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

Meloxym 5 mg/ml solution for injection for dogs and cats

2 Sept 2026

PRODUCT SUMMARY

EU procedure number	FR/V/0531/001/MR
Name, strength and pharmaceutical form	Meloxym 5 mg/ml solution for injection for dogs and cats
Applicant	Chanelle Pharmaceuticals Manufacturing Limited Ida Industrial Estate Dublin Road H62 FH90 Loughrea Ireland
Active substance(s)	Meloxicam
ATC vetcode	QM01AC06
Target species	Dogs and cats
Indication for use	Dogs: 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. Cats: Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.

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 (EU) 2019/6 as amended.
Reference product (RP)	Metacam 5 mg/ml solution for injection for dogs and cats of BOEHRINGER INGELHEIM VETMEDICA (24/03/2000).
Marketing authorisation holder	BOEHRINGER INGELHEIM VETMEDICA
MS where the RP is or has been authorised	/
Marketing authorisation number EU procedure number	EMEA/V/C/033
Date of authorisation	24/03/2000
Date of completion of the original mutual recognition procedure	7 August 2026
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	20/12/2018
Concerned Member States for original procedure	IE
Concerned Member States for subsequent recognition procedure	/
Withdrawn CMS during original mutual recognition procedure	/

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 5 mg/ml de meloxicam as active substance and the excipients Ethanol (96 %), Poloxamer 188, Macrogol 400, Glycine, Disodium edetate, Sodium hydroxide, Hydrochloric acid concentrated, Meglumine and Water for injections.

The container and closure system are detailed in the SPC and comply with the regulations.

The veterinary medicinal product is an established pharmaceutical form and its development is adequately described, in accordance with the corresponding European guidelines.

B. Description of the manufacturing method

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

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 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

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

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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 sites 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.

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

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3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Pharmacological studies

Two *in vivo* bioequivalence studies in dogs and cats with the reference veterinary medicinal product were provided. A comparison of the physicochemical properties of the two veterinary medicinal products was carried out. On the basis of these data, it is concluded that the candidate product is bioequivalent to the reference product METACAM 5 MG/ML SOLUTION FOR DOGS AND CATS from BOEHRINGER INGELHEIM VETMEDICA laboratories.

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

Toxicological studies

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

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

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 (preclinical studies and clinical trials)

A. Pre-Clinical Studies

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference VMP has been demonstrated, pre-clinical studies are not required.

Tolerance in the target species of animals

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

The aspects relating to tolerance in the target animal species for this veterinary medicinal product are identical to those of the reference veterinary medicinal product. The adverse reactions listed in the package leaflet and labelling of this veterinary medicinal product are the same as those of the reference veterinary medicinal product and reflect the type and incidence of expected side effects.

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

B. Clinical trials

As this is a generic application according to Article 18 of Regulation (EU) 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.