FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A 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

Date: 03/11/2014

French agency for food, environnemental and occupational health safety– French Agency for Veterinary Medicinal Products
La Haute Marche – Javené BP 90203 - 35302 Fougères Cédex - Téléphone : + 33 (0)2 99 94 78 78 - Télécopie : + 33 (0)2 99 94 78 99 - www.anses.fr

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0276/001/DC
Name, strength and pharmaceutical form	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
Applicant	Eurovet Animal Health B.V. Handelsweg 25 5531 AE Bladel, The Netherlands
Active substance(s)	Thiamphenicol
ATC Vetcode	QD06AX
Target species	Horses, cattle, goats, sheep, pigs, mink, rabbits
Indication for use	In all target species: - Treatment of superficial wound infections caused by micro-organisms sensitive 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 sensitive to thiamphenicol.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	21/10/2014
Concerned Member States for original procedure	AT, BE, DE, DK, ES, FI, IE, IT, NL, PL, PT, SE, UK

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC. The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains 28.5 mg/g thiamphenicol and excipients curcumine (E100), acetone, dimethylacetamide, copolymer of vinylpyrrolidone and vinyl acetate (30/70), ethanol, triacetin and dimethylether.

The container/closure system is an aluminium pressurised containers. The particulars of the containers and controls performed are provided and conform to the regulation.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.
Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is thiamphenicol, an established substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.
The active substance specification is considered adequate to control the quality of the material.
Batch analytical data demonstrating compliance with this specification have been provided.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable.

F. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.
Satisfactory validation data for the analytical methods have been provided.
Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

G. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.
Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

The tested product can be considered as bioequivalent with the reference product NEGEROL AEROSOL marketed by CEVA SANTE ANIMALE.
Based on the similarity of the formulations, the two products can be considered bioequivalent according to exemption 7.1.b) of the current Guideline for the conduct of bioequivalence studies for veterinary medicinal products, (EMEA/CVMP/016/00—Rev.2).

The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

The toxicological aspects of this product are identical to the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant has provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted.

MRLs

a. active substances

The active substance, thiamphenicol, is included in table 1 of the MRL regulation 37/2010, as follows,

Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification	Regulation
thiamphenicol	All food producing species	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	For fin fish the muscle MRL relates to « muscle and skin in natural proportions ». MRLs for fat, liver and kidney do not apply for fish. For porcine and poultry species, the fat MRL relates to "skin and fat in natural proportions" Not for use in animals from which eggs are produced for human consumption	Antiinfectious agents/ Antibiotics	37/2010 of 22.12.2009

b. excipients

The MRL status of excipients of the tested product is indicated in the following table.

Excipient	MRL status
Acetone	Out of scope, for cutaneous use only
Dimethylacetamide	Table 1, all species, no MRL required
Copolymer of vinylpyrrolidone and vinyl acetate (30/70)	Out of scope, for cutaneous use only
Ethanol	Table 1, all species, no MRL required, for use as excipient
Curcumine (E100)	Table 1, all species, no MRL required, Enumber
Triacetin	Table 1, all species, no MRL required, Enumber
Dimethylether	Out of scope, for use as a propellant for topical administration

Withdrawal Periods

The following withdrawal periods will be applied:

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

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

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The applicant has not provided a tolerance study which is acceptable because the tested product and the reference products are bioequivalent and share similar formulations.

Resistance

An overview of the level of resistance to thiamphenicol in target pathogens based on recent bibliographical data has been submitted. Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims of the tested product are based on the reference product.

V. OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.