



**Veterinary  
Medicines  
Directorate**

**United Kingdom  
Veterinary Medicines Directorate  
Woodham Lane  
New Haw  
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Surrey KT15 3LS**

**NATIONAL PROCEDURE**

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

**Lozenord 5 mg/ml Solution for Injection for Dogs and Cats**

**Date Created: October 2025**

## **MODULE 1**

### **PRODUCT SUMMARY**

Name, strength and pharmaceutical form	Lozenord 5 mg/ml Solution for Injection for Dogs and Cats, Solution for injection
Applicant	Accord Healthcare B.V, Winthontlaan 200, Utrecht, 3526 KV, Netherlands
Active substance	Meloxicam
ATC Vetcode	QM01AC06
Target species	Cats Dogs
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.

## **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](http://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	23/07/2025

#### I. SCIENTIFIC OVERVIEW

The product was submitted for a generic application for authorisation in Great Britain (GB), in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended. The reference product is Metacam 5 mg/ml solution for injection for dogs and cats, marketed by Boehringer Ingelheim Vetmedica GmbH, which has been authorised in UK/GB since 2000. The applicant claimed exemption from the requirement for bioequivalence studies in accordance with exemptions 7.1.a) and 7.1.b) of the Guideline on the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMA/CVMP/016/2000-Rev.4) for the intravenous and subcutaneous routes of administration respectively.

Lozenord 5 mg/ml Solution for Injection for Dogs and Cats contains 5 mg/ml meloxicam. The product is indicated in dogs for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and the reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery. In cats it is indicated for the alleviation of mild to moderate post-operative pain and inflammation following surgical procedures.

For musculo-skeletal disorders in dogs, the product should be administered as a single subcutaneous injection at a dosage of 0.2 mg/kg. This can be followed by a suitable oral meloxicam formulation, given 24 hours after administration of the injection. For the reduction of post-operative pain in dogs, the product should be administered as a single intravenous or subcutaneous injection at a dosage of 0.2 mg/kg before surgery.

For the reduction of post-operative pain in cats, the product should be given as a single subcutaneous injection at a dosage of 0.3 mg/kg before surgery.

The distribution category in GB 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 SPC<sup>1</sup>. 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<sup>2</sup> 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.

## **II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS**

### ***II.A. Composition***

The product contains meloxicam and the excipients ethanol anhydrous, poloxamer 188, sodium chloride, glycine, sodium hydroxide, hydrochloric acid, glycofuroil, meglumine and water for injections.

The container/closure system consists of a colourless, 10ml type-I glass injection vial, closed with a grey chlorobutyl fluorotec rubber stopper and sealed with an aluminium cap and flip off plastic tamper evident top. The vial is contained in a cardboard box. 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 (Ph. Eur.) and provided with 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.

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<sup>1</sup> SPC – Summary of Product Characteristics.

<sup>2</sup> Efficacy – The production of a desired or intended result.

All the excipients, except glycofurol, are stated to be in compliance with their respective Ph. Eur. monographs. Glycofurol is not a new excipient as it is used in other authorised veterinary medicinal products within the UK. The specification for glycofurol is provided alongside a certificate of analysis from the supplier, demonstrating compliance with the specification, and methods of analysis.

The container-closure system of the finished product is acceptable.

#### ***II.C.4. Substances of Biological Origin***

There are no substances within the scope of the Transmissible spongiform encephalopathy (TSE) Guideline present or used in the manufacture of this product.

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

The tests performed during production are described and acceptable.

#### ***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 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.

The claim of a 28-day stability after broaching is based on the demonstration of stability for a batch broached and stored for 28 days at 20-25°C.

### **G. Other Information**

The shelf life of the product as packaged for sale is 2 years. The shelf life after first opening the immediate packaging is 28 days.

The vial should be kept in the outer carton in order to protect from light.

### **III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACOTOXICOLOGICAL)**

Due to the legal basis of the application, no new pharmacological or toxicological studies were submitted.

As the product was accepted to be bioequivalent to the reference product, the warnings and precautions on the product literature are the same and are adequate to ensure safety of the product to users/the environment. An extra warning regarding pregnant women and those attempting to conceive was included. This was because recently authorised products of the same pharmaceutical form with the same concentration of the active substance also detail this.

#### **III.A Safety Documentation**

##### **Pharmacological Studies**

As is appropriate for the legal basis of the application, no new pharmacological studies were submitted.

The pharmacodynamics and pharmacokinetics of the active ingredient are the same as the reference product.

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) which acts by inhibition of prostaglandin synthesis, exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects.

Following subcutaneous administration, meloxicam is completely bioavailable and more than 97% is bound to plasma proteins.

In both dogs and cats, meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound.

In both dogs and cats, meloxicam is eliminated with a half-life of 24 hours. In dogs, approximately 75% of the administered dose is eliminated via faeces and the remainder via urine. In cats 79% is eliminated in faeces and the rest in urine.

### ***Toxicological Studies***

As is appropriate for the legal basis of the application, no new toxicological studies were submitted.

### ***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 embryofoetal 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. As a result, environmental exposure will be low and a Phase II ERA was not required.

## **IV. CLINICAL DOCUMENTATION**

As this is a generic application, and bioequivalence with the reference product has been accepted, efficacy studies are not required.

The efficacy claims, dosing regimens, and pharmacology 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](http://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.

([www.gov.uk/check-animal-medicine-licensed](http://www.gov.uk/check-animal-medicine-licensed))