot, interdigital dermatitis, digital dermatitis caused by micro-organisms susceptible to thiamphenicol.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. See also section 4.11.

4.4 Special warnings for each target species

Clean the affected area thoroughly before spraying. After administration of the product 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 when spraying in the vicinity of the head. The animal should be prevented from licking the treated area, or treated areas on other animals.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacterial resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In cases of accidental eye contact, this product may cause irritation. The use of eye protection (such as safety glasses) is recommended. Do not spray towards a person. If irritation occurs, seek medical advice and show the label or package leaflet to the physician.

Asthma and rhinitis may occur following inhalation. Do not inhale vapours. Apply the product in the open air, or in a sufficiently ventilated area.

This product can be toxic when ingested.
Contact with the treated area should be avoided and children should not be allowed to play with treated pet animals until the application site is dry.
Do not eat, drink or smoke during administration.

Hypersensitivity (allergy) to thiamphenicol may occur rarely. People with known hypersensitivity to thiamphenicol should avoid contact with the veterinary medicinal product. Should symptoms occur such as swelling of the face, lips or eyes or difficulty in breathing, seek urgent medical attention.

Wash hands after use.

Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Cutaneous use. Shake the container thoroughly before spraying.
Spray the solution on the affected area for 3 seconds (equivalent to approximately 45 mg thiamphenicol) once a day. Treatment can be repeated depending on the healing process, up to 3 consecutive days.
The container should be held at a distance of approximately 15-20 cm from the area to be sprayed. For optimal use, wounds should be cleaned before application.
The spray container is suitable to be used in upright and inverted positions.

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

None known.

4.11 Withdrawal period(s)

Meat and offal:
- horses, cattle, goats, sheep, rabbits: zero days.
- pigs: 14 days.

Milk: 0 hours.
Do not use on the udder of lactating animals if their milk is intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibiotic for dermatological use, other antibiotic

ATCvet code: QD06AX

5.1 Pharmacodynamic properties

Thiamphenicol is a broad-spectrum antimicrobial agent, structurally similar to chloramphenicol. It is bacteriostatic for both Gram-positive and Gram-negative bacteria and acts by blocking the protein synthesis.
The most common mechanism of resistance to thiamphenicol is acquired by microorganisms via a plasmid-encoded acetyltransferase that inactivates the drug. Cross-resistance of thiamphenicol with chloramphenicol is complete in bacteria which possess chloramphenicol acetyltransferases (CATs). Acetylation of the hydroxyl groups by CATs prevents drug binding to the 50S ribosomal subunit. There are also other mechanisms of resistance, such as efflux systems, inactivation by phophotransferases, and mutation of the target site or permeability barriers. The CAT genes are commonly found on plasmids and most of these plasmids carry one or more additional resistance genes.

5.2 Pharmacokinetic particulars

The absorption of thiamphenicol following dermal administration is negligible.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Curcumine (E100)
Acetone
Dimethylacetamide

Copolymer of vinylpyrrolidone and vinyl acetate (30/70)
Ethanol
Triacetin
Dimethylether

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 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°C. Keep away from heat/hot surfaces/sparks/open flames and other ignition sources. No smoking.

6.5 Nature and composition of immediate packaging

Aluminium pressurised containers with epoxy phenolic pigment lacquer of 50, 150, 200, 300 and 400 ml:

- Polyamide/polyethylene valve mechanism integrated in aluminium container top
- Polypropylene spray nozzle with polyoxymethylene nebuliser.

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 product 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 16849/4051

9. DATE OF FIRST AUTHORISATION

13 January 2015

10. DATE OF REVISION OF THE TEXT

30 October 2019

Approved 30 October 2019