anses
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

Melodyne 1,5 mg/mL suspension buvable pour chiens

National Procedure 15743/NAT

15 September 2025

PRODUCT SUMMARY

EU procedure number	NAT/15743
Name, strength and pharmaceutical form	Melodyne 1,5 mg/mL suspension buvable pour chiens
Applicant	CEVA SANTE ANIMALE 8 rue de Logrono, 33500 Libourne France
Active substance(s)	Meloxicam
ATC vetcode	QM01AC06
Target species	Dogs
Indication for use	Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

Melodyne 1,5 mg/mL suspension buvable pour chiens	NAT/15743
CEVA SANTE ANIMALE	National Procedure
Publicly available assessment report	

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.
Reference product (RP)	Metacam 1.5 mg/mL oral suspension for dogs
Marketing authorisation holder	Boehringer Ingelheim Vetmedica GmbH
Marketing authorisation number EU procedure number	EU/2/97/004
Date of authorisation	24/03/2000
Date of completion of the original procedure	07/08/2025

*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 (physicochemical, biological or microbiological information)

A. Product description

The VMP contains the active substance meloxicam at a concentration of 1.5 mg/mL and the following excipients: sodium benzoate, xanthan gum, anhydrous colloidal silica, sorbitol liquid (non-crystallising), glycerol, xylitol, citric acid and purified water.

The container/closure system is as described on the SPC. The particulars of the containers and performed controls are provided and conform to the regulation.

The choice of the formulation and 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 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.

Scientific data 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.

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

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.

An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

G. Other information

Not applicable.

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 and the environment.

A. Safety tests

Pharmacological studies

See part 4.

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

Pharmacology

Bioequivalence has been demonstrated between the candidate product and the reference product Metacam 1.5 mg/mL oral suspension for dogs based on two *in vivo* bioequivalence studies.

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.