



FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT
FOR A VETERINARY MEDICINAL PRODUCT

CLINDASEPTIN 25MG/ML ORAL SOLUTION FOR CATS AND DOGS

Date: 26/04/2012

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0236/001/DC
Name, strength and pharmaceutical form	CLINDASEPTIN 25MG/ML ORAL SOLUTION FOR CATS AND DOGS
Applicant	Chanelle Pharmaceuticals Manufacturing Limited Dublin Road, Loughrea, co. Galway, Ireland
Active substance(s)	Clindamycin (as hydrochloride)
ATC Vetcode	QJ01FF01.
Target species	Cats and dogs.
Indication for use	<p>Cats: For the treatment of infected wounds and abscesses caused by clindamycin-sensitive species of <i>Staphylococcus spp</i> and <i>Streptococcus spp</i>.</p> <p>Dogs:</p> <ul style="list-style-type: none">• For the treatment of infected wounds, abscesses and oral cavity/dental infections caused by or associated with clindamycin-sensitive species of <i>Staphylococcus spp</i>, <i>Streptococcus spp</i>, <i>Bacteroides spp</i>, <i>Fusobacterium necrophorum</i>, <i>Clostridium perfringens</i>• 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 <i>Staphylococcus aureus</i>

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	Decentralised Application (in accordance with Article 13(1) Generic application according of Directive 2001/82/EC)
Date of completion of the decentralised procedure	21/02/2012
Concerned Member States for original procedure	AT – BE – CZ – DE – DK – ES – IE – IT – NL – PL – PT – SE – SK - 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 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 25 mg/ml clindamycin (as hydrochloride) and excipients ethanol 96 per cent, sorbitol liquid (non-crystallising), disodium edetate, propylene glycol, sodium saccharin, citric acid monohydrate and purified water.

The container is a polyethylene terephthalate bottle of 22 ml with HDPE/LDPE tamper proof closure supplied with a low density polyethylene measuring syringe. The particulars of the containers and controls performed are provided and conform to the regulation.

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 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

Based on information provided in support of this application, it is accepted that the test product is bioequivalent to the reference product ANTIROBE DROPS of PFIZER HOLDING FRANCE.

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.