Date of Approval: July 29, 2022

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-727

Meloxicam

Injectable Solution

Dogs and Cats

Dogs: Meloxicam Injection is indicated in dogs for the control of pain and inflammation associated with osteoarthritis.

Cats: For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery.

Sponsored by:

Felix Pharmaceuticals Pvt. Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-727

B. Sponsor

Felix Pharmaceuticals Pvt. Ltd.
25-28 North Wall Quay
Dublin 1, Ireland

Drug Labeler Code: 086101

U.S. Agent Name and Address:
James H. Schafer, DVM
Schafer Veterinary Consultants, LLC
800 Helena Court
Fort Collins, CO 80524

C. Proprietary Name

Meloxicam

D. Drug Product Established Name

meloxicam

E. Pharmacological Category

Non-steroidal anti-inflammatory drug (NSAID)

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

5 mg/mL

H. How Supplied

10 mL vial

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Dogs: Meloxicam injection should be administered initially as a single dose, at 0.09 mg/lb (0.2 mg/kg) body weight intravenously (IV) or subcutaneously (SQ), followed, after 24 hours, by meloxicam oral suspension at the daily dose of 0.045 mg/lb (0.1 mg/kg) body weight, either mixed with food or placed directly in the mouth.

Cats: Administer a **single, one-time subcutaneous dose** of Meloxicam injection to cats at a dose of 0.14 mg/lb (0.3 mg/kg) body weight. **Use of additional meloxicam or other NSAIDs is contraindicated.** To ensure accuracy of dosing, the use of a 1 mL graduated syringe is recommended.

K. Route of Administration

Dogs: Intravenous or subcutaneous injection

Cats: Subcutaneous injection

L. Species/Class

Dogs and cats

M. Indications

Dogs: Meloxicam Injection is indicated in dogs for the control of pain and inflammation associated with osteoarthritis.

Cats: For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery.

N. Reference Listed New Animal Drug (RLNAD)

Metacam®; meloxicam; NADA 141-219; Boehringer Ingelheim Animal Health USA, Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Felix Pharmaceuticals Pvt. Ltd., was granted a biowaiver for the generic product Meloxicam 5 mg/mL solution for injection. The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Metacam® (meloxicam) 5 mg/mL solution for injection, sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 141-219, and was approved for use in dogs on November 12, 2003, and in cats on October 28, 2004.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs and cats. Because this new animal drug is not intended for use in food-producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Meloxicam:

Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Meloxicam, when used according to the label, is safe and effective for the indications listed in Section I.M. above.