FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
La Haute Marche
Javené BP 90203
35302 FOUGERES cedex
FRANCE

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Zodon 25 mg/ml oral solution for cats and dogs
Zodon vet (DK, NO)
Zodon vet 25 mg/ml oral solution for cats and dogs (BE)
Givix vet (SE)
Zodon, 25 mg/ml oral solution for cats and dogs (EE, LT, LV)

Date: JUNE 2018

French agency for food, environnemental and occupational health safety– French Agency for Veterinary Medicinal Products
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MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0259/001/DC
Name, strength and pharmaceutical form	Zodon 25 mg/ml oral solution for cats and dogs Zodon vet (DK, NO) Zodon vet 25 mg/ml oral solution for cats and dogs (BE) Givix vet (SE)
Applicant	SOGEVAL 200 AVENUE DE MAYENNE ZONE INDUSTRIELLE DES TOUCHES 53000 LAVAL FRANCE
Active substance(s)	Clindamycin (as hydrochloride)
ATC Vetcode	QJ01FF01
Target species	Cats and dogs
Indication for use	Infections caused by clindamycin sensitive germs such as: Cats: For the treatment of infected wounds and abscesses caused by clindamycin-sensitive species of *Staphylococcus spp* and *Streptococcus spp*. Dogs: • For the treatment of infected wounds, abscesses and oral cavity/dental infections caused by or associated with clindamycinsensitive species of *Staphylococcus spp*, *Streptococcus spp*, *Bacteroides spp*, *Fusobacterium necrophorum*, *Clostridium perfringens* • Adjunctive treatment of mechanical or surgical periodontal therapy in the treatment of infections of the gingival and periodontal tissues • For the treatment of osteomyelitis caused by *Staphylococcus aureus*

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	29/01/2014
Concerned Member States for original procedure	AT, BE, DK, FI, DE, EL, IE, IT, LU, NL, NO, PT, ES, SE, UK
Concerned Member States for repeat use procedure (2nd wave)	BG, EE, HU, Lt, LV, PL, RO

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 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 clindamycin hydrochloride as active substance and excipients glycerol (E422), sorbitol liquid, sucrose, ethanol 96°, propylene glycol, “grilled note” flavour, monohydrate citric acid (E330) and purified water.

The finished product is an oral solution supplied in glass bottle with a childproof cap and a syringe for oral use. The particulars of the containers and controls performed are provided and conform to the regulation.

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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 clindamycin hydrochloride, an established active substance described in the European Veterinary 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

A re-test period for the active substance is set in the certificates of suitability issued by EDQM.

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.
An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

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 test product is bioequivalent to the reference product, ANTIROBE DROPS of PFIZER HOLDING FRANCE.
An exemption from the requirement to provide a bioequivalence study was accepted.

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

These products are intended for non-food producing species, thus there was no necessity to provide data for this section.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The applicant has not provided tolerance study which is acceptable because the tested product and the reference product are bioequivalent and the excipients of the tested product are deemed unproblematic as regards tolerance.

Resistance

The applicant has provided a satisfactory review of target pathogen susceptibility to clindamycin.
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 for this product are equivalent to those of 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.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the veterinary Heads of Agencies website (www.HEVRA.org).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Repeat use procedure

Following procedure FR/V/0259/001/E/001, the following CMS accepted to grant the product a marketing authorisation. No change was brought to the SPC.