

Date of Index Listing: March 24, 2022

FREEDOM OF INFORMATION SUMMARY

ORIGINAL REQUEST FOR ADDITION TO THE INDEX OF LEGALLY MARKETED
UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES

MIF 900-033

MeloxiLab-Rat™

(meloxicam extended-release injection)

Rats

“For the control of post-procedural pain in rats”

Requested by:
Wildlife Pharmaceuticals, Inc.

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I. GENERAL INFORMATION:

File Number:

MIF 900-033

Requestor:

Wildlife Pharmaceuticals, Inc.
1230 West Ash Street, Suite D
Windsor, CO 80550

Proprietary Name:

MeloxiLab-Rat™

Established Name:

Meloxicam extended-release injection

Pharmacological Category:

Non-steroidal anti-inflammatory drug (NSAID); analgesic

Dosage Form:

Sterile injectable solution

Amount of Active Ingredient:

2 mg meloxicam/mL

How Supplied:

5 mL vial

Dispensing Status:

by Prescription (Rx)

Dosage/Dosage Regimen:

4 mg/kg body weight, single injection

Route of Administration:

Subcutaneous injection

Species/Class:

Rats

Indication:

For the control of post-procedural pain in rats

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY:

In accordance with 21 CFR part 516, a qualified expert panel evaluated the target animal safety and effectiveness of MeloxiLab-Rat™ for subcutaneous injection in rats, for the control of post-procedural pain, to determine whether the benefits of using MeloxiLab-Rat™ for the proposed use outweigh its risks to the target animals. The members of the qualified expert panel were:

- Lon V. Kendall, DVM, PhD, DACLAM (Panel Leader)
- Cassondra Bauer, MS, DVM, DACVPM, DACLAM
- Chuck Locuson, PhD

A. Findings of the Qualified Expert Panel:

The qualified expert panel thoroughly reviewed all available literature concerning the use of meloxicam in major and minor animal species. The source of this information included a list of peer-reviewed scientific publications, book chapters, and unpublished studies involving the use of meloxicam (single injection and sustained-release formulations) across many different animal species, including rats. Approximately 78 pieces of relevant literature were available for review and provided information on the following related topics: the pharmacokinetics of meloxicam in rats and other species, the use of meloxicam and sustained-release meloxicam formulations in animals, and the current dosing recommendations of meloxicam in rats. Included in the list of relevant literature was one investigational study (Foley et. al; unpublished) conducted in Sprague Dawley rats that used the same formulation as MeloxiLab-Rat™ at the recommended dosage of 4 mg/kg body weight administered by a single subcutaneous injection.

Based on the panel's thorough review of available literature and personal experience using meloxicam in rats, the panel believed MeloxiLab-Rat™ to be an attractive and safe non-opiate alternative to existing options for analgesia and post-procedural pain control in rats. The panel concluded that the benefits of using MeloxiLab-Rat™, a sustained-release formulation of meloxicam, for the control of post-procedural pain in rats outweigh the risks to the target animals.

B. Literature Considered by the Qualified Expert Panel:

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- challenges and prospects. *International journal of pharmaceutics*. 2016 Dec 30;515(1-2):757-73.
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III. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to MeloxiLab-Rat™:

WARNINGS

Human safety: Not for use in humans. Keep this and all medications out of reach of children.

MeloxiLab-Rat™ is intended for use in rats only and should be used under the supervision of a licensed veterinarian in a clinical or laboratory setting.

Exercise caution to avoid accidental self-injection. Avoid contact of this product with skin and eyes. In case of contact, eyes and skin should be liberally flushed with water for 15 minutes. Consult a physician if irritation persists. In the case of accidental human ingestion, seek medical advice immediately and show the package insert or the label to the physician.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse drug reactions or to obtain a copy of the SDS for this product call 1-970-795-0927.

Note to physician: This product contains an injectable non-steroidal anti-inflammatory (NSAID).

IV. AGENCY CONCLUSIONS:

The information submitted in support of this request for MeloxiLab-Rat™ to be added to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (Index) for the control of post procedural pain in rats, satisfies the requirements of section 572 of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 516:

A. DETERMINATION OF ELIGIBILITY FOR INDEXING:

As part of the determination of eligibility for inclusion in the Index, FDA determined that the drug for this intended use in rats was safe to the user, did not individually or cumulatively have a significant effect on the human environment, and that the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new animal drug was sufficient to demonstrate that the requestor has established appropriate specifications for the manufacture of the new animal drug. Additionally, the requestor has committed to manufacture the drug in accordance with current good manufacturing practices (CGMP).

The Index is only available for new animal drugs intended for use in minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals and for new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the

standard of section 512(d) of the act. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for granting this request for addition to the Index.

B. QUALIFIED EXPERT PANEL:

The qualified expert panel for MeloxiLab-Rat™ met the selection criteria listed in 21 CFR 516.141(b). The panel satisfactorily completed its responsibilities in accordance with 21 CFR part 516 in determining the target animal safety and effectiveness of MeloxiLab-Rat™ for the control of post procedural pain in rats.

C. MARKETING STATUS:

MeloxiLab-Rat™ will be marketed by prescription.

D. EXCLUSIVITY:

Products listed in the Index do not qualify for exclusive marketing rights.