



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

**FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS**

**14 RUE CLAUDE BOURGELAT – PARC D’ACTIVITES DE LA GRANDE MARCHE  
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**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY  
MEDICINAL PRODUCT**

Melodyne 5 mg/mL solution injectable pour chiens et chats

**National Procedure 15744/NAT**

Melodyne 5 mg/mL solution injectable pour chiens et chats	NAT/15744
CEVA SANTE ANIMALE	National Procedure
Publicly available assessment report	

## PRODUCT SUMMARY

Procedure number	NAT/15744
Name, strength and pharmaceutical form	Melodyne 5 mg/mL solution injectable pour chiens et chats
Applicant	CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne France
Active substance(s)	Meloxicam
ATC vetcode	QM01AC06
Target species	Dogs and cats
Indication for use	<p><b>Dogs:</b> Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.</p> <p><b>Cats:</b> Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery</p>

Melodyne 5 mg/mL solution injectable pour chiens et chats	NAT/15744
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).

Melodyne 5 mg/mL solution injectable pour chiens et chats	NAT/15744
CEVA SANTE ANIMALE	National Procedure
Publicly available assessment report	

## SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	Metacam 5 mg/mL solution for injection for dogs and cats
Marketing authorisation holder	Boehringer Ingelheim Vetmedica GmbH
EU procedure number	EU/2/97/004
Date of authorisation	24/03/2000
Date of completion of the original procedure	10 February 2025
Concerned Member States for original procedure	FR (National procedure)

\*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.

Melodyne 5 mg/mL solution injectable pour chiens et chats	NAT/15744
CEVA SANTE ANIMALE	National Procedure
Publicly available assessment report	

## 2. QUALITY DOCUMENTATION

### A. Product description

The VMP contains 5 mg/mL of meloxicam and the excipients ethanol, anhydrous, poloxamer, glycofurol, meglumine, glycine, sodium chloride, sodium hydroxide, hydrochloric acid, concentrated and water for injections.

The container/closure system is clear, type I glass vial of 10 mL, closed with grey flurotec (copolymer of ethylene and tetrafluoroethylene) chlorobutyl rubber stopper and sealed with aluminum flip-off seal.

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.

The VMP is manufactured in accordance with the European Pharmacopoeia (Ph. Eur.) and relevant European guidelines.

### C. Production and control of starting materials

The active substance is meloxicam, 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.

Certificate of suitability issued by the EDQM has 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.

Melodyne 5 mg/mL solution injectable pour chiens et chats	NAT/15744
CEVA SANTE ANIMALE	National Procedure
Publicly available assessment report	

### 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 mentioned on the certificate of suitability issued by the 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.

The in-use shelf life of the broached VMP is supported by the data provided. The recommendations in the product leaflet should be followed.

### G. Other information

Not applicable.

## 3. SAFETY DOCUMENTATION

### 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, results of toxicological tests 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, results of other studies are not required.

#### ***User safety***

A user safety assessment in compliance with the relevant guideline was performed. A risk was identified for pregnant and childbearing women.

Melodyne 5 mg/mL solution injectable pour chiens et chats	NAT/15744
CEVA SANTE ANIMALE	National Procedure
Publicly available assessment report	

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

### ***Environmental Risk Assessment***

#### **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.

## **4. EFFICACY 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, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

### **A. Pre-Clinical Studies**

#### ***Pharmacology***

Given the legal basis of this application and the claim of bioequivalence between candidate and reference products, the omission of pharmacodynamics/pharmacokinetics data is considered acceptable, as this information may be extrapolated from the reference product.

The bioequivalence was demonstrated according to the section 7.1 of the bioequivalence GL EMA/CVMP/016/2000-Rev4\*.

#### ***Dose determination and confirmation***

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, dose determination and confirmation studies are not required. The reference is made to the originator dossier and the same dosage as per the reference product applies for the candidate product.

#### ***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 are not required. The same adverse events (type and incidence) as observed with the reference product are mentioned in the product literature.

### **B. Clinical trials**

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

Melodyne 5 mg/mL solution injectable pour chiens et chats	NAT/15744
CEVA SANTE ANIMALE	National Procedure
Publicly available assessment report	

## 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.