

IPAR



**Publicly Available Assessment Report for a
Veterinary Medicinal Product**

Meloxyl 0.5 mg/ml oral suspension for cats

PRODUCT SUMMARY

EU Procedure Number	IE/V/0882/001/MR
Name, Strength, Pharmaceutical Form	Meloxyl 0.5 mg/ml oral suspension for cats
Active Substances(s)	Meloxicam
Applicant	Chanelle Pharmaceuticals Manufacturing Limited
Legal Basis of Application	Article 18 of Regulation (EU) 2019/6 (generic)
Target Species	Cats
Indications For Use	Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery. Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats.
ATCvet Code	QM01AC06
Date veterinary medicinal product first authorised in the Reference Member State	15/07/2022
Date of completion of the mutual recognition procedure	09/10/2023
CMS	ES, FR, PT

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in the relevant Articles of Regulation (EU) 2019/6. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland. The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released onto the market. It has been shown that the product can be safely used in the target species cats, any reactions observed are indicated in the SPC.

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 efficacy of the product was demonstrated according to the claims made in the SPC.

The overall benefit/risk analysis is in favour of granting a marketing authorisation.

SPC – Summary of product Characteristics.

II. QUALITY ASPECTS**A. Qualitative and Quantitative Particulars**

The product contains the active substance meloxicam at 0.5 mg/ml and the excipients glycerol, citric acid monohydrate, xanthan gum, povidone, sodium dihydrogen phosphate monohydrate, sodium benzoate, simethicone emulsion, honey flavour, colloidal anhydrous silica and purified water.

The container/closure system consists of white high density polyethylene bottles containing 10 ml or 15 ml of product or polypropylene bottles containing 3 ml or 5 ml of product. The bottles are closed with tamper proof child resistant closures. Each bottle is supplied with a 1 ml measuring syringe which consists of a polypropylene barrel and a high density polyethylene plunger/piston.

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

B. Method of Preparation of the Product

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

Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. 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 has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

D. Control on Intermediate Products

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 product.

Satisfactory validation data for the analytical methods has been provided.

Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

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

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

The product is an oral suspension intended for use in cats, with meloxicam as the active ingredient. Meloxicam has been developed as an anti-inflammatory and anti-rheumatic for cats and has been well known in veterinary medicine for more than 10 years.

III. SAFETY ASSESSMENT**III.A Safety Documentation**

The absence of toxicological and tolerance data is acceptable as bioequivalence is established between the reference product (Metacam 0.5 mg/ml oral suspension for cats) and the candidate product (Meloxyl 0.5 mg/ml oral suspension for cats). In this context, results of toxicological and tolerance tests are not required, since they are assumed to be identical to those of the reference product.

User Safety

Meloxyl contains additional excipients compared to the reference product. Thus, the applicant presented a qualitative risk assessment to determine if any of these have any impact on the risk that the generic product may pose to users, including children. It is concluded that the potential risks to the user following the use of Meloxyl 0.5 mg/ml oral suspension are identical to those following the use of Metacam 0.5 mg/ml oral suspension.

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

Environmental Safety

The conclusion is supported that the ERA can stop at phase I, and no phase II is required because the veterinary medicinal product will only be used in non-food producing animals. The product is not expected to pose a risk for the environment when used according to the SPC.

IV. CLINICAL ASSESSMENT

As this application is submitted as a generic application according to Article 18, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.I. Pre-Clinical Studies

The applicant has provided an *in vivo* study in cats to investigate the bioequivalence between the test product and the reference product (Metacam 0.5 mg/ml oral suspension for cats).

The two formulations were compared after a single oral administration of 0.2 mg/kg body weight to cats (n=12 per group, aged 1-2 years) according to a cross-over design with a wash-out period of 14 days.

During the trial, gastrointestinal signs were noted in some animals (diarrhoea, salivation, vomiting, faeces containing mucus and/or blood), confirming the narrow margin of safety recognised previously in cats.

The values of area under the curve (AUC_t and AUC_{∞}) were 17454.7 and 18521.5 ng.h/ml, respectively, for Meloxyl, and 19402.6 and 19923.3 ng.h/ml, respectively, for the reference product. The 14-day wash-out period was considered sufficiently long, and the 90% confidence intervals for the ratio of population means (test/reference) for AUC and C_{max} fell within the bioequivalence acceptance limits of 80-125% and 70-143%, respectively. The maximum observed concentration (C_{max}) and time (median) when C_{max} was observed (T_{max}) were 647.08 ng/ml and 6 [3-9] hours for Meloxyl, compared to 840.81 ng/ml and 3 [1-12] hours for the reference product. The applicant has justified the widened confidence interval for C_{max} because of the known variability of this parameter after oral administration of meloxicam.

Bioequivalence has been demonstrated between Meloxyl and the reference product Metacam oral suspension in cats and therefore Meloxyl is expected to be as safe and efficacious as the reference product.

Tolerance in the Target Species

Since this is a generic product and bioequivalence with the reference product has been demonstrated, results of tolerance tests are not required. Moreover, the excipients used in the product are well known and widely used in other pharmaceutical products. Furthermore, apart from transient gastrointestinal side effects, which are known adverse effects with NSAIDs and which support the narrow margin of safety recognised previously in cats, no serious adverse effects were reported in the bioequivalence study. As bioequivalence has been demonstrated, the expected tolerance profile in the field is expected to be the same as that of the reference product.

Resistance

Not applicable

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(s) is favourable.

VI. 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 HPRA website.

This section 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.