Date of Approval: December 22, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-762

Carofenvet™

(carprofen)

Injectable Solution

Dogs

Carofenvet™ is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

Sponsored by:

Cronus Pharma Specialities India Private Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-762

B. Sponsor

Cronus Pharma Specialities India Private Ltd.,
Sy No–99/1, M/s GMR Hyderabad Aviation SEZ Ltd.,
Mamidipalli Village, Shamshabad Mandal,
Ranga Reddy, Hyderabad, Telangana, 501218, India

Drug Labeler Code: 069043

C. Proprietary Name

Carofenvet™

D. Drug Product Established Name

carprofen

E. Pharmacological Category

Non-steroidal anti-inflammatory drug

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

50 mg/mL

H. How Supplied

20 mL and 50 mL multi-dose vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

The recommended dosage for subcutaneous administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as either 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. For control of postoperative pain, administer approximately 2 hours before the procedure.

K. Route of Administration

Subcutaneous injection

L. Species/Class

Dogs

M. Indication

Carofenvet™ is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

N. Reference Listed New Animal Drug (RLNAD)

RIMADYL®; carprofen; NADA 141-199; Zoetis 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, Cronus Pharma Specialities India Private Ltd., was granted a biowaiver for the generic product Carofenvet™ (carprofen) injectable solution. 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 RIMADYL® (carprofen) injectable solution, sponsored by Zoetis Inc., under NADA 141-199, and was approved for use in dogs on March 3, 2003.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. 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 Carofenvet™:

Keep out of reach of children. Not for human use. Consult a physician in cases of accidental human exposure.

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 Carofenvet™, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.