IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Clindaseptin 150 mg capsules for dogs

PRODUCT SUMMARY

EU Procedure number	IE/V/0112/006/MR
Name, strength and pharmaceutical form	Clindaspetin 150 mg capsules for dogs
Active substance(s)	Clindamycin
Applicant	Chanelle Pharmaceuticals Manufacturing Limited, Loughrea, Co. Galway, Ireland
Legal basis of application	Application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of completion of procedure	26th February 2014
Target species	Dog
Indication for use	For the treatment of Infected wounds, abscesses and oral cavity/dental infections caused by or associated with clindamycin-sensitive species of; ·*Staphylococcus*. ·*Streptococcus*. ·*Bacteroides* ·*Fusobacterium necrophorum* ·*Clostridium perfringens* Osteomyelitis ·*Staphylococcus aureus*
ATCvet code	QJ01FF01
Concerned Member States	DE, DK, ES, FR, PT, SE

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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 benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A.Qualitative and Quantitative Particulars

The product contains 150 mg clindamycin (as clindamycin hydrochloride) per capsule and the excipients lactose monohydrate, maize starch, magnesium stearate and talc.The capsule contains the ingredients gelatine, water, azorubine E122, indigo carmine FD&C Blue 2 E132 and titanium dioxide E171.
The product is presented in blister strips composed of white PVC/PE/PVdC film and sealed with aluminium foil.Blister strips contain either 2, 4, 6, 8 or 10 capsules per strip.A total of 99 different pack sizes are proposed ranging from 2 capsules per pack to 1000 capsules per pack.
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 at 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 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.

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

Certificates of suitability issued by the EDQM have been provided for gelatine and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D.Control on Intermediate Products

Not applicable.

E.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.

F.Stability

The stability of the active substance has been established in accordance with applicable European guidelines.

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.

G.Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This application is a line extension of the authorised product Clinacin 150 mg Tablets for Dogs. Clinacin dog tablets were authorised in accordance with Article 13a of the Directive, as amended (so called 'bibliographical' applications).

III.A Safety Testing

Pharmacological Studies

The applicant provided a review of the pharmacodynamic and pharmacokinetic aspects of clindamycin.

Clindamycin is primarily a bacteriostatic antibiotic of the lincosamide group, which acts by inhibition of protein synthesis. Clindamycin is a chlorinated analogue of lincomycin.The antibiotic activity of clindamycin is based on the inhibition of bacterial synthesis.Reversible coupling to the 50 s subunit of the bacterial ribosome inhibits *inter alia* the translation of tRNA-bound amino acids, thereby preventing elongation of the peptide chain.Because of this, the mode of action of clindamycin is predominantly bacteriostatic.
Clindamycin has been shown to have *in-vitro* activity against the following organisms; *Staphylococcus* spp; *Streptococcus* spp; *Bacteroides* spp; *Fusobacterium* spp; and *Clostridium* spp.
Clindamycin and lincomycin show cross-resistance, which is common also to erythromycin and other macrolides antibiotics. Acquired resistance can occur, by methylation of the ribosomal binding site via chromosomal mutation in gram positive organisms, or by plasmid-mediated mechanisms in gram negative organisms.

The applicant conducted *in vitro* dissolution studies between the test product and the authorised product, Clinacin tablets. This study confirmed comparable dissolution for Clinacin tablets and Clindaseptin capsules in all dissolution media for the active substance, clindamycin. It was concluded that equivalent bioavailability can be expected. Based on *in vitro* dissolution it is accepted that the safety profile for both Clindaseptin capsules and Clinacin tablets will be similar.

Toxicological Studies

Based on *in vitro* dissolution it is accepted that the products are bioequivalent and that the safety profile for both Clindaseptin capsules for dogs and Clinacin tablets for dogs will be similar.
Refer to the assessment report for Clinacin tablets for dogs.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the product does not present any greater risk to the user relative to that posed by the authorised product, Clinacin tablets for dogs. The product is presented in blister and foil packaging in order to minimise the risk of exposure to children.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

Phase I

The environmental risk assessment can stop in Phase I because the product is intended for use in companion animals only.

Conclusion

Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Pharmacology

The applicant conducted *in vitro* dissolution studies between the test product and the authorised product, Clinacin tablets. This study confirmed comparable dissolution for Clinacin tablets and Clindaseptin capsules in all dissolution media for the active substance, clindamycin. It was concluded that equivalent bioavailability can be expected. Based on *in vitro* dissolution it is accepted that the efficacy profile for both Clindaseptin capsules and Clinacin tablets will be similar.

Tolerance in the Target Species of Animals

Given that:

- *In vitro* dissolution profiles for the test and authorised product are comparable in all dissolution media for clindamycin, indicating similar rate of release following ingestion, and
- The proposed conditions of use of Clindaseptin capsules are identical to those of the authorised product, Clinacin tablets,

it can be assumed that Clindaseptin capsules are unlikely to present any greater risk to the target animal relative to that posed by the product, Clinacin tablets.

Adequate warnings and precautions appear on the product literature.

Resistance

It can be accepted that the resistance profile of the product should reflect that of the tablet forms currently authorised. No difference in efficacy is to be expected.

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

Based on *in vitro* dissolution it is accepted that the products are bioequivalent and that the efficacy profile for both Clindaseptin capsules and Clinacin tablets for dogs will be similar.

The efficacy claims for this product reflect those authorised for Clinacin tablets and can be accepted.

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 benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. 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 HPRA website.

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.

Changes:
None.