

JUL - 8 1997

FREEDOM OF INFORMATION SUMMARY

S/NADA

141-053

Rimadyl® Caplets
(carprofen)

"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

NADA 141-053

FOIS-1

141-053

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FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number: 141-053

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

Established Name: carprofen

Trade Name: Rimadyl[®] Caplets

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

Effect of Supplement: The supplement to NADA 141-053 provides revisions to 21 CFR 520.309 *Indications for Use*. To add a claim for the control of postoperative pain associated with soft tissue and orthopedic surgery in dogs.

II. INDICATIONS FOR USE

Rimadyl[®] Caplets 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.

III. DOSAGE FORM, ROUTES OF ADMINISTRATION AND RECOMMENDED DOSAGE

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

B. Route of Administration: Oral

C. 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. Caplets are scored and dosage should be calculated in half-caplet increments.

IV. EFFECTIVENESS

A. Dosage Characterization:

Clinical effectiveness of the recommended dosage of 1 mg/lb body weight twice daily for the relief of pain associated with osteoarthritis was established in association with the

approval of Rimadyl® caplets for dogs (NADA 141-053). Clinical effectiveness of the dosage of 2 mg/lb body weight once daily for the relief of pain associated with osteoarthritis was demonstrated by a supplement to NADA 141-053, dated August 20, 2001.

Field study data supplied in the supplement to NADA 141-053, for administration of 2 mg/lb body weight once daily, demonstrated effectiveness of Rimadyl® caplets for the relief of pain and inflammation associated with osteoarthritis. With support for effectiveness for the relief of pain associated with osteoarthritis following the administration of a single daily dose of Rimadyl® caplets, a dose of 2 mg/lb once daily was selected for effectiveness confirmation in the control of postoperative pain in a U.S. multicenter field study.

B. Substantial Evidence:

The effectiveness of Rimadyl® caplets for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs presented as veterinary patients was evaluated in three controlled studies involving a variety of surgical procedures. The studies were conducted at twenty-one veterinary clinics throughout the U.S. Results of these studies demonstrate that Rimadyl® caplets are safe and effective when administered at a dose of 2 mg/lb of body weight once daily.

The intensity of surgical pain varied with the procedure performed, the duration of the procedure, the surgical technique used, and individual response to pain; therefore, the requirement for pain control may have varied for different surgical procedures. The safety of Rimadyl® caplets in the field was also assessed.

Surgical inductions included the use of combinations of tranquilizers, barbiturates, inhalant anesthetics, anticholinergics, antibiotics and parenteral fluids.

C. Field Efficacy and Safety for the Relief of Postoperative Pain Associated with Surgical Repair of Cruciate Injuries in Dogs (Study No. 1963C-60-99-304)

1. Type of Study: Multicentered Field Study
2. Investigators:

Name
Dr. Jeffrey L. Berzon Vet Specialists of Connecticut West Hartford, CT 06117
Dr. James F. Biggart Veterinary Surgery Service, Inc. Berkeley, CA 94710
Dr. R.Scott Buzhardt The Animal Center Zachary, LA 70791
Dr. James M. Fingerroth Vet Specialists of Rochester Rochester, NY 14623
Dr. Paul E. Howard Vermont Veterinary Surgical Center Colchester, VT 05446

Name
Dr. Stephen L. Jones Lakeside Animal Hospital Moncks Corner, SC 29461
Dr. Steven A. Martinez Washington State University Pullman, WA 99164
Dr. Rodney Oakley Veterinary Specialty Hospital of the Carolinas, Cary, NC 27511
Dr. Roger L. Sifferman Bradford Park Vet Hospital Springfield, MO 65804

3. General Design:

- a. Purpose: The objective of the study was to evaluate the effectiveness and safety of Rimadyl[®] at a dosage of 2 mg/lb (4.4 mg/kg) administered orally approximately 2 hours prior to surgery, then once daily as needed for 3 days, for the control of postoperative pain associated with surgical repair of cruciate injuries in dogs.
- b. Test Animals: Seventy-six client-owned dogs (40 females and 36 males) from 9 locations, ranging in age from 10 months to 14 years, entered the study. Dogs presenting in the course of clinical practice for surgical repair of cruciate injury were admitted to the study. A total of 38 dogs were treated with Rimadyl[®] and 38 dogs received placebo; these groups represented 42 pure-bred and 34 mixed-bred dogs. Surgical procedures included joint stabilization and/or arthrotomy (fabellar suture, imbrication, and fibular head transposition).
- c. Control Drug: Placebo (same as carprofen formulation without the active ingredient).
- d. Dosage Form: The caplets administered were the same as the market formulation.
- e. Route of Administration: Oral
- f. Dosages used: 2 mg/lb administered approximately 2 hours prior to surgery, then once daily as needed, for 3 days.
- g. Test Duration: 4 days

h. Parameters measured: Clinical assessment of pain was performed by the veterinarian prior to surgery (Day -1 or Day 0), approximately 4, 8, and 12 hours post-surgery, twice daily on Days 1, 2, 3, and once on Day 4. The procedure for assessing the animals' pain included observation of demeanor, attention and response, interest in food and water, movements in a confined space, palpation of the surgical site and flexing and extending the affected joint. The degree of pain was quantified using a Visual Analog Scale (VAS).

Hematology, clinical chemistry, coagulation, urine and fecal occult blood analyses were performed prior to treatment, and upon study completion (Day 4). Approximately 24 hours post-surgery (Day 1), coagulation status was measured.

Effectiveness was based upon *a priori* contrasts among least squares means of VAS scores to assess the difference between placebo and Rimadyl[®] treatments. In addition, the number of animals withdrawn from the study due to lack of effectiveness was compared for each treatment.

Safety was evaluated by comparing the clinical pathology results from samples collected prior to surgery to the results from samples collected on Day 1 and Day 4. In addition, the abnormal health observations following treatment were summarized.

4. Results: Sixty-three of the 76 dogs enrolled in the study were included in the complete effectiveness analysis. Thirteen dogs were excluded from part (n = 7) or the entire (n = 6) efficacy analysis due to protocol deviations or failure to meet the enrollment criteria. Duration of treatment is summarized in Table 1. Rimadyl[®]-treated dogs were significantly less painful 4, 12, 24, approximately 28 hours post-surgery, on the second assessment on Day 3, and on the final assessment on Day 4 after surgery ($P \leq 0.05$). Results of pain assessment using VAS are provided in Table 2. Five placebo-treated dogs and 1 Rimadyl[®]-treated dog were withdrawn due to lack of effectiveness.

Table 1. Duration of Treatment

Treatment Days	Treatment		Overall
	Placebo	Rimadyl [®]	
Day 0	6	3	9
Days 0 and 1	3	3	6
Days 0, 1, and 2	5	2	7
Days 0, 2, and 3	1	0	1
Days 0, 1, 2, and 3	23	29	52
Total	38	37	75

Table 2. Analysis of Pain Assessment Using a Visual Analog Scale

Assessment	Visual Analog Scale Score (mm)				P-values
	Placebo		Rimadyl [®]		
	n ^a	LSM ^b	n ^a	LSM ^b	
<u>Day 0</u>					
preoperative	32	8.33 ± 3.92	31	7.14 ± 4.03	0.7030
1 st postoperative	32	39.25 ± 3.94	33	31.54 ± 4.02	0.0200
2 nd postoperative	31	36.65 ± 3.95	33	30.60 ± 4.02	0.0629
3 rd postoperative	30	35.70 ± 3.95	33	28.36 ± 4.02	0.0271
<u>Day 1</u>					
1 st assessment	30	34.26 ± 3.95	33	27.54 ± 4.02	0.0412
2 nd assessment	30	32.20 ± 3.95	33	24.79 ± 4.02	0.0257
<u>Day 2</u>					
1 st assessment	30	29.06 ± 3.95	33	24.21 ± 4.02	0.1320
2 nd assessment	30	28.53 ± 3.95	33	22.18 ± 4.02	0.0526
<u>Day 3</u>					
1 st assessment	30	25.20 ± 3.95	33	20.09 ± 4.02	0.1138
2 nd assessment	30	25.30 ± 3.95	33	18.33 ± 4.02	0.0349
<u>Day 4</u>					
1 st assessment	30	23.50 ± 3.95	33	16.09 ± 4.02	0.0258

^a Not all animals had every pain assessment completed, therefore, the sum of animals listed under Day 0 to Day 3 may not equal the number of treated animals.

^b Least squares means ± standard error of the mean (SEM)

5. Statistical Analysis: *A priori* contrasts among least squares means of the VAS scores using a repeated measures model were used to assess the difference between placebo and Rimadyl[®] treatments at each time point. The analyses were performed using SAS

6.12 (Statistical Analysis System). Statistical difference was assessed at the 5% level of significance ($P \leq 0.05$).

6. **Conclusions:** Under clinical conditions of use, Rimadyl® administered orally at 2 mg/lb (4.4. mg/kg) approximately 2 hours prior to surgery and once daily thereafter, as needed, for 3 days is safe and effective in controlling postoperative pain associated with cruciate injury repair in dogs.
7. **Adverse Reactions:** Clinical pathology data indicated that Rimadyl® was well tolerated. Changes in clinical pathology variables were similar in dogs administered Rimadyl® compared with the placebo cases. One Rimadyl®-treated dog had a two-fold increase in alkaline phosphatase. No clinical signs associated with this laboratory change were seen. There were no notable differences in mean values for hematology (including platelet counts), clinical chemistry, urinalysis results, or fecal occult blood detection between treatment groups. There were no notable differences in mean values for variables measuring coagulation status (prothrombin time, partial thromboplastin time and fibrinogen) between treatment groups. There were no serious adverse drug experiences or mortalities related to Rimadyl®. Similar types and numbers of abnormal health observations were reported between placebo and Rimadyl®-treated dogs and are summarized in Table 3.

Table 3. Abnormal Health Observations reported during field study (number of dogs = 76)

Abnormal Health	Rimadyl® (% of dogs)	Placebo (% of dogs)
Diarrhea/soft stool ^a	5.3	0.0
Traumatic Pain and Swelling of Limbs	2.6	2.6
Dermatitis/skin lesion	2.6	2.6
Wound Drainage	2.6	0.0
Oral/periodontal Disease	2.6	0.0
Urinary tract disease	2.6	0.0
Vomiting	2.6	0.0
Ocular Disease	2.6	0.0
Pyrexia	0.0	5.3
Salivation	0.0	2.6

^a Includes soft stool, fecal incontinence

D. Field Efficacy and Safety for the Relief of Postoperative Pain Associated with Soft Tissue Surgery in Dogs (Studies 1963C-60-99-305 and 1963C-60-99-306)

1. Type of Study: Multicentered Field Studies

2. Investigators:

Name	Name
Dr. Douglas C. Andrews Falmouth Veterinary Hospital Falmouth, ME 04105	Dr. David Lukof Harleysville Veterinary Hospital Harleysville, PA 19438
Dr. H. Lee Butler Huntingdon Animal Clinic Huntingdon, TN 38344	Dr. Mark Marks Marks Veterinary Hospital Lawrence, KS 66047
Dr. R.Scott Buzhardt The Animal Center Zachary, LA 70791	Dr. John Means North Hampton Animal Hospital North Hampton, NH 03862
Dr. Peter Davis Pine Tree Veterinary Hospital Augusta, ME 04330	Dr. Dean Rund Grant Avenue Pet Hospital Springfield, MO 65807
Dr. Stuart Gluckman Mendon Village Animal Care Mendon, NY 14506	Dr. Roger L. Sifferman Bradford Park Vet Hospital Springfield, MO 65804
Dr. David Hancock Perinton Animal Hospital Victor, NY 14564	Dr. Susan B. Thompson Pet Vet Animal Hospital Mt. Pleasant, SC 29464
Dr. Stephen L. Jones Lakeside Animal Hospital Moncks Corner, SC 29461	Dr. Paul Urband East Haddam Veterinary Clinic East Haddam, CT 06423
Dr. Sharon Lachette White Haven Veterinary Hospital White Haven, PA 18661	

3. General Design:

- a. Purpose: The objective of these studies was to evaluate the effectiveness and safety of Rimadyl[®] at a dosage of 2 mg/lb (4.4 mg/kg) administered orally approximately 2 hours prior to surgery and once daily thereafter, as needed for 2 days, for the control of postoperative pain associated with soft tissue surgery (ovariohysterectomy and aural procedures) in dogs.
- b. Test Animals: Two hundred and twenty-one (180 females and 41 males) client-owned dogs from 15 locations, ranging in age from 4 weeks to 12 years, entered the study. Dogs presenting in the course of clinical practice for aural (ear) surgery or elective ovariohysterectomy were admitted to the study. The preponderance of females was due to the inclusion of ovariohysterectomy as

one of the soft tissue surgeries. A total of 110 dogs were treated with Rimadyl® and 111 dogs received placebo; these groups represented 164 purebred and 57 mixed-bred dogs. Aural surgeries included hematoma repair, ear crop, lateral canal resection, bullae osteotomy, and growth removal.

- c. Control Drug: Placebo (same as carprofen formulation without the active ingredient).
- d. Dosage Form: The caplets administered were the same as the market formulation.
- e. Route of Administration: Oral
- f. Dosages used: 2 mg/lb administered approximately 2 hours prior to surgery, then once daily as needed for 2 days.
- g. Test Duration: 3 days
- h. Parameters measured: Clinical assessment of pain was performed by the veterinarian prior to surgery (Day -1 or Day 0), approximately 4, 8, and 12 hours post-surgery, twice daily on Days 1, 2, and once on Day 3. The procedure for assessing the animals' pain included observation of demeanor, attention and response, interest in food and water, movements in a confined space and palpation of the surgical site. The degree of pain was quantified using a Visual Analog Scale (VAS).

Hematology, clinical chemistry, coagulation, urine and fecal occult blood analyses were performed prior to treatment, and upon study completion (Day 3). Approximately 24 hours post-surgery (Day 1), coagulation status was measured.

Effectiveness was based upon *a priori* contrasts among least squares means of VAS scores to assess the difference between placebo and Rimadyl® treatments. In addition, the number of animals withdrawn from the study due to lack of effectiveness was compared for each treatment.

Safety was evaluated by comparing the clinical pathology results from samples collected prior to surgery to the results from samples collected on Day 1 and Day 3. In addition, the abnormal health observations following treatment were summarized.

- 4. Results: Two hundred and four of the 221 dogs enrolled in the study were included in the complete effectiveness analysis. Seventeen dogs were excluded from part (n = 11) or the entire (n = 6) effectiveness analysis due to protocol deviations or failure to meet the enrollment criteria. Duration of treatment is summarized in Table 4. Dogs treated with Rimadyl® were significantly less painful 4, 8, 12, 24, 30, and 54 hours post-surgery ($P \leq 0.05$). Results of pain assessment using VAS are provided in Table 5. One placebo-treated dog and 1 Rimadyl®-treated dog were withdrawn due to lack of effectiveness.

Table 4. Duration of Treatment

Days of Test Article Administration	Treatment		Overall
	Placebo	Rimadyl®	
Day 0	61	74	135
Days 0 and 1	24	11	35
Days 0 and 2	2	1	3
Days 0, 1, and 2	23	21	44
Total	110	107	217

Table 5. Analysis of Pain Assessment Using a Visual Analog Scale

Assessment	Visual Analog Scale Score (mm)				P-values
	Placebo		Rimadyl®		
	n ^a	LSM ^b	n ^a	LSM ^b	
<u>Day 0</u>					
preoperative	105	0.71 ± 1.97	100	1.67 ± 1.978	0.5389
1 st postoperative	109	21.34 ± 1.963	104	17.27 ± 1.971	0.0098
2 nd postoperative	109	22.20 ± 1.963	104	16.74 ± 1.973	0.0007
3 rd postoperative	109	20.34 ± 1.963	104	15.52 ± 1.974	0.0025
<u>Day 1</u>					
1 st assessment	109	18.48 ± 1.964	104	15.22 ± 1.974	0.0380
2 nd assessment	108	14.87 ± 1.964	104	10.79 ± 1.974	0.0097
<u>Day 2</u>					
1 st assessment	108	11.45 ± 1.965	104	9.25 ± 1.974	0.1580
2 nd assessment	108	9.67 ± 1.965	104	5.80 ± 1.974	0.0141
<u>Day 3</u>					
only assessment	107	8.30 ± 1.968	104	6.31 ± 1.974	0.2034

^a Not all animals had every pain assessment completed, therefore, the sum of animals listed under Day 0 to Day 3 may not equal the number of treated animals.

^b Least squares means ± standard error of the mean (SEM)

5. Statistical Analysis: *A priori* contrasts among least squares means of the VAS scores using a repeated measures model were used to assess the difference between placebo and Rimadyl® treatments at each time point. The analyses were performed using SAS 6.12 (Statistical Analysis System). Statistical difference was assessed at the 5% level of significance ($P \leq 0.05$).
6. Conclusions: Under clinical conditions of use, Rimadyl® administered orally at 2 mg/lb (4.4 mg/kg) approximately 2 hours prior to surgery, then once daily, as needed

for 2 days, is safe and effective in controlling postoperative pain associated with soft tissue surgery in dogs.

7. Adverse Reactions: Clinical pathology data indicated that Rimadyl[®] was well tolerated. Changes in clinical pathology variables were similar in dogs administered Rimadyl[®] compared with the placebo cases. Nineteen Rimadyl[®]- and 12 placebo-treated dogs had normal baseline and positive Day 3 fecal occult blood results. One Rimadyl[®]-treated dog had a greater than two-fold increase in ALT (alanine transferase). One Rimadyl[®]-treated dog had an elevated baseline ALT, which additionally increased greater than two-fold by Day 3. Sixteen Rimadyl[®]- and 14 placebo-treated cases had normal baseline and elevated Day 3 WBCs (white blood cell counts). Three Rimadyl[®]- and 1 placebo-treated dog had a greater than two-fold increase in GGT (gamma-glutamyl transpeptidase). None of these animals showed clinical signs associated with these laboratory changes. There were no notable differences in mean values for hematology (including platelet counts), clinical chemistry, urinalyses, or fecal occult blood detection between treatment groups. There were no notable differences in mean values for variables measuring coagulation status (prothrombin time, partial thromboplastin time and fibrinogen) between treatment groups. There were no serious adverse drug experiences or mortalities related to Rimadyl[®]. Similar types and numbers of abnormal health observations were reported between placebo and Rimadyl[®]-treated dogs and are summarized in Table 6.

Table 6. Abnormal Health observations reported during field study
(number of dogs = 221)

Abnormal Health	Rimadyl[®] (% of dogs)	Placebo (% of dogs)
Vomiting	12.7	18.0
Diarrhea/soft stool	6.4	8.1
Ocular Disease	2.7	0.0
Inappetence	1.8	0.0
Apnea	1.8	0.0
Dermatitis/skin lesion	1.8	0.0
Dehydration	0.9	0.0
Abscess	0.9	0.0
Abdominal Distension	0.9	0.0
Constipation	0.9	0.0
Oral/periodontal disease	0.9	0.0
Pyrexia	0.9	0.0
Wound Drainage	0.9	0.0
Urinary Tract Disease	0.9	1.8
Cyanosis	0.9	0.0
Dysrhythmia	0.9	0.0
Hypothermia	0.9	0.0

^a Includes soft stool, fecal incontinence

V. 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.

VI. 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: "Keep out of reach of children. Not for human use. Consult a physician in case of accidental ingestion by humans."

VII. 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® caplets 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 qualifies for three years of marketing exclusivity beginning on the date of approval because the supplemental application contains 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. The three years of marketing exclusivity applies only to the alternate indication for control of postoperative pain for which the supplemental application was approved.

<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

VIII. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

Package Insert

Client Information Sheet

Bottle:

25 mg- bottles of 14, 60 and 180 caplets

75 mg- bottles of 14, 60 and 180 caplets

100 mg- bottles of 14, 60 and 180 caplets

Each scored caplet contains 25 mg of carprofen. **Indications:** Rimadyl is indicated for the relief of pain and control of postoperative pain associated with soft tissue inflammation associated with orthopedic surgery and for the relief of postoperative pain associated with soft tissue inflammation. **Dosage:** Always provide Client Information Sheet with pre- and orthopedic surgeries in dogs. **Dosage:** The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight 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 (2.2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments. Made in USA 025 85-8560-X1

RIMADYL® (carprofen)

Caplets

Non-steroidal anti-inflammatory drug

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

25 mg



14 caplets - For trial use only. Not for sale.

NADA #141-053; Approved by FDA



Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only. Do not use in cats.** Please Refer to Insert for Complete Warnings and Precautions

Store at controlled room temperature 15°-30°C (59°-86°F).

Distributed by



Animal Health

Easton, PA 18041, USA

Div. of Pfizer Inc., NY, NY 10017



150%

RIMADYL®
(carprofen)
Caplets
Non-steroidal anti-inflammatory drug
For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

25 mg



60 caplets

NADA #141-053, Approved by FDA



Each scored caplet contains 25 mg of carprofen.
Indications: Rimadyl 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.
Dosage: Always provide Client Information Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/lb of body weight twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.
Made in USA

075 86-8600-X1

Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only. Do not use in cats.**
Please Refer to Insert for Complete Warnings and Precautions

Store at controlled room temperature 15°-30°C (59°-86°F).

Distributed by



Animal Health
A Division of
Pfizer Inc., NY, NY 10007



0 87219 04745 3

150%

Each scored caplet contains 25 mg of carprofen.
Indications: Rimadyl 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.
Dosage: Always provide Client Information Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/lb (4.5 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/lb (2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.
Made in USA

OZS 85-9801-X1

RIMADYL®

(carprofen)

Caplets

Non-steroidal anti-inflammatory drug

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

25 mg



180 caplets

NADA #141-053, Approved by FDA

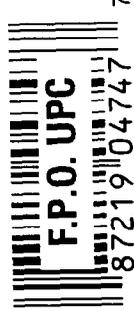
Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only.** Do not use in cats.
Precautions: Please Refer to Insert for Complete Warnings and Precautions

Store at controlled room temperature 15°-30°C (59°-86°F).

Manufactured by



Animal Health
Kenilworth, NJ 07033, USA
Div. of Pfizer Inc., NY, NY 10017



7

150%

Each scored caplet contains 25 mg of carprofen. **Indications:** Rimadyl 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. **Dosage:** Always provide Client Information Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight 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 (2.2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.
 025 85-8661-X1
 Made in USA

RIMADYL® (carprofen)

Caplets

Non-steroidal anti-inflammatory drug

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian

75 mg



14 caplets - For trial use only. Not for sale.

NADA #141-053. Approved by FDA



Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only.** Do not use in cats. **Please Refer to Insert for Complete Warnings and Precautions**

Store at controlled room temperature 15°-30°C (59°-86°F).

Distributed by **Pfizer** **Animal Health**
 Kenilworth, NJ 07033
 Exton, PA 19341, USA
 Div of Pfizer Inc., NY, NY 10017



150%

Each scored caplet contains 75 mg of carprofen.
Indications: Rimadyl 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.
Dosage: Always provide client instruction Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight 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 (2.2 mg/kg) twice daily, for the control of postoperative pain, administered approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.

RIMADYL®

(carprofen)

Caplets

Non-steroidal anti-inflammatory drug

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

75 mg



60 caplets

NADA #141-053, Approved by FDA



Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only. Do not use in cats.**
Please Refer to Insert for Complete Warnings and Precautions
Store at controlled room temperature 15°-30°C (59°-86°F).



Animal Health
Econ, PA 19341, USA
Div. of Pfizer Inc., NY, NY 10017

THE TIME



OSPREY LAB
MILWAUKEE



87219 04749

Made in USA
1 025 85-8602-X1

150%

RIMADYL®
(carprofen)

Caplets

Non-steroidal anti-inflammatory drug

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian

75 mg



180 caplets

NADA #141-053, Approved by FDA



Each scored caplet contains 75 mg of carprofen. Indications: Rimadyl 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. Dosage: Always provide Client Information Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight 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 (2.2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.

Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. For use in dogs only. Do not use in cats. Please Refer to Insert for Complete Warnings and Precautions. Store at controlled room temperature (15-30°C (59-86°F)).



Distributed by
Animal Health
A Division of
Pfizer Inc., New York, NY



Made in USA
075 85-6603-X1

Each scored caplet contains 100 mg of carprofen.
Indications: Rimadyl 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.
Dosage: Always provide Client Information Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) to 4 mg/lb (8.8 mg/kg) twice daily or divided and administered as 2 mg/lb (2.2 mg/kg) once daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.
Made in USA 025 85-8562-X1

RIMADYL® (carprofen) Caplets

Non-steroidal anti-inflammatory drug
For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

100 mg



14 caplets - For trial use only. Not for sale.

NADA #141-053, Approved by FDA



Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only.** Do not use in cats.
Please Refer to Insert for Complete Warnings and Precautions

Store at controlled room temperature 15°-30°C (59°-86°F).



Distributed by

Animal Health
Kenilworth, PA 19341, USA
Div. of Pfizer Inc. NY NY 10017

U.S. PAT. & TRADEMARK OFFICE



REGISTERED TRADEMARK



150%

Each scored caplet contains 100 mg of carprofen.
Indications: Rimadyl 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.
Dosage: Always provide Client Information Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/lb (4 mg/kg) of body weight once daily or divided and administered as 2 mg/lb (2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.

RIMADYL®
(carprofen)

Caplets

Non-steroidal anti-inflammatory drug

For oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

100 mg



60 caplets

NADA #141-053, Approved by FDA



Warnings: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. **For use in dogs only.** Do not use in cats.

Please Refer to Insert for Complete Warnings and Precautions
Store at controlled room temperature 15°-30°C (59°-86°F).

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Animal Health
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TAKE TIME



OBSERVE LABEL
DIRECTIONS



F.P.O. UPC

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Made in USA
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150%

RIMADYL®

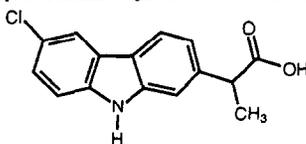
(carprofen)
Caplets

Non-steroidal anti-inflammatory drug

For oral use in dogs only

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Rimadyl (carprofen) is a non-steroidal anti-inflammatory drug (NSAID) of the propionic acid class that includes ibuprofen, naproxen, and ketoprofen. Carprofen is the nonproprietary designation for a substituted carbazole, 6-chloro- α -methyl-9H-carbazole-2-acetic acid. The empirical formula is $C_{15}H_{12}ClNO_2$ and the molecular weight 273.72. The chemical structure of carprofen is



Carprofen is a white, crystalline compound. It is freely soluble in ethanol, but practically insoluble in water at 25°C.

CLINICAL PHARMACOLOGY: Carprofen is a non-narcotic, non-steroidal anti-inflammatory agent with characteristic analgesic and antipyretic activity approximately equipotent to indomethacin in animal models.¹

The mechanism of action of carprofen, like that of other NSAIDs, is believed to be associated with the inhibition of cyclooxygenase activity. Two unique cyclooxygenases have been described in mammals.² The constitutive cyclooxygenase, COX-1, synthesizes prostaglandins necessary for normal gastrointestinal and renal function. The inducible cyclooxygenase, COX-2, generates prostaglandins involved in inflammation. Inhibition of COX-1 is thought to be associated with gastrointestinal and renal toxicity while inhibition of COX-2 provides anti-inflammatory activity. The specificity of a particular NSAID for COX-2 versus COX-1 may vary from species to species.³ In an *in vitro* study using canine cell cultures, carprofen demonstrated selective inhibition of COX-2 versus COX-1. Clinical relevance of these data has not been shown. Carprofen has also been shown to inhibit the release of several prostaglandins in two inflammatory cell systems: rat polymorphonuclear leukocytes (PMN) and human rheumatoid synovial cells, indicating inhibition of acute (PMN system) and chronic (synovial cell system) inflammatory reactions.¹

Several studies have demonstrated that carprofen has modulatory effects on both humoral and cellular immune responses.⁴⁻⁹ Data also indicate that carprofen inhibits the production of osteoclast-activating factor (OAF), PGE₁, and PGE₂ by its inhibitory effects on prostaglandin biosynthesis.¹

Based upon comparison with data obtained from intravenous administration, carprofen is rapidly and nearly completely absorbed (more than 90% bioavailable) when administered orally.¹⁰ Peak blood plasma concentrations are achieved in 1-3 hours after oral administration of 1, 5, and 25 mg/kg to dogs. The mean terminal half-life of carprofen is approximately 8 hours (range 4.5-9.8 hours) after single oral doses varying from 1-25 mg/kg of body weight. After a 100 mg single intravenous bolus dose, the mean elimination half-life was approximately 11.7 hours in the dog. Rimadyl is more than 99% bound to plasma protein and exhibits a very small volume of distribution.

Carprofen is eliminated in the dog primarily by biotransformation in the liver followed by rapid excretion of the resulting metabolites (the ester glucuronide of carprofen and the ether glucuronides of 2 phenolic metabolites, 7-hydroxy carprofen and 8-hydroxy carprofen) in the feces (70-80%) and urine (10-20%). Some enterohepatic circulation of the drug is observed.

INDICATIONS: Rimadyl 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.

DOSAGE AND ADMINISTRATION: Always provide Client Information Sheet with prescription. The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight 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 (2.2 mg/kg) twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure. Caplets are scored and dosage should be calculated in half-caplet increments.

EFFECTIVENESS: Confirmation of the effectiveness of Rimadyl for the relief of pain and inflammation associated with osteoarthritis, and for the control of postoperative pain associated with soft tissue and orthopedic surgeries was demonstrated in 5 placebo-controlled, masked studies examining the anti-inflammatory and analgesic effectiveness of Rimadyl caplets in various breeds of dogs.

Separate placebo-controlled, masked, multicenter field studies confirmed the anti-inflammatory and analgesic effectiveness of Rimadyl caplets when dosed at 2 mg/lb once daily or when divided and administered at 1 mg/lb twice daily. In these two field studies, dogs diagnosed with osteoarthritis showed statistically significant overall improvement based on lameness evaluations by the veterinarian and owner observations when administered Rimadyl at labeled dosages.

Separate placebo-controlled, masked, multicenter field studies confirmed the effectiveness of Rimadyl caplets for the control of postoperative pain when dosed at 2 mg/lb once daily in various breeds of dogs. In these studies, dogs presented for ovariohysterectomy, cruciate repair and aural surgeries were administered Rimadyl preoperatively and for a maximum of 3 days (soft tissue) or 4 days (orthopedic) postoperatively. In general, dogs administered Rimadyl showed statistically significant improvement in pain scores compared to controls.

ANIMAL SAFETY STUDIES: Laboratory studies in unanesthetized dogs and clinical field studies have demonstrated that Rimadyl is well tolerated in dogs after oral administration.

In target animal safety studies, Rimadyl was administered orally to healthy Beagle dogs at 1, 3, and 5 mg/lb twice daily (1, 3 and 5 times the recommended total daily dose) for 42 consecutive days with no significant adverse reactions. Serum albumin for a single female dog receiving 5 mg/lb twice daily decreased to 2.1 g/dL after 2 weeks of treatment, returned to the pre-treatment value (2.6 g/dL) after 4 weeks of treatment, and was 2.3 g/dL at the final 6-week evaluation. Over the 6-week treatment period, black or bloody stools were observed in 1 dog (1 incident) treated with 1 mg/lb twice daily and in 1 dog (2 incidents) treated with 3 mg/lb twice daily. Redness of the colonic mucosa was observed in 1 male that received 3 mg/lb twice daily.

Two of 8 dogs receiving 10 mg/lb orally twice daily (10 times the recommended total daily dose) for 14 days exhibited hyperalbuminemia. The mean albumin level in the dogs receiving this dose was lower (2.38 g/dL) than each of 2 placebo control groups (2.88 and 2.93 g/dL, respectively). Three incidents of black or bloody stool were observed in 1 dog. Five of 8 dogs exhibited reddened areas of duodenal mucosa on gross pathologic examination. Histologic examination of these areas revealed no evidence of ulceration, but did show minimal congestion of the lamina propria in 2 of the 5 dogs.

In separate safety studies lasting 13 and 52 weeks, respectively, dogs were administered orally up to 11.4 mg/lb/day (5.7 times the recommended total daily dose of 2 mg/lb) of carprofen. In both studies, the drug was well tolerated clinically by all of the animals. No gross or histologic changes were seen in any of the treated animals. In both studies, dogs receiving the highest doses had average increases in serum L-alanine aminotransferase (ALT) of approximately 20 IU.

In the 52 week study, minor dermatologic changes occurred in dogs in each of the treatment groups but not in the control dogs. The changes were described as slight redness or rash and were diagnosed as non-specific dermatitis. The possibility exists that these mild lesions were treatment related, but no dose relationship was observed.

Clinical field studies were conducted with 549 dogs of different breeds at the recommended oral doses for 14 days (297 dogs were included in a study evaluating 1 mg/lb twice daily and 252 dogs were included in a separate study evaluating 2 mg/lb once daily). In both studies the drug was clinically well tolerated and the incidence of clinical adverse reactions for Rimadyl-treated animals was no higher than placebo-treated animals (placebo contained inactive ingredients found in Rimadyl).

NSAIDs possess the potential to induce gastrointestinal ulceration, concomitant use of Rimadyl with other anti-inflammatory drugs, such as corticosteroids and NSAIDs, should be avoided or very closely monitored. Sensitivity to drug-associated adverse reactions varies with the individual patient. For example, Rimadyl treatment was not associated with renal toxicity or gastrointestinal ulceration in well-controlled safety studies of up to ten times the dose in dogs.

Rimadyl is not recommended for use in dogs with bleeding disorders (e.g., Von Willebrand's disease), as safety has not been established in dogs with these disorders. The safe use of Rimadyl in animals less than 6 weeks of age, pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established. Studies to determine the activity of Rimadyl when administered concomitantly with other protein-bound or similarly metabolized drugs have not been conducted. Drug compatibility should be monitored closely in patients requiring additional therapy. Such drugs commonly used include cardiac, anticonvulsant and behavioral medications. It has been suggested that treatment with carprofen may reduce the level of inhalant anesthetics needed.¹⁵

If additional pain medication is warranted after administration of the total daily dose of Rimadyl, alternative analgesia should be considered. The use of another NSAID is not recommended.

INFORMATION FOR DOG OWNERS:

Rimadyl, like other drugs of its class, is not free from adverse reactions. Owners should be advised of the potential for adverse reactions and be informed of the clinical signs associated with drug intolerance. Adverse reactions may include decreased appetite, vomiting, diarrhea, dark or tarry stools, increased water consumption, increased urination, pale gums due to anemia, yellowing of gums, skin or white of the eye due to jaundice, lethargy, incoordination, seizure, or behavioral changes. Serious adverse reactions associated with this drug class can occur without warning and in rare situations result in death (see Adverse Reactions). Owners should be advised to discontinue Rimadyl therapy and contact their veterinarian immediately if signs of intolerance are observed. The vast majority of patients with drug related adverse reactions have recovered when the signs are recognized, the drug is withdrawn, and veterinary care, if appropriate, is initiated. Owners should be advised of the importance of periodic follow up for all dogs during administration of any NSAID.

WARNINGS: Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. For use in dogs only. Do not use in cats.

All dogs should undergo a thorough history and physical examination before initiation of NSAID therapy. Appropriate laboratory tests to establish hematological and serum biochemical baseline data prior to, and periodically during, administration of any NSAID should be considered. Owners should be advised to observe for signs of potential drug toxicity (see Information for Dog Owners and Adverse Reactions).

ADVERSE REACTIONS: During investigational studies of osteoarthritis with twice daily administration of 1 mg/lb, no clinically significant adverse reactions were reported. Some clinical signs were observed during field studies (n=291) which were similar for carprofen- and placebo-treated dogs. Incidences of the following were observed in both groups: vomiting (4%), diarrhea (4%), changes in appetite (3%), lethargy (1.4%), behavioral changes (1%), and constipation (0.3%). The product vehicle served as control.

There were no serious adverse events reported during clinical field studies of osteoarthritis with once daily administration of 2 mg/lb. The following categories of abnormal health observations were reported. The product vehicle served as control.

Percentage of Dogs with Abnormal Health Observations Reported in Osteoarthritis Field Study (2 mg/lb once daily)

Observation	Rimadyl (n=129)	Placebo (n=132)
Inappetence	1.6	1.5
Vomiting	3.1	3.8
Diarrhea/Soft stool	3.1	4.5
Behavior change	0.8	0.8
Dermatitis	0.8	0.8
PUPD	0.8	—
SAP increase	7.8	8.3
ALT increase	5.4	4.5
AST increase	2.3	0.8
BUN increase	3.1	1.5
Bilirubinemia	16.3	12.1
Katouria	14.7	9.1

Clinical pathology parameters listed represent reports of increases from pre-treatment values, medical judgement is necessary to determine clinical relevance.

During investigational studies of surgical pain for the caplet formulation, no clinically significant adverse reactions were reported. The product vehicle served as control.

Percentage of Dogs with Abnormal Health Observations Reported in Surgical Pain Field Studies with Caplets (2 mg/lb once daily)

Observation*	Rimadyl (n=148)	Placebo (n=148)
Vomiting	10.1	13.4
Diarrhea/soft stool	6.1	6.0
Ocular disease	2.7	0
Inappetence	1.4	0
Dermatitis/skin lesion	2.0	1.3
Dysrhythmia	0.7	0
Apnea	1.4	0
Oral/perioral disease	1.4	0
Pyrexia	0.7	1.3
Urinary tract disease	1.4	1.3
Wound drainage	1.4	0

* A single dog may have experienced more than one occurrence of an event.

Post-Approval Experience

Although not all adverse reactions are reported, the following adverse reactions are based on voluntary post-approval adverse drug experience reporting. The categories of adverse reactions are listed in decreasing order of frequency by body system.

Gastrointestinal: Vomiting, diarrhea, constipation, inappetence, melena, hematemesis, gastrointestinal ulceration, gastrointestinal bleeding, pancreatitis.

Hepatic: Inappetence, vomiting, jaundice, acute hepatic toxicity, hepatic enzyme elevation, abnormal liver function test(s), hyperbilirubinemia, bilirubinuria, hyposalbuminemia. Approximately one-fourth of hepatic reports were in Labrador Retrievers.

Neurologic: Ataxia, paresis, paralysis, seizures, vestibular signs, disorientation.

Urinary: Hematuria, polyuria, polydipsia, urinary incontinence, urinary tract infection, azotemia, acute renal failure, tubular abnormalities including acute tubular necrosis, renal tubular acidosis, glucosuria.

Behavioral: Sedation, lethargy, hyperactivity, restlessness, aggressiveness.

Hematologic: Immune-mediated hemolytic anemia, immune-mediated thrombocytopenia, blood loss anemia, epistaxis.

Dermatologic: Pruritus, increased shedding, alopecia, pyotraumatic moist dermatitis (hot spots), necrotizing panniculitis/vasculitis, ventral ecchymosis.

Immunologic or hypersensitivity: Facial swelling, hives, erythema.

In rare situations, death has been associated with some of the adverse reactions listed above.

To report a suspected adverse reaction call 1-800-366-5288.

STORAGE: Store at controlled room temperature 15°-30°C (59°-86°F).

HOW SUPPLIED: Rimadyl caplets are scored, and contain 25 mg, 75 mg, or 100 mg of carprofen per caplet. Each caplet size is packaged in bottles containing 14, 60, or 180 caplets.

REFERENCES:

- Baruth H, et al. In: Anti-Inflammatory and Anti-Rheumatic Drugs, Vol. II, Newer Anti-Inflammatory Drugs, Ransford KO, ed. CRC Press, Boca Raton, pp. 33-47, 1986.
- Vane JR, Botting RM. Mechanism of action of anti-inflammatory drugs. *Scand J Rheumatol* 25:102, pp. 9-21.
- Grossman CJ, Wiseman J, Lucas FS, et al. Inhibition of constitutive and inducible cyclooxygenase activity in human platelets and mononuclear cells by NSAIDs and COX-2 inhibitors. *Inflammation Research* 44:253-257, 1995.



RIMADYL® (carprofen)
DOG OWNER
INFORMATION
-DO NOT REMOVE-
 Caplets

Dog Owner Information about RIMADYL® Caplets (carprofen) Rimadyl® (pronounced "Rim-a-dill") for Osteoarthritis Pain Generic name: carprofen ("car-prō-fen")

This summary contains important information about Rimadyl. You should read this information before you start giving your dog Rimadyl and review it each time the prescription is refilled. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Rimadyl.

What is Rimadyl?

Rimadyl is a nonsteroidal anti-inflammatory drug (NSAID) that is used to reduce pain and inflammation (soreness) due to osteoarthritis and pain following surgery in dogs. Rimadyl is a prescription drug for dogs. It is available as a [REDACTED] and is given to dogs by mouth.

Osteoarthritis (OA) is a painful condition caused by "wear and tear" of cartilage and other parts of the joints that may result in the following changes or signs in your dog:

- Limping or lameness
- Decreased activity or exercise (reluctance to stand, climb stairs, jump or run, or difficulty in performing these activities)
- Stiffness or decreased movement of joints

To control surgical pain (e.g. for surgeries such as spays, ear procedures or orthopedic repairs) your veterinarian may administer Rimadyl before the procedure and recommend that your dog be treated for several days after going home.

What kind of results can I expect when my dog is on Rimadyl?

While Rimadyl is not a cure for osteoarthritis, it can relieve the pain and inflammation of OA and improve your dog's mobility.

- Response varies from dog to dog but can be quite dramatic.
- In most dogs, improvement can be seen in a matter of days.
- If Rimadyl is discontinued or not given as directed, your dog's pain and inflammation may come back.

Who should not take Rimadyl?

Your dog should not be given Rimadyl if he/she:

- Has had an allergic reaction to carprofen, the active ingredient of Rimadyl.
- Has had an allergic reaction to aspirin or other NSAIDs (for example etodolac or phenylbutazone) such as hives, facial swelling, or red or itchy skin.

Rimadyl should be given to dogs only. Cats should not be given Rimadyl. Call your veterinarian immediately if your

Tell your veterinarian about:

- Any other medical problems or allergies that your dog has now or has had.
- All medicines that you are giving your dog or plan to give your dog, including those you can get without a prescription.

Tell your veterinarian if your dog is:

- Pregnant, nursing or if you plan to breed your dog.

What are the possible side effects that may occur in my dog during Rimadyl therapy?

Rimadyl, like other drugs, may cause some side effects. Serious but rare side effects have been reported in dogs taking NSAIDs, including Rimadyl. Serious side effects can occur with or without warning and in rare situations result in death.

The most common NSAID-related side effects generally involve the stomach (such as bleeding ulcers), and liver or kidney problems. Look for the following side effects that can indicate your dog may be having a problem with Rimadyl or may have another medical problem:

- Decrease or increase in appetite
- Vomiting
- Change in bowel movements (such as diarrhea, or black, tarry or bloody stools)
- Change in behavior (such as decreased or increased activity level, incoordination, seizure or aggression)
- Yellowing of gums, skin, or whites of the eyes (jaundice)
- Change in drinking habits (frequency, amount consumed)
- Change in urination habits (frequency, color, or smell)
- Change in skin (redness, scabs, or scratching)

It is important to stop therapy and contact your veterinarian immediately if you think your dog has a medical problem or side effect from Rimadyl therapy. If you have additional questions about possible side effects, talk to your veterinarian.

Can Rimadyl be given with other medicines?

Rimadyl should not be given with other NSAIDs (for example, aspirin, etodolac) or steroids (for example, cortisone, prednisone, dexamethasone, triamcinolone).

Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to give with Rimadyl. This should include other medicines that you can get without a prescription. Your veterinarian may want to check that all of your dog's medicines can be given together.