



**Veterinary
Medicines
Directorate**

**United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

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

Chanoxidyl 2 mg/ml Solution for Injection for Cats

Date Created: February 2026

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Chanoxidyl 2 mg/ml Solution for Injection for Cats, Solution for injection
Applicant	C&H Generics Ltd, c/o Michael McEvoy and Co, Seville House, New Dock Street, Galway, Ireland
Active substance	Meloxicam
ATC Vetcode	QM01AC06
Target species	Cats
Indication for use	Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

www.gov.uk/check-animal-medicine-licensed

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	17/12/2025

I. SCIENTIFIC OVERVIEW

The product was submitted for a generic application for authorisations in Great Britain (GB) and Northern Ireland (NI) in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended. The reference product is Metacam 2 mg/ml solution for injection for cats authorised in GB and NI in 2010 and marketed by Boehringer Ingelheim Vetmedica GmbH.

Chanoxidyl Solution for Injection for Cats contains 2 mg/ml meloxicam. The product is indicated for the alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats.

When administration of meloxicam is to be continued as an oral follow-up therapy, it is recommended to give a single subcutaneous injection of Chanoxidyl at a dosage of 0.2 mg meloxicam/kg body weight before surgery. To continue treatment for up to five days, this initial dose may be followed 24 hours later by administration of an oral suspension veterinary medicinal product containing meloxicam authorised for cats at a dosage of 0.05 mg meloxicam/kg body weight.

When no oral follow-up treatment is possible, it is recommended to give a single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight before surgery.

The distribution category in GB & NI is POM-V, the same as the reference product.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC¹. The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy² of the product was demonstrated

¹ SPC – Summary of Product Characteristics.

² Efficacy – The production of a desired or intended result.

according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains meloxicam and the excipients anhydrous ethanol, meglumine, macrogol 300, poloxamer 188, glycine, disodium edetate, sodium hydroxide, hydrochloric acid and water for injections.

The container/closure system consists of a colourless glass vial of 10 ml or 20 ml, closed with a bromobutyl rubber stopper and sealed with an aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative are justified.

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substance is meloxicam, an established active substance described in the European Pharmacopoeia, and supported by an Active Substance Master File (ASMF) and a Certificate of Suitability (CEP). 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.

The excipients of the formula are well known pharmaceutical ingredients covered by Ph. Eur. monographs.

The container closure system has been satisfactorily tested and relevant information was provided.

II.C.4. Substances of Biological Origin

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

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.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 product. 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. Control tests on the finished product are those appropriate for the pharmaceutical form.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable regulatory 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 regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

The shelf life of the veterinary medicinal product as packaged for sale is 1 year. The shelf life after first opening the immediate packaging is 28 days.

The vial should be kept in the outer carton, to protect it from light. The product does not require any special temperature storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACOTOXICOLOGICAL)

Due to the application type, no pharmacological or toxicological data have been submitted which is acceptable. The applicant claimed bioequivalence with the reference product due to them being the same qualitative and qualitative composition.

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

III.A Safety Documentation

Pharmacological Studies

No new studies were submitted but it is known that meloxicam is a non-steroidal anti-inflammatory drug (NSAID) which acts by inhibition of prostaglandin synthesis. Therefore, it exerts anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue.

Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations are reached approximately 1.5 hours post administration. More than 97 % of meloxicam is bound to plasma proteins and it is eliminated with a half-life of 24 hours. 21 % of the recovered dose is eliminated in urine and 79 % in the faeces.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that the product is not considered to present an unacceptable risk to the user when used as recommended.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- Accidental self-injection may give rise to pain. People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.
- In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

The applicant provided a Phase I environmental risk assessment containing sufficient information to conclude that the assessment ends at Phase I, as the product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

The product is not expected to pose a risk to the environment when used as recommended.

IV. CLINICAL DOCUMENTATION

Due to the legal base of the application and as bioequivalence with the reference product was accepted, no new pharmacodynamic, tolerance and/or clinical data was required.

The indications and dosing regimens for the product are equivalent to those of the reference product.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics the benefit/risk profile of the product is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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