

FREEDOM OF INFORMATION SUMMARY

Supplemental NADA

141-111

Rimadyl[®] Chewable Tablets
(carprofen)

An additional claim for chewable tablet: "for the control of postoperative pain associated with soft tissue and orthopedic surgery in dogs"

PFIZER, INC.
235 East 42nd Street
New York, NY 10017

TABLE OF CONTENTS

I.	GENERAL INFORMATION	3
	Indications for use	3
	Dosage form, route of administration and dosage	3
II.	EFFECTIVENESS	4
	Dosage Characterization	4
III.	TARGET ANIMAL SAFETY	4
IV.	HUMAN SAFETY	4
V.	AGENCY CONCLUSIONS	4
VI.	ATTACHMENTS (labeling)	5

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number: 141-111

Sponsor: Pfizer Inc
235 East 42nd St.
New York, NY 10017

Established Name: carprofen

Proprietary Name: Rimadyl[®] Chewable Tablets

Dosage Form: Oral tablets

How Supplied: Scored chewable tablets are packaged in bottles containing 14, 60, or 180 tablets.

How Dispensed: Rx - U.S. Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

Amount of Active Ingredient: Each tablet contains 25 mg, 75 mg, or 100 mg of carprofen per tablet.

Route of Administration: Oral

Species/Class: Dogs/Canine

Recommended Dosage: The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total dose may be administered as 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Tablets are scored and dosage should be calculated in half-caplet increments. Tablets can be halved by placing the tablet on a hard surface and pressing down on both sides of the score. Rimadyl[®] Chewable Tablets are palatable and willingly consumed by most dogs. Tablets may be fed free choice or placed on food. Care should be taken to ensure that the dog consumes the complete dose.

Pharmaceutical Category: Non-steroidal anti-inflammatory drug

Indications: Rimadyl[®] Chewable Tablets are indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgery in dogs.

Effect of Supplement: The supplement to NADA 141-111 provides revisions to 21CFR 520.309 *Indications for Use*. The supplement provides for an additional claim for carprofen chewable tablets for the control of postoperative pain associated with soft tissue and orthopedic surgery in dogs.

II. EFFECTIVENESS

A. Dosage Characterization:

Effectiveness of the dosage of 1 mg/lb body (2.2 mg/kg) weight twice daily for the relief of pain associated with osteoarthritis was established in the original approval of Rimadyl[®] Chewable Tablets for dogs (NADA 141-111), dated May 14, 1999.

Effectiveness of the 2 mg/lb (4.4 mg/kg) body weight once daily dosage for the relief of pain associated with osteoarthritis was established by a supplement to NADA 141-111, dated November 26, 2001. Effectiveness of Rimadyl[®] Caplets (NADA 141-053) at a dosage of 2 mg/lb (4.4 mg/kg) body weight once daily for the control of pain associated with soft tissue and orthopedic surgery in dogs was demonstrated by a supplement dated, July 8, 2002. Based on the comparable bioavailability between caplet and chewable tablet (see NADA 141-111 FOI Summary, dated May 14, 1999), Rimadyl[®] Chewable Tablets administered at a dosage of 2 mg/lb (4.4 mg/kg) body weight once daily are safe and effective for the control of pain associated with soft tissue and orthopedic surgery in dogs.

B. Substantial Evidence:

No new substantial evidence was required for this approval.

III. TARGET ANIMAL SAFETY

Studies demonstrating the safety of Rimadyl[®] for use in dogs are contained in the original FOI Summary dated October 25, 1996. No new animal safety data were required for approval of this supplement.

IV. HUMAN SAFETY

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for human use. Keep this and all drugs out of the reach of children. Consult a physician in case of accidental ingestion by humans."

V. AGENCY CONCLUSIONS

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing

regulations. The data demonstrates that Rimadyl[®] Chewable Tablets for dogs, when administered under labeled conditions of use, are safe and effective for the intended use.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose and provide guidance in the control of postoperative pain. Furthermore, the veterinarian monitors patients for possible adverse effects of the drug.

Under Section 512(c)(2)(F)(iii) of the FFDCFA, this approval for non-food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for the approval of the application and conducted or sponsored by the applicant.

<u>U.S. Patent Number</u>	<u>Date of Expiration</u>
US 4,264,500	February 28, 2003
US 6,013,808	April 15, 2019

VI. ATTACHMENTS

Facsimile Labeling is attached as indicated below:

Package Insert

Patient Package Insert

Bottle