AGENCE NATIONALE DU

MEDICAMENT VETERINAIRE

**FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY**

**FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS**

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT**

# Bioclindavet 75 mg chewable tablets for dogs
# Bioclindavet 275 mg chewable tablets for dogs

# PRODUCT SUMMARY

| | |
|---|---|
| EU procedure number | FR/V/0483/001-002/DC |
| Name, strength and pharmaceutical form | Bioclindavet 75 mg chewable tablets for dogs<br>Bioclindavet 275 mg chewable tablets for dogs |
| Applicant | AXIENCE<br>14 RUE SCANDICCI, TOUR ESSOR<br>93500 PANTIN<br>FRANCE |
| Active substance(s) | Clindamycin |
| ATC vetcode | QJ01FF01 |
| Target species | Dogs |
| Indication for use | For oral use.<br><br>Recommended dose:<br>• Infected wounds, abscesses and oral cavity/dental infections: 11 mg clindamycin per kg of bodyweight per 24 hours for a maximum of 28 days. The duration of treatment depends on the decision of the responsible veterinarian.<br><br>• Treatment of bone infections (osteomyelitis): 11 mg clindamycin per kg of body weight per 12 hours for a period of 28 days minimum. The treatment should be discontinued if no therapeutic effect is observed in the first 14 days. |

## 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 (75 mg)<br>Hybrid application of Regulation (EU) 2019/6 application in accordance with Article 19(1) of Regulation (EC) 2019/6 as amended (275 mg) |
| Reference product (RP) | ANTIROBE 75 mg |
| Marketing authorisation holder | ZOETIS FRANCE |
| Marketing authorisation number<br>EU procedure number | FR/V/7548631 4/1989 |
| Date of authorisation | 27/09/1989 |
| Proprietary data have been submitted for the following part of the dossier | Change in strength (275 mg) |
| Date of completion of the original decentralised procedure | 01/10/2025 |
| Concerned Member States for original procedure | AT, BE, BG, CY, DE, ES, IE, IT, NL, RO, SK |

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

## 1. SCIENTIFIC OVERVIEW

The veterinary medicinal products (VMP) are 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 observed reactions are indicated in the SPC.

The VMP are 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 hydrochloride (75 mg and 275 mg) and the excipients cellulose microcrystalline, lactose monohydrate, silica, colloidal hydrated, croscarmellose sodium, copovidone, meat flavor and magnesium stearate.

The container/closure system is PVC/PE/PVDC-aluminium blisters of 10 tablets.

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 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.

Scientific data and 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 is mentioned on the certificates of suitability for the active substance.

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)

As these are generic/hybrid applications according to Article 18/19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of safety tests are not required.

The safety aspects of these VMP are identical to the reference VMP.

Warnings and precautions as listed on the product literature are the similar to those of the reference VMP and are adequate to ensure safety of the product to users / the environment / consumers.

### A. Safety tests

***Pharmacological studies***

See Part 4.A.

### *Toxicological studies*

As this is generic/hybrid applications according to Articles 18/19(1) of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of safety tests are not required.

### *Other studies*

As this is generic/hybrid applications according to Articles 18/19(1) of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of safety tests are not required.

### *Observations in humans*

The applicant has provided general information in humans related to the active ingredient.

### *Development of resistance and related risk in humans*

The applicant provided sufficient bibliographical data in support of the application to meet the current legal requirements. No guidance is currently available on how to assess the risk of development of resistance and related risks in humans. See also part 4.A.

Adequate warnings and precautions appear on the product literature.

### *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 VMP.

### *Environmental Risk Assessment*

This is a generic/hybrid applications according to Articles 18/19(1) of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated. According to the reflection paper on the interpretation of article 18(7) and since a VMP, which have been authorised after 1 October 2005, with the same active substance indicated for use in the same target species when administered at the same or a higher total dose as the proposed generic VMP, has been found, an Environmental Risk Assessment is not required.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and are adequate to ensure safety of the environment.

## 4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As these are generic/hybrid applications according to Article 18/19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required.

The efficacy claims for these VMP are equivalent to those of the reference VMP.

### *A. Pre-Clinical Studies*

#### *Pharmacology*

The applicant has conducted an *in vivo* bioequivalence study in the target species, dogs.

Bioequivalence with a reference VMP has been demonstrated.

#### *Development of resistance and related risk in animals*

As these are generic/hybrid applications according to Article 18/19 of Regulation (EC) 2019/6, information about the level of resistance, as known from bibliographic data, shall be provided. The applicant provided a review of bibliographical data on antimicrobial resistance for pathogens of clinical relevance for the claimed indication in the target animal species.

Adequate warnings and precautions appear on the product literature.

#### *Dose determination and confirmation*

As these are generic/hybrid applications according to Article 18/19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, dose determination and confirmation studies are not required.

#### *Tolerance in the target species of animals*

As this is generic/hybrid applications according to Articles 18/19(1) of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of tolerance studies are not required.

The safety aspects of this VMP are identical to the reference VMP.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and are adequate to ensure safety of the product to target species of animals.

### *B. Clinical trials*

As these are generic/hybrid applications according to Article 18/19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, clinical trials are not required.

## 5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP are 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.

## POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP :

None