AGENCE NATIONALE DU
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French agency for veterinary medicinal products

AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail
FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND SAFETY
14 rue Claude Bourgelat – PA de la Grande Marche – Javené - CS 70611 – F-35306 FOUGERES Cedex
www.anses.fr — @Anses_fr

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Soluclin 25 mg/ml oral solution for cats and dogs (AT, BE, ES, HU, IE, IT, LT, LV, NL, NO, PL, PT, UK(NI), FR) Soluclin vet 25 mg/ml oral solution for cats and dogs (SE/DK/FI) Soluclin (EE)

Date: 6 March 2023

PRODUCT SUMMARY

EU procedure number	*FR/V/0455/001/DC*
Name, strength and pharmaceutical form	Soluclin 25 mg/ml oral solution for cats and dogs (AT, BE, ES, HU, IE, IT, LT, LV, NL, NO, PL, PT, UK(NI), FR) Soluclin vet 25 mg/ml oral solution for cats and dogs (SE/DK/FI) Soluclin (EE)
Applicant	CP-PHARMA OSTLANDRING 13 31303 BURGDORF Germany
Active substance(s)	*clindamycin hydrochloride*
ATC vetcode	*QJ01FF01*
Target species	*Cats and Dogs*
Indication for use	*Cats:* *For the treatment of infected wounds and abscesses caused by clindamycin-susceptible 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 clindamycin-sensitive 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.*

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Date of completion of the original decentralisedprocedure	21/02/2023
Concerned Member States for original procedure	AT, BE, DE, DK, EE, ES, FI, HU, IE, IT, LT, LV, NL, NO, PL, PT, SE, UK.
Withdrawn CMS during original decentralised procedure	The company decided to withdraw the application in Germany. At the time of withdrawal, DE considered that the data provided did not allow to conclude on a positive benefit-risk balance as potential serious risk to public health was raised.

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

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

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains clindamycin as hydrochloride (25 mg/mL) and the excipients sorbitol, liquid (non-crystallising), glycerol, propylene glycol, ethanol (96 per cent), water, purified, sodium cyclamate, sucralose, anise flavor, hydrochloric acid and sodium hydroxide.

The packaging of the finished product is as described on the SPC.Details of the device with which the VMP will be administered are provided, as applicable.

The choice of the formulation is justified.

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

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

C. Production and control of starting materials

The active substance is clindamycin hydrochloride, an established active substance described in the European Pharmacopeia. 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.

Certificates of suitability issued by the EDQM have been provided 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.

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

D. Control tests carried out on isolated intermediates during the manufacturing process

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 VMP.

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 tests

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 VMP throughout its shelf life when stored under the approved conditions.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Toxicological studies

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of toxicological tests are not required.

Development of resistance and related risk in humans

The applicant has provided bibliographical information on the risk of resistance development and the potential spread of resistance in the environment resulting from the use of the antimicrobial veterinary medicinal product. In order to limit the spread of resistant bacteria, general hygiene precautions appear on the product literature.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that the risks of the candidate product is comparable to those of the reference product.

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

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will only be used in non-food animals.

B. Residues documentation

The product is only indicated for use in non-food species, *i.e*. dogs and cats, and as such there are no consumer safety issues to address

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

A. Pre-Clinical Studies

CLINDA is an oral solution containing clindamycin. This product is indicated in cats and dogs.

It is a generic application for a marketing authorisation in accordance with Article 18 of the European Regulation (EU) 2019/6.

Pharmacology

Pharmaceutical form
The test and the reference products have the same pharmaceutical form: oral solution.

Active substance qualitative and quantitative composition
The test and reference products have the same qualitative and quantitative composition in active substance: 25 mg of clindamycin per mL of product.

Bioequivalence study
Bioequivalence is demonstrated according to the section 7.1 of the GL (EMA/CVMP/016/200-Rev.4*).

Development of resistance and related risk in animals

Bibliography on the European epidemiological situation for the main target pathogens was provided. The incidence of resistance to lincosamides in *Staphylococcus* spp. appears to be wide-ranging in Europe with a weighted arithmetic mean of resistance about 25% in *Staphylococcus pseudintermedius* and in *Staphylococcus aureus*. Cross-resistance has been shown between clindamycin and different antimicrobials belonging to lincosamides and macrolides classes.

Adequate warnings and precautions appear on the product literature.

Dose determination and confirmation

As this is a generic application and bioequivalence with the reference product is accepted, dose determination and dose confirmation studies are not required in accordance with Article 18 of the European Regulation (EU) 2019/6.

Tolerance in the target species of animals

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of tolerance tests are not required.

The product literature accurately reflects the type and incidence of adverse effects, which might be expected.

B. Clinical trials

As this is a generic application and bioequivalence with the reference product is accepted, clinical trials are not required in accordance with Article 18 of the European Regulation (EU) 2019/6. The efficacy claims for this product are equivalent to those of the reference product.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.