Approved: Nov 26 2001

FREEDOM OF INFORMATION SUMMARY

Rimadyl® (carprofen) Chewable Tablets for Dogs

S/NADA 141-111

Pfizer Inc
235 East 42nd Street
New York, New York 10017

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FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number: 141-111

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

Generic Name: carprofen

Trade Name: Rimadyl® Chewable Tablets

Marketing Status: Rx

Effect of Supplement: This supplement provides for flexibility in administration of the total daily dose of Rimadyl® Chewable Tablets. The drug may be administered orally at 2 milligrams per pound of body weight once daily or 1 milligram per pound of body weight twice daily.

II. INDICATIONS FOR USE

Rimadyl® is indicated for the relief of pain and inflammation associated with osteoarthritis in dogs.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION AND RECOMMENDED DOSAGE

A. Dosage Form: Rimadyl® is available as 25, 75, and 100 mg scored tablets.

B. Route of Administration: Oral

C. Recommended Dosage: The recommended dosage for oral administration to dogs is 2 mg/lb daily. The total daily dose may be administered as 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb twice daily. Rimadyl® Chewable Tablets are scored and the dosage should be calculated in half-tablet 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.

IV. EFFECTIVENESS

Clinical effectiveness of the recommended dosage of 1 mg/lb body weight twice daily is contained in the original Freedom of Information Summary for NADA 141-111. Clinical effectiveness of the recommended dosage of 2 mg/lb body weight once daily is

contained in the supplement to the Freedom of Information Summary for NADA 141-053.

Reference is made to comparable relative bioavailability of Rimadyl® Caplets and Rimadyl® Chewable Tablets contained in original Freedom of Information for NADA 141-111. This study supports the comparable bioavailability of the caplet and chewable tablet when administered at a rate of 2 mg/lb total daily dose.

Dosage Characterization

Based on the approved 2 mg/lb total daily dose for Rimadyl® Caplets (NADA 141-053) and its comparable bioavailability to Rimadyl® Chewable Tablets (NADA 141-111), Rimadyl® Chewable tablets administered at a dosage of 2 mg/lb body weight once daily is expected to be effective for the relief of pain and inflammation associated with osteoarthritis in dogs. No additional clinical effectiveness data were required for approval.

V. ANIMAL SAFETY

Studies demonstrating the safety of Rimadyl® Chewable Tablets for use in dogs are contained in the original FOI summary for the approval for Rimadyl® Chewable Tablets (NADA 141-111) dated May 14, 1999. No new animal safety data were required for approval of this supplement.

VI. HUMAN SAFETY

Human Safety Relative to Food Consumption:

Data on human food safety, pertaining to consumption of drug residues in food, were not required for approval of this supplement. Rimadyl® Chewable Tablets are approved for use in dogs only.

Human Safety Relative to Possession, Handling and Administration:

Labeling contains adequate caution/warning statements.

VII. AGENCY CONCLUSIONS

The data in support of this NADA comply with the requirements of Section 512 of the Act and Section 514 of the implementing regulations. The data demonstrate that Rimadyl® Chewable Tablets (carprofen), when used under labeled conditions of use, are safe and effective.

Rimadyl® Chewable Tablets are restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose canine osteoarthritis and to monitor response to treatment.

Under section 512(c)(2)(F)(iii) of the FFDCA, 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 and conducted or sponsored by the applicant.

Pfizer Inc Patent Nos.	US 4,264,500 expires February 28, 2003
	US 6,013,808 expires April 15, 2019

VIII. LABELING

Package insert
Bottle