IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

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

PRODUCT SUMMARY

EU Procedure number	IE/V/0560/001/DC
Name, strength and pharmaceutical form	Lozenord 5 mg/ml solution for injection for dogs and cats
Active substances(s)	Meloxicam
Applicant	Accord Healthcare B.V. Winthontlaan 200 Utrecht 3526KV Netherlands
Legal basis of application	Generic application in accordance with Article 18 of Regulation (EU) 2019/6
Date of completion of procedure	18/12/2024
Target species	Dogs, 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.
ATCvet code	QM01AC06
Concerned Member States	BE, DE, ES, FR, IT, NL, PL, UK(NI)

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 on the market.
It has been shown that the product can be safely used in the target species.
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.

II. QUALITY ASPECTS

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A. Qualitative and Quantitative Particulars

The product contains the active substance meloxicam at 5 mg/ml and the excipients ethanol anhydrous, poloxamer 188, glycofurol, meglumine, glycine, sodium chloride, sodium hydroxide, hydrochloric acid and water for injections.

The container/closure system consists of type 1 glass vial with a grey chlorobutyl fluorotec rubber stopper and sealed with aluminium cap an flip off plastic tamper evident top.

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 is 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)

This application for '*Lozenord 5 mg/ml solution for injection*,' containing the active substance meloxicam, was submitted in accordance with the requirements of Article 18 of Regulation (EU) 2019/6 (that is, a generic application). The reference product cited is '*Metacam 5 mg/ml solution for injection*'(EU/2/97/004/006), which is authorised through the centralised procedure and is accepted as a suitable reference product.
The applicant has claimed a waiver from bioequivalence study requirements (to demonstrate *in vivo* bioequivalence) based on compliance with the conditions set out in sections 7.1.a) and 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. These conditions have been fulfilled; therefore the omission of documentation on safety and efficacy is deemed to be acceptable.
As this is a generic application (according to Article 18), and bioequivalence with a reference product has been accepted, results of safety tests are not required. The safety aspects of this product are identical to the reference product.
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 and the environment.

III. SAFETY ASSESSMENT

Pharmacological Studies
No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference product has been accepted, results of pharmacological tests are not required**.**

Toxicological Studies
No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference product has been accepted, results of toxicological tests are not required.

User Safety
The applicant has provided a brief user safety assessment. It is accepted that the candidate product does not pose any greater risk to the user than the reference product, and as such, the user safety warnings as accepted by CVMP for the reference product may also be considered applicable for '*Lozenord 5 mg/ml solution for injection*.'
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product, as follows:
"*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."

Environmental Risk Assessment
Phase I
An environmental risk assessment that is compliant with relevant guidance was submitted. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP is intended for use in non-food producing animals.

Conclusion
Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

IV. CLINICAL ASSESSMENT

As this is a generic application according to Article 18, and bioequivalence with a suitable 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.A Pre-Clinical Studies

Pharmacology
No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference product has been accepted, results of pharmacological tests are not required**.**

Tolerance in the Target Species of Animals

No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference product has been accepted, results of target animal safety tests are not required**.**

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference product has been accepted, results of efficacy tests are not required**.**

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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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.

Changes:

None.