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AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

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

**FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS**

**14 RUE CLAUDE BOURGELAT – PARC D'ACTIVITES DE LA GRANDE MARCHE JAVENE – CS 70611 – 35306 FOUGERES**

# PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

# ARTHROKAN CLEMENT THEKAN 1,5 MG/ML SUSPENSION BUVABLE POUR CHIENS

**06 November 2024**

# PRODUCT SUMMARY

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|---|---|
| Procedure | National Procedure 15672/NAT |
| Name, strength and pharmaceutical form | ARTHROKAN CLEMENT THEKAN 1,5 MG/ML SUSPENSION BUVABLE POUR CHIENS |
| Applicant | C & H GENERICS / C/O MICHAEL MCEVOY & CO., SEVILLE HOUSE, NEW DOCK STREET – GALWAY – IRLANDE |
| Active substance(s) | Méloxicam |
| ATC vetcode | QM01AC06 |
| Target species | Chiens |
| Indication for use | Réduction de l'inflammation et de la douleur lors de troubles musculo-squelettiques aigus et chroniques. |

# 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

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|---|---|
| Legal basis of original application* | Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended. |
| Reference product (RP) | METACAM 1.5 MG/ML ORAL SUSPENSION FOR DOGS |
| Marketing authorisation holder | BOEHRINGER INGELHEIM VETMEDICA |
| Marketing authorisation number<br>EU procedure number | EU/2/97/004 |
| Date of authorisation | 24/03/2000 |
| Date of completion of the original procedure | 15/10/2024 |

*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 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 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

### A. Product description

The VMP contains the active substance meloxicam and the following excipients: Saccharin sodium, Carmellose sodium, Silica colloidal anhydrous, Citric acid monohydrate, Sorbitol liquid (non-crystallising), Disodium phosphate dodecahydrate, Sodium Benzoate, Honey Flavour and Purified water.

The container/closure system is described in the SPC, with two graduated syringes provided with each vial.

The choice of the formulation and the presence of preservative are 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 meloxicam, an established substance 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 a certificate of suitability issued by the EDQM have been provided to support the proposed supplier.

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

## 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

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

## 3. SAFETY DOCUMENTATION

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 safety tests are not required.

Warnings and precautions as listed on the product literature 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 a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, toxicological studies are not required.

#### *Other 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, other studies are not required.

#### *User safety*

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows risks for children after accidental exposure to an unused syringe, to uneaten treated food or via licking from a treated dog. Risks were also identified for adults and pregnant women during administration of the product and for pregnant women via licking from a treated dog or cleaning the dog's bowl.

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.

**Phase I:**

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*

Not applicable.

## 4. EFFICACY DOCUMENTATION

### *A. Pre-Clinical Studies*

A GLP in vivo bioequivalence study was performed in dogs after single medication with the VMP versus the reference product. The dogs received a single oral administration of 0.2 mg meloxicam per kg body weight. The study was designed as a two period, two treatment, two-sequence crossover with 14 days wash out period.

Sporadic instance of diarrhoea was recorded in some animals in each group and thin faeces was recorded once. Those effects are well-known with meloxicam.

The results of this study indicate that the 90% confidence intervals for both AUC0-inf and Cmax lie within the narrower limits of 80- 125%. Based on these data, it was accepted that the VMP ARTHROKAN CLEMENT THEKAN 1,5 MG/ML SUSPENSION BUVABLE POUR CHIENS is bioequivalent to the reference product, METACAM 1.5 MG/ML ORAL SUSPENSION FOR DOGS.

### *Pharmacology*

Bioequivalence between the VMP and the reference product has been demonstrated via an *in* vivo bioequivalence study in dogs after a single oral administration of 0.2 mg/kg bw. Consequently, as details on pharmacodynamics and pharmacokinetics in the target species have been sufficiently described in the file of the reference product, no further documentation is needed.

### *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, tolerance studies in the target species, dogs, are not required.

### *B. Clinical trials*

No clinical trials were performed.

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

## 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.